Chapter 3
Identifying Value(s): A Reflection on the Ethical Aspects of MCDA in Healthcare Decisionmaking

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Abstract *Background*: A number of ethical theories have been developed over many centuries, such as deontology, consequentialism (including utilitarianism), virtue ethics, and, more recently, for example, Rawls' *Theory of Justice* and Habermas' *Ethics of Discussion*, which have been investigated further in healthcare. These major ethical positions and procedural theories integrate many ethical aspects with which decisionmakers, in particular at policy level, are struggling to deliver the best treatments to patients, protect population health, and build sustainable healthcare systems (triple aim). While ethical dilemmas, rooted in this triple aim, are becoming more critical and the demand for accountable processes is rising, multi-criteria decision analysis (MCDA) offers an opportunity to integrate ethical aspects in an innovative manner to enhance accountability for reasonableness (A4R).

Objectives: This chapter is a first attempt to explore how MCDA may integrate ethical aspects inherent to healthcare decisionmaking. The reflection proposed here is primarily rooted in the real-life constraints of decisionmaking at the HTA/Ministry of Health (MoH) level, rather than in specific ethical positions.

Method: This chapter explores the ethical aspects of each MCDA development step, following the eight-step outline of the ISPOR Task Force on MCDA, as well as the legitimacy of decisions from the HTA/MoH perspective, using the triple aim as the goal to illustrate this exploration. For each step, we discuss the substantive and procedural elements of major ethical positions and procedural theories that such method can integrate.

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Results: Legitimacy of decisions on healthcare interventions requires inclusion of representative stakeholders for both the design and operationalization of the MCDA to ensure that criteria included and their consideration are in agreement with the mission and values of the institution. Consideration of the triple aim as the goal of the MCDA (step 1) results in the definition of a broad range of criteria (step 2) derived from ethical aspects, such as the "imperative to help" at the patient level, the "prioritization of those who are worst off," and the aim to achieve the "greatest good for the greatest number" to best serve the population, as well as maintain the sustainability of the healthcare system. The first two MCDA steps foster reflection, collaboration, and communication across stakeholders to define common ground upon which to establish what constitutes the holistic value of interventions, i.e., integrating all ethical aspects of the triple aim. Synthesis of evidence to consider these criteria (step 4) requires elements of practical wisdom to provide clear, transparent, and systematic evidence. Other aspects of MCDA, such as weighting (step 3), scoring (step 5), aggregating of weights and scores (step 6), and managing uncertainty (step 7), include ethical elements of practical wisdom as well as additional procedural values, such as transparency of values, consistency, participation, accountability, and deliberation. The criteria and their consideration through the MCDA process can result in an accountable and reasonable measure of "holistic value" of interventions contributing the most to the triple aim.

Conclusion: This reflection suggests that MCDA can be designed to integrate numerous ethical aspects inherent to healthcare decisionmaking. By enhancing their operationalization, MCDA can support accountable and reasonable decision processes rooted in a holistic consideration of value of healthcare interventions. Reflection on the ethical aspects of MCDA in healthcare is in its infancy, and further research on each aspect presented here is warranted.

3.1 Introduction

A number of ethical theories have been developed over the centuries, such as deontology, consequentialism (including utilitarianism) (Cleret de Langavant 2001), virtue ethics, and, more recently, for example, Rawls' *Theory of Justice* and Habermas' *Ethics of Discussion*, which have been investigated further in healthcare. These positions integrate many ethical aspects with which decisionmakers, in particular at policy level (HTA, Ministry of Health (MoH)), are struggling to ensure quality of care and delivery of the best treatments to patients, to serve population health, and to maintain sustainability of the healthcare system (triple aim: care, health, costs (Berwick et al. 2008)). Ethical dilemmas, rooted in the difficulty to achieve the triple aim, are becoming more critical, and the demand for accountable processes is rising.

This chapter does not attempt to summarize the reflection of some of the greatest thinkers of humankind but to shed some light on the ethical elements that are evoked

