Ethical Evaluation in HTA

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Introduction

Fundamentally, a health technology assessment (HTA) aims to help inform the overall question "what is good in health (including social and long-term) care?" Ethics analysis aims to provide a systematic reflection about what is of importance to those developing, using, and affected by a particular health technology and provides guidance about the course of action that best reflects this importance. Ethical issues are present in the assessment of every health technology. Nevertheless, the extent to which these issues are explicitly identified and discussed may vary and will depend on the decision that is being informed by the HTA, the expertise available, and the willingness to make ethics an explicit part of the discussion of the appropriateness of the health technology being assessed.

Our objective in this chapter is not to provide an introduction about how to conduct ethics analysis in HTA. We believe working examples of how ethics analysis proceeds are illustrated well in the many references contained here, and highly selective examples of partial analyses may be misleading and counterproductive. Instead, we aim to provide a brief description of the nature and importance of ethics analysis in HTA, the approaches that have been proposed and used, how approaches may differ depending on the type of health technology being examined, and provide some examples of recent ethics analysis. We end the chapter with a list of books and journal articles for those wishing to delve more deeply into this fundamental topic in HTA.

What is ethics analysis in HTA and why is it needed?

Ethics is at the core of the HTA decision-making process and an inherent part of HTA. Recognizing this, early and more recent definitions explicitly include ethical issues within the scope of assessment (Autti-Rämö 2007; INAHTA 2019; WHO 2019). Decision-making consistently involves facts and values because determining the best thing to do within a specific context involves value judgments that are made on the factual analysis of this context. Substantiated value judgments (Legault et al. 2018) allow for more transparency in the final conclusion. Since the fundamental goal of the HTA process and its reports is to guide the decision-makers, an ethical consideration of the implied value judgments in the final recommendation or decision should be communicated in the final report and therefore become an active part of the HTA process.

Given the implicit nature of value judgments in the decisions made during the HTA process, eliciting these implicit value judgments is the first approach proposed for integrating ethics into HTA.

Eliciting value judgments is a reflexive process by which reasonable grounds of the evaluation that guide the decision-making process are clarified. Such a reflective approach on the decision-making process in HTA provides an opportunity for HTA producers to take into consideration the different ethical aspects involved in their activities. The HTA producer's awareness of the value judgment implied in their process can influence and provide grounds to the choices made throughout the HTA process. One approach to gaining this awareness is the Socratic approach proposed by Hofmann (2015). In the Socratic approach, relevant moral questions guide the identification and elucidation of some of the most fundamental value judgements. An example would be to ask, in the context of the evaluation of bariatric surgery for morbid obesity, whether this health technology challenges our conception of the treatment of disease, for example, by modifying healthy organs in order to reduce disease symptoms.

A new drug, a new medical device or a new health intervention has many impacts. Notwithstanding their importance, clinical effectiveness, safety and cost-effectiveness represent only three impacts among others. Not only is the clinical state of the patient impacted, but so is their quality of life in his or her social setting. Sometimes the introduction of new health technologies have a major impact on health professionals' practices and their organizational settings as well as their procedures. Ethical analysis often regroups the analysis of such impacts as proposed by Busse and colleagues (2002) as psychological, social and ethical impacts. Other reports gather them under the heading of "contextual considerations" or "ethical, legal, and social considerations." Usually the information gathered under these headings list different ethical issues related to what is assessed. When a systematic analysis of the ethical dimensions involved is carried out in a way similar to that done for clinical effectiveness, safety or cost-effectiveness, this is another way of integrating ethics into HTA. This type of analysis requires an ethical framework that structures the analysis. Different ethical approaches have been proposed and used in HTA reports.

What approaches for ethical analysis have been used?

In the literature, the following approaches have been identified for addressing ethical issues in HTA: principlism, casuistry, coherence analysis, wide reflexive equilibrium, axiology, social shaping of technology, constructive technology and the triangular method (Assasi 2014). These approaches, and their applicability, which are described in more detail elsewhere (Assasi 2014; Hofmann 2014), can be divided into norm-based and value-based approaches. In norm-based approaches, the facts that will be correlated to a moral norm must be made explicit in order to identify conformity or non-conformity with the norm.