by the triple aim and A4R considerations by HTA/MoH; a high-level overview is provided to introduce basic concepts. Virtue ethics is the oldest concept in occidental ethics, set forth by Plato and Aristotle. It holds that an act is morally good if it corresponds to what a virtuous person would do. It emphasizes the character of the virtuous person, who applies practical wisdom and goodness to motivate and guide his/her decisions (Hursthouse 2013). In this context, the virtuous person is the norm, rather than duty (as in deontology) or pragmatism (as in consequentialism). Deontology, derived from the Greek deon ("duty"), is an ethical position that holds those actions to be morally right that conform to established rules or duties. Kant (1724–1804) held that the moral value of an action is not related to its consequences but to the moral duty to which it responds, which manifests as an imperative to act. The "imperative to help" in medicine was outlined by Hippocrates (460–370 BCE) in the Hippocratic Oath: "I will prescribe for the good of my patients according to my ability and my judgment and never do harm to anyone," underscoring the moral obligations of beneficence and non-maleficence, which, according to the oath, requires medical practitioners to use their "ability and judgment" or, in other terms, their expertise and knowledge of the consequences of the medical act. Consequentialism (including utilitarianism) holds that an action is good if its consequences are good. According to utilitarianism, developed by Bentham (1748–1832) and Mill (1806–1873), an action must be guided by its utility; thus, societies should pursue the "greatest good for the greatest number" (maximize utility), a theory that had a strong influence on public policies (Driver 2014).

Contemporary ethical approaches include, among others, the *Theory of Justice* set forth by Rawls, (Rawls 1971) which holds that "priority should be given to those who are worst off." Although there are various models of distributive justice (e.g., libertarian, communitarian, egalitarian, and utilitarian), solidarity, i.e., giving priority to those most in need, is a key concept rooted in an egalitarian justice model and upheld as a principle in many healthcare systems (Kieslich 2012; Hoedemaekers and Dekkers 2003). Daniels' model of distributive justice aims for fair distribution of life opportunities (Daniels 2001).

Procedural theories have also been set forth, such as Habermas' *Ethics of Discussion* (Habermas 1984) and, more recently, deliberative practices (Danis et al. 2010). In their seminal work on accountability for reasonableness (A4R), Daniels and Sabin proposed four conditions to ensure that a decisionmaking process is legitimate (Daniels and Sabin 1997; Daniels 1999): publicity (decisions and rationales accessible publicly), revision and appeals (opportunity for challenge and revision), enforcement (regulations to ensure that the other A4R conditions are met), and relevant reasons. The latter refers to the rationales upon which decisions are based and which should be rooted in principles that are accepted as relevant by "fair-minded" people.

Principlism, developed by Beauchamp and Childress, proposes four moral principles to guide decisionmaking in medicine: beneficence ("do good to others"), non-maleficence ("avoid harming others"), respect for autonomy ("treat others as free agents"), and justice ("fair distribution of benefits and burdens") (Beauchamp and Childress 2001).

These major ethical positions and procedural theories, considered to some extent conflicting, are at play in healthcare policy decisionmaking, and the pursuit to integrate them in pragmatic approaches is ongoing. Policy decisionmaking inevitably involves value judgments (Littlejohns et al. 2012) rooted in individual and social values that can be classified into substantive values (relevant reasons or criteria on which decisions are made, e.g., effectiveness, costs) and procedural values (values the process itself reflects and which are critical to legitimize the decision). (Clark and Weale 2012) While evidence-based medicine and health technology assessment emerged in the twentieth century to improve understanding of the consequences of healthcare interventions (or in other terms their true value) for better decisions at the clinical and policy levels (Battista and Hodge 2009; Jenicek 2006), there is a need for pragmatic and accountable processes to support the operationalization of social values, the integration of ethical aspects inherent to healthcare decisions, and the tackling of ethical dilemmas.

MCDA offers an opportunity to integrate ethical aspects in an innovative manner to enhance accountability for reasonableness (Daniels and Sabin 1997; Daniels 1999). Although MCDA has been used extensively in many fields for several decades (e.g., engineering), its exploration for application in healthcare is fairly recent. This chapter is a first attempt to explore how MCDA might integrate some of the ethical aspects inherent to healthcare decisionmaking. The reflection proposed here is primarily rooted in the real-life constraints of decisionmaking at the HTA/MoH level, rather than in specific ethical positions.

This chapter explores the ethical aspects of each MCDA development step, following the eight-step outline of the MCDA ISPOR task force, as well as the legitimacy of decisions, from the HTA/MoH perspective where ethical dilemmas are most challenging, to illustrate this exploration. It is acknowledged that MCDA can also serve more specific functions (e.g., benefit-risk assessment in its traditional sense), but for the sake of exploring MCDA and ethics from a broad perspective, we constructed this chapter to reflect on the development of an MCDA model that aims at identifying interventions that best achieve the triple aim. For each step of the MCDA, we discuss the substantive and procedural aspects of major ethical positions and procedural theories that such methods can integrate.

3.2 Who Should Decide? Legitimacy of Decisions and Representativeness of MCDA Users

Legitimacy of decisions on healthcare interventions requires inclusion of representative stakeholders in the deliberations that are supported by the MCDA framework, as well as in its design, to ensure that criteria included and the way they are considered are in agreement with the mission and values of the institution. Decisionmaking committees are meant to represent the society/population they are serving, and legitimacy rests on inclusion of the diversity of perspectives that stakeholders may have. According to Daniels' and Sabin's seminal A4R framework

(Daniels and Sabin 1997; Daniels 1999), the relevance condition for legitimacy requires that rationales for decisions rest on evidence, reasons, and principles that fair-minded people can agree are relevant for the decision. Martin et al. (2002) have explored who these fair-minded people should be and stated that the following constituencies be included in a representative decisionmaking committee: committee chair, administrator, medical specialist, medical generalist, public representative, and patient representative. More recently, according to Rosenberg-Yunger et al. (2012), decisionmaking committees should include multiple stakeholders including healthcare professionals, academics, managers/administrators, patients, and/or public representatives, while industry representatives should be involved on other aspects of the process but not in the decisionmaking committee. Garrido et al. (2016) suggested that HTA committee members "may include representatives of patients, providers, payers, government or manufacturers, as well as clinical and methodological experts." Procedural values of MCDA are illustrated in Fig. 3.1. MCDA allows capturing the perspectives of all participants in a structured manner,

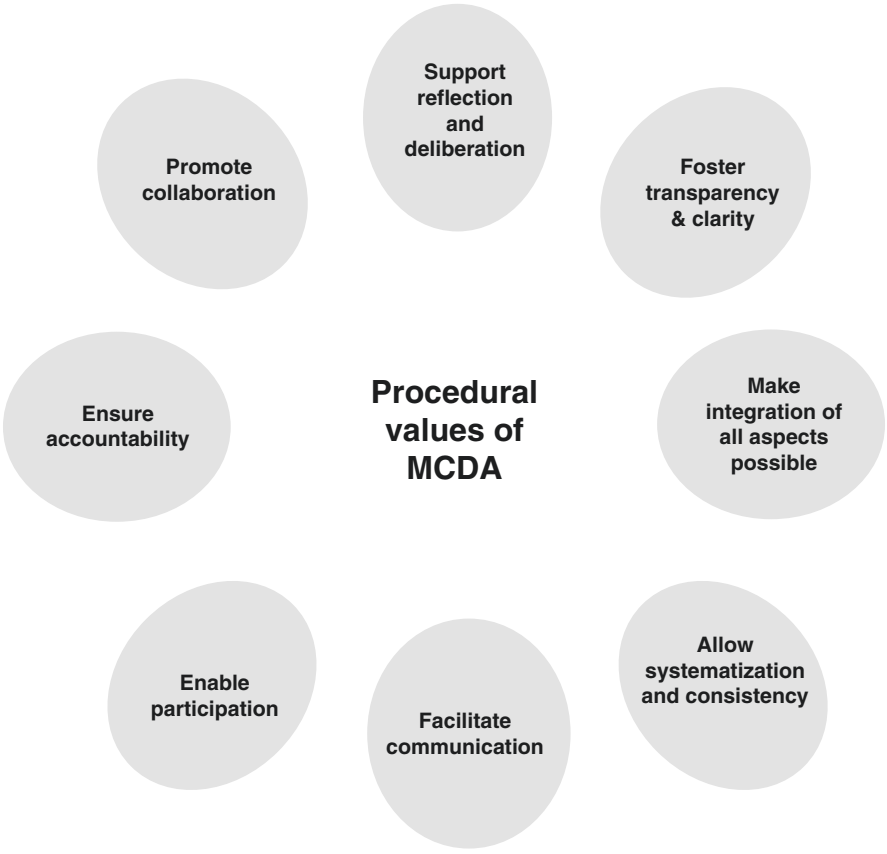

Fig. 3.1 Procedural values embedded in the development and application of MCDA

thus clarifying the individual and group reasoning and supporting deliberation among all committee members, which is hard to achieve without an appropriate method. By the same token, MCDA can be used to consult large groups of individuals. When designed to support reflection, MCDA provides a pragmatic means to enhance the legitimacy of decisions and their acceptability.

3.3 How to Decide?

3.3.1 Step 1: Defining the Decision Problem

In their seminal work on the triple aim of healthcare (care, health, and cost), Berwick et al. (2008), Centers for Medicare and Medicaid Services (2015) proposed that high-value healthcare will be achieved only if stakeholders pursue a broad system of linked goals related to patient health, population health, and healthcare system resource management.