In value-based approaches, the impacts of the health technology (e.g. harms, benefits, social-cultural issues) will be subject to ethical evaluation (Patenaude 2017; Assasi 2014).

To guide practices for integrating ethical analysis in HTA, the proposed framework of Assasi et al. (2016) can be useful. The framework consists of three building blocks:

1. A flowchart that provides an overview of the steps to be taken for conducting ethical analysis in HTA
2. A more detailed description of the different steps, based on earlier work:
    - define the objectives and scope of the evaluation
    - perform stakeholder analysis
    - assess organizational capacities
    - frame ethical evaluation questions
    - perform ethical analysis
    - deliberate with experts and stakeholders
    - knowledge exchange/translation to decision-making
3. An overview of commonly used tools for ethical analysis in HTA.

Three main approaches to ethical analysis are commonly found in HTA reports. The first identifies, without further analysis, the ethical issues that can be raised by the introduction of a health technology. The four principles of bioethics, as articulated and made popular as principlism by Beauchamp and Childress (1994), are often used to report the ethical issues related to beneficence and non-maleficence such as quality of life, personal preferences, value of social or economic impacts for the patient, autonomy such as free and informed consent, and justice such as equity in the delivery of treatment.

The second approach not only identifies the ethical issues at stake, but also describes the social debates surrounding them, such as in the guide of the Haute Authoritéen Santé (2016) which weights the relative force of the arguments presented for each of them.

A third kind of approach goes a step further and evaluates the issues by using a specific ethical or moral approach such as casuistry, coherence analysis, wide reflective equilibrium and the ‘triangular model’ based on a human-centred approach (EUnetHTA 2014). As one might suspect from this brief overview, there is no universal approach for integrating ethics in HTA and there is a lack of consensus on a practical method for conducting ethical analysis (Bellemare 2018).

Moreover, the choice of a particular approach is not value-free; it must be justified by a moral point of view (Patenaude 2017).

What different approaches might be taken, for example, for single technologies, for complex technologies, for innovative technologies?

As the diversity of approaches for addressing ethical issues in HTA, there are several approaches for carrying out a full HTA. The European network for Health Technology Assessment (EUnetHTA) represents one important initiative to offer a common framework for addressing the different HTA domains, also including the ethical one (Kristensen 2009). The HTA Core Model® (HTA Core Model) is a standardized synthesis of available methods intended to address all relevant considerations in the HTA process. The basic idea of the HTA Core Model is to structure the contents of an HTA into pieces of information. The HTA Core Model does not purport to solve the philosophical debate, but to offer a tool for identifying, explicating and organizing ethical issues for HTA organizations, irrespective of their resources (material, time and knowledge). It has three elements: a question-based approach that covers issues essential for ethical analysis within HTA; a brief explanation of methods that can be used to approach the issues; and a discussion on the integration of ethical analysis into the process of HTA (Saarni 2008; Sacchini 2016).

There exists no explicit HTA Core Model application for complex health technologies, such as disease management or public health programs. The Collaborative Project INTEGRATE-HTA (integrated health technology assessment for evaluating complex technologies) aimed to developed concepts and methods for HTA to enable a patient-centred, integrated assessment of the effectiveness, and the economic, social, cultural, legal, and ethical issues of complex health technologies that takes context and implementation into account. INTEGRATE-HTA is explicitly addressing the complexity of health technologies. It represents an attempt to overcome two possible limitations of the HTA Core Model. On the one hand, it addresses the risk of separation between the more technical or quantifiable (e.g. effectiveness, safety, economic) and non-technical (e.g. organizational, ethical, legal and social) domains. On the other hand, INTEGRATE-HTA more explicitly focuses on the process, including the public-patient involvement in scoping questions for the development of HTA as well as the actual decision-making process.

More specifically