Compassion is the ethical foundation and fundamental impetus of healthcare (Lown 2015), which aims at prevention of ill health, cure, relief of pain and suffering, and avoidance of premature death (ultimate goals of healthcare (Callahan 1999)). While a well-functioning healthcare system is not an end in itself, it is inextricably linked to the ultimate goals of healthcare because it is the only instrument through which the healthcare sector can generate health. As acknowledged by developers of the triple aim, pursuing this broad system of linked goals can "provide enormous gains" but are also associated with "potential disruption in the status quo" and require broad reflection across stakeholders. Integration of the triple aim into a comprehensive (or holistic) MCDA could provide a road map for all stakeholders to *reflect* and identify what constitutes high-value healthcare and thus advance the ultimate goals of healthcare through a *collaborative* and *participatory* approach.

Thus, from the HTA/MoH perspective, the decision problem could be defined as: "Identify the value of interventions with regard to the triple aim of healthcare, ensuring that all underlying ethical aspects are included." Regarding procedural values, the development of MCDA approaches to achieve the triple aim stimulates *reflection* and *collaboration,* while promoting exchange and *communication* across stakeholders. Thus it provides common ground upon which to establish what constitutes value from a triple aim perspective.

3.3.2 Step 2: Selecting and Structuring Criteria

Setting the triple aim as the goal (step 1) of the MCDA framework results in the selection of a broad range of criteria (step 2) to include ethical elements such as the "imperative to help" at the patient level; the "prioritization of those who are worst

off," while aiming at the "greatest good for the greatest number" at the population level; as well as the "sustainability" of the healthcare system. Balancing these, often competing, ethical demands require practical wisdom to motivate and guide the decision, as illustrated in Fig. 3.2 (Hursthouse 2013). The resolution of these ethical dilemmas is ultimately driven by universal and specific values related to the ethical and legal traditions of each society which the decision committee at HTA or MoH levels represents (Schlander et al. 2014).

It is postulated that these ethical elements can be translated into objectives and operationalized into decision criteria (quantitatively or qualitatively, or a mix of

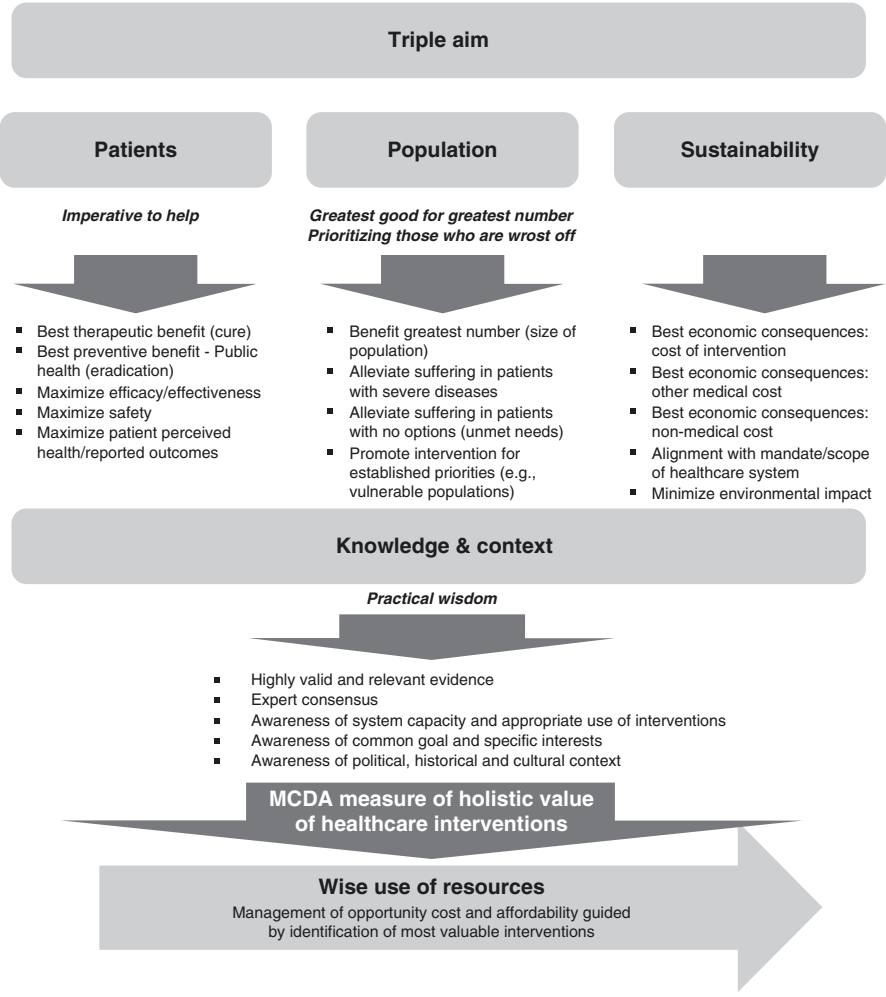

Fig. 3.2 Triple aim, underlying ethical aspects and transformation into criteria for an MCDA measure of holistic value of interventions to guide wise use of resources and management of opportunity costs

both) to design an MCDA framework that allows identifying interventions that contribute most to the triple aim of healthcare (i.e., the most beneficial or most valuable interventions). Of note, we acknowledge that the classification of Fig. 3.2, proposed as a starting point to advance reflection on these matters, is subject to debate.

3.3.2.1 Patient

Among the most evident criteria that contribute to the value of a healthcare intervention at the patient level is the type of health benefit it can provide. This is directly related to the fundamental impetus of compassion to relieve and prevent suffering. Ethical commitment of societies and clinicians to both prevention and alleviation of suffering calls for an evenhanded approach that does not a priori value therapeutic benefits above preventive benefits. The concept of quality-adjusted life years (QALYs) accommodates both prevention and therapy; however, being an artificial construct, it also creates a "mental distance" from natural notions, such as disease eradication, cure, or symptom relief, which relate closer to the way decisionmakers think. MCDA can integrate the type of preventive service and type of alleviating/therapeutic service as separate criteria to retain these natural notions in the deliberation while ensuring that all types of health benefit are part of the value measurement.

When exploring further the ethical impetus of beneficence, aiming at preventing and alleviating suffering to the greatest extent (i.e., toward the greatest improvement of the current situation) can be translated into criteria that reflect the extent of benefit from a clinical standpoint (effectiveness) as well as from a patient perspective ("patient-perceived health"). Also related to the patient perspective are the principles of respect for patient autonomy and dignity, two critical aspects of healthcare, as set forth in the principlism of Beauchamp and Childress (2001). Finally, as implied in the Hippocratic Oath, the imperative to help needs to be balanced with the safety and tolerability of the intervention, "never do harm" or non-maleficence. Both the immediate and the long-term unfavorable effects must be considered to address this ethical imperative.

3.3.2.2 Population

At the population level, prevention and alleviation of suffering in as many individuals as possible, that is, "doing good for the greatest number," can be operationalized by including the size of the population potentially benefiting from an intervention as a criterion, thus assigning higher value to interventions benefiting larger numbers of individuals.

"First helping those who are worst off," also often referred to as fairness in real-life situations, can be translated into the criterion disease severity. Thus, interventions targeting (i.e., preventing, curing, or alleviating) severe diseases will have higher value than those targeting less severe diseases. Ranking of

diseases according to severity is not a simple task, although some work has been done in this direction (Shah 2009; Ottersen 2013; Lindemark et al. 2014). Individual judgment on what constitutes "severe" will vary based on personal experience, perspective, and perception of suffering. Unmet medical needs (e.g., orphan diseases or absence of effective intervention) also relate to the notion of prioritizing those who are worst off and can translate into a criterion of "unmet needs," which is a way to address inequalities across therapeutic areas.

National policy makers may further operationalize fairness by defining priorities based on those who are worst off in a given society (e.g., vulnerable populations, rare diseases, remote populations). Inclusion of a criterion that assesses to what extent an intervention is aligned with defined priorities ensures that interventions targeting established priorities are more valued than those not aligned with these priorities.

3.3.2.3 Healthcare Systems

To ensure sustainability, consideration of the economic consequences of an intervention in an MCDA model implies that interventions that reduce treatment costs or free up other medical and nonmedical resources (i.e., use and preserve medical, societal, and individual resources wisely from a broad perspective) have greater value than those that increase treatment costs or deplete medical and nonmedical resources. Including these criteria in an MCDA model stimulates development and promotion of healthcare interventions and programs that possess these intrinsic values, e.g., reducing treatment costs or freeing up other medical and nonmedical resources. Conversely, not including economic aspects in the MCDA framework may fail to discriminate between interventions that do or do not contribute to the triple aim. Daniels et al. (2015) recently pointed out the pharmacological treatment of chronic hepatitis C as an example of a potentially unsustainable intervention that poses difficult ethical issues if, due to high cost, coverage can be provided only for some and not for others (see also comment below on opportunity costs).

When integrating economic aspects in an MCDA framework, a distinction is often made by decisionmakers between costs consequences that will occur with less uncertainty (i.e., cost of the intervention per se and its implementation) and those that will occur with higher uncertainty, that is, the impact of the intervention on other medical as well as nonmedical costs, which are often modeled rather than based on real-life data. MCDA can be designed to provide clarity on this aspect by dealing with these costs through separate criteria.

Certain interventions present a challenge as they may be deemed by some to fall outside the mandate and scope of the healthcare system (e.g., growth hormone for height, assisted reproduction, lifestyle drugs). To address this, a criterion can be introduced in the MCDA to consider the ethical implications of covering these interventions by the healthcare system.

Finally, at the societal level, consideration of the environmental impact of healthcare interventions is becoming more and more an element of value (Tanios

et al. 2013). Including a criterion on the impact of the intervention on the environment implies giving more value to interventions that cause minimal environmental damage and can create an impetus to develop and promote interventions that are environmentally sustainable for the benefit of all.

3.3.2.4 Knowledge and Context

Practical wisdom is a combination of explicit knowledge rooted in formal evidence, knowledge rooted in experience, knowledge of the context, common sense, and implicit judgments. Knowledge, based on understanding of the clinical and economic consequences of interventions, is a key element of practical wisdom and requires long-term real-life data. The ethical implications of data availability and quality are evident as claims about an intervention may or may not be substantiated in real life, implying a risk of selecting interventions that may contribute little to the triple aim. Knowledge comes from evidence generated through studies, which may be of variable relevance and quality, from direct experience of clinicians, which is to some extent captured in clinical practice guidelines, and from patients. If solid knowledge is considered an element of value, two criteria, quality of evidence and expert consensus, may be added. This design will ensure that interventions with solid knowledge will be valued higher than those with limited knowledge.

Since evidence generation comes at a cost, formal data collection tends to focus on new, complex interventions and products, while data for programs and simple interventions is often lacking, which creates a strong bias toward the former. To respond to this dilemma, one may consider that knowledge generation is a social responsibility and also that, in some cases, common sense is a reasonably acceptable source of knowledge. Including an MCDA criterion that measures the strength of evidence can create an impetus for broader research on what constitutes solid and meaningful evidence and perhaps a more formal integration of common sense to demonstrate value of all types of interventions.

The healthcare system's capacity to implement and ensure appropriate use of an intervention is a common consideration by HTA and MoH. This can be seen as an aspect of practical wisdom, which requires knowledge of the system's infrastructure, legislation, organization, barriers, and skills. Introducing an appropriate criterion into the MCDA (most likely qualitatively) gives structure to these considerations and implies that interventions that are easy to implement and have low inherent risks of inappropriate use are more valuable.

Awareness of the context in which the intervention is to be implemented is related to practical wisdom. Being aware of stakeholder pressures and barriers helps ensure that decisions are fair-minded and driven by the triple aim and not unduly influenced by special interests. Being aware of the political, historical, and cultural context is important for assessing the feasibility of implementing the intervention. For example, precedence of decisions on similar interventions or the impact of the intervention on research and innovation (as new treatments often provide new

scientific knowledge) may have an impact on the overall value at the time of decisionmaking.

Beyond defining criteria by their underlying ethical positions, an MCDA model should also follow MCDA methodological requirements, briefly summarized below, as described in detail in the chapter by Dean et al. (UK Department for Communities and Local Government 2009):

- Nonredundancy *(avoid double counting criteria)*
- Mutual independence *(criteria can be assessed independently)*
- Operationalizability *(appropriate measurement scales and data are available)*
- Completeness *(all criteria important for decisionmaking are included)*
- Clustering *(criteria structured in a conceptually meaningful manner)*

Values related to the process of identifying and selecting criteria are critical as this process stimulates *reflection* on how to translate ethical positions into pragmatic tools across the decision continuum from developers to regulators, policymakers, clinicians, and patients. In addition, the process of selecting criteria to develop an MCDA model rooted in the triple aim fosters *systematization* and *consistency*, *participation*, and *collaboration* to assess and identify what constitutes value.

Regarding the type of MCDA and the MCDA process, implementation of an MCDA approach might be, in a first instance, a qualitative operationalization of criteria to support *deliberation* and *communication* across stakeholders. Quantitative operationalization of these criteria involves some additional ethical aspects and procedural values, which are outlined below.

3.3.3 Step 3 of MCDA: Weighting Criteria

Ethical aspects of weighting decision criteria include the wisdom that comes from becoming aware of the ethical trade-offs within which each of us operates (our individual value system), its variability across stakeholders and how it relates to the triple aim (and its underlying ethical aspects). Indeed, although weighting of criteria is inherent to any decisionmaking, it is often made implicitly.

Key procedural values related to criteria weighting include *participation* and *reflection* embedded in the process by which each stakeholder can reflect on trade-offs between criteria and clarify their positions with regard to how they tackle ethical dilemmas, which ethical aspect predominates in their reasoning and other aspects of the deliberation. In a committee, the diversity of perspectives thus revealed can be integrated into the evaluation using a weighting technique most suitable to the group. The selection process for standing committees or panelists applying MCDA has also ethical implications, for example, inclusion of patients or patient representatives may impact on the perceived legitimacy of decisions in an era of patient-centered care.

Many weight elicitation techniques are available and should be selected according to needs and preferences (Dolan 2010) (see Chapter 4). The weighting process itself promotes *transparency* of the values considered and enables consultation of large groups of stakeholders and citizens via surveys (*participation*), as was performed by the Ministry of Health in Colombia (see Chapter 8 by Castro et al.).

3.3.4 Step 4 of MCDA: Providing Evidence to Measure Performance

Consideration of criteria requires evidence for these criteria, including scientific and colloquial evidence and common sense. The type of data selected and provided to decisionmakers has ethical implications and involves numerous value judgments (Hofmann et al. 2014a, b). Efficient, understandable, and meaningful communication of evidence, including standardized presentation (e.g., absolute vs relative data, range of variations across studies), is essential to ensure informed decisionmaking. The process of distilling information is not trivial and must be done to provide sufficient and necessary data for decisionmakers to form their judgments and proceed toward a decision. Providing decisionmakers with unbiased and pragmatic support is crucial for measuring the true value of an intervention, which, although it remains uncertain, can be approached by exploring it from various perspectives, which MCDA facilitates. Thus, MCDA processes stimulate *transparency* and clarity of the evidence (scientific and colloquial) at the criteria level and *systematization* of the evidence distillation process.

In addition, at the group level (e.g., decisionmaking committee), MCDA provides a structured process to share insights and colloquial evidence among members of the group, which can significantly enriches reflection and promotes a *participatory* evaluation and deliberation process.

3.3.5 Step 5: Scoring the Criteria to Evaluate Performance of the Intervention

As recently highlighted, value judgments are involved in every aspect of assessing a healthcare intervention as well as in appraisal and decisionmaking (Hofmann et al. 2014a).

As with weighting, scoring fosters *participation*, *reflection*, and *systematization*. The choice of scoring method has strong implications for the level of *transparency* and *accountability* of the process. Constructed scoring scales capture a judgment of the evidence, thus making transparent how the available evidence was interpreted. (For example, for the criterion "comparative safety," the scale could be defined to range from "much better safety than comparator" to "much worse safety

than comparator.") The alternative, defining the high and low end of the scale based on a mathematical transformation of data, for example, frequency of adverse events, can create a mental distance between the scores and the interpretation of data. Since decisionmakers ultimately have to make a judgment on the evidence, the extent to which the scoring process supports their judgment must be considered in designing an MCDA approach that ensures *accountability*.

3.3.6 Step 6: Aggregating Data for Ranking, Investing, and Disinvesting

A quantitative MCDA model requires combining weights and scores to measure value (value model), which allows ranking interventions based on a measure of value defined by the criteria included in the model.

However, comprehensive understanding of the value of an intervention often includes aspects that cannot easily be measured. Indeed, certain criteria identified through analysis of ethical underpinnings in the previous section (e.g., cultural context) may not be amenable to quantitative consideration because scoring scales cannot be defined systematically. Nevertheless, consideration of these criteria might impact the value of the intervention, highlighting the need for nuance that can be met by a comprehensive MCDA that includes both quantitative and qualitative criteria. Such an MCDA can thus provide guidance on investing in the most valuable interventions and disinvesting in less valuable interventions, rooted in a definition of value that integrates conflicting ethical positions related to the triple aim that are operationalized in the criteria.

3.3.7 Step 7: Dealing with Uncertainty

Acknowledging uncertainty and providing means to explore it support the legitimacy of the MCDA process.

A fundamental uncertainty is whether the criteria included actually capture all the concepts that reflect what one aims to measure. This requires a thorough iterative validation process of the concepts underlying the criteria, bearing in mind the principles of MCDA and the objectives that the framework is meant to achieve. Exploration of the face validity of results obtained with the MCDA exercise is a prerequisite to avoid major misrepresentations of participant views.

Weighting explores trade-offs, which are expected to vary across stakeholders representing different views of the society. Uncertainty here is more a question of the representativeness of the committee members for a system-level decision than of mathematical calculations. Mathematics, however, are helpful to capture the diversity and transform the participatory process into a value measurement with an estimation of variability using appropriate statistics.

Uncertainty related to scoring includes uncertainty on the evidence, which is a fact in decisionmaking, and uncertainty on the interpretation of the meaning of the evidence, which can be captured, for example, by allowing users to provide ranges of scores.

A number of technical aspects, such as developing value functions for each criterion, the uncertainty related to the assumptions that have to be made to develop these, and the aggregation model (linear vs more complex) are described in more detail in the chapter by Oudshorn et al. From the procedural value standpoint, simplicity is important to limit the mental distance between the MCDA framework and the natural reflection and deliberation that takes place in decisionmaking.

3.3.8 Step 8: Reporting Results, Deliberation, Decision, Communication, and Implementation

Results of the MCDA-supported reflection, be they quantitative, semiquantitative, or qualitative, must be reported with clarity to those who apply the framework to ensure that face validity can be ascertained. Reporting of results is not trivial and quite critical for legitimacy. It should be done ideally during the deliberation, as a key procedural value of MCDA is its ability to clarify and support the deliberation process (Baltussen et al. 2016; Jansen et al. 2016). MCDA helps also communicating the reasoning that takes place during the committee's deliberation. *Clarity* on this reasoning facilitates acceptability by stakeholders. In this way, MCDA can be viewed as a method to operationalize accountability for reasonableness (A4R).

Once value related to the triple aim (holistic value) has been measured through the MCDA, implementation requires a financial exercise to invest in those healthcare interventions with high value and disinvest in those with low value. Such holistic value measurement provides a solid basis for ranking interventions and guides wise use of resources, which is characterized by opportunity cost and feasibility considerations (Fig. 3.2). Indeed, opportunity costs, in the sense of resources forgone due to the implementation of a new intervention, are at the root of ethical management of collectively funded healthcare systems (Claxton et al. 2015). Management of opportunity costs and affordability requires a financial exercise to estimate the total economic impact of interventions on a given system (Peacock et al. 2007). MCDA can thus help build sustainable healthcare systems.

3.4 Conclusion

This reflection suggests that MCDA can operationalize numerous ethical aspects and enhance the A4R framework set forth by Daniels and Sabin almost two decades ago (Daniels and Sabin 1997). Healthcare decisionmakers at all levels increasingly

face ethical dilemmas in accommodating various mandates and constraints including those of patients, clinicians, policymakers, payers, and developers. MCDA might provide an opportunity, a road map, to open the path to a collective reflection on accountable and socially responsible identification of interventions that contribute the most to the triple aim of healthcare. Indeed, building on the principles of the A4R framework, MCDA can be designed to make explicit the values, competing ethical dilemmas, and uncertainty inherent to healthcare decisionmaking while furthering participatory and transparent processes (Baeroe and Baltussen 2014; Baltussen and Niessen 2006).

When making a decision in the name of the population they serve, decisionmakers struggle to achieve a balance between the imperative to help individual patients, to serve the population as a whole in a fair manner, and to maintain health system sustainability. While the MCDA method does not resolve ethical dilemmas, its strength lies in its ability to explicitly identify, make, and communicate trade-offs among competing ethical claims. It does so by clearly defining the relevant criteria that reflect the values and principles of a given institution or society it represents and by helping stakeholders identifying trade-offs. This makes reasoning more powerful and more transparent, which can facilitate understanding and acceptance of the coverage decision. It can also foster development of healthcare interventions with best value regarding the triple aim.

Thus, selecting criteria for an MCDA for an HTA/MoH application has strong ethical implications. For example, if the criterion *disease severity* is included and considered under the assumption that an intervention for a severe disease has a higher value than for a disease that is not severe (this assumption is translated into the scoring scale: high end of the scale = severe disease; low end of the scale = very mild condition), the resulting MCDA value measurement of the healthcare intervention embeds, by design, the ethical aspect that those who are worst off (with a severe disease) should be prioritized, an aspect of fairness. They are prioritized in the sense that the intervention is given more value because it is for a severe disease relative to an intervention for a mild condition. By applying this reasoning to all the criteria of an MCDA rooted in the triple aim, the apparently conflicting goals, and their underlying ethical aspects:

- Serving the individual patient (imperative to help with best type of benefit, best efficacy, safety, and PRO – aspects of deontology)
- Serving the population (benefit large number of individuals [greatest benefit to greatest number – an aspect of utilitarianism]; prioritize those who are worst off and with severe diseases and unmet needs – an aspect of distributive justice)
- Ensuring sustainability (reduce cost of intervention and other costs – an aspect of utilitarianism) can be balanced based on knowledge (relevant and valid evidence, expert knowledge, contextual knowledge – an aspect of practical wisdom) and insights from committee members to make a decision that fair-minded people would find reasonable. Of note, this approach is at the root of the development of the open source, EVIDEM framework (Goetghebeur et al. 2008; Collaboration

2015; EVIDEM 2015), which was designed and is continuously developed with input from stakeholders from around the world over the past 10 years to put ethics in action.

This chapter is meant to initiate the discussion on the ethical aspects of MCDA. Because this field is in its infancy, further research on each aspect presented here is warranted.

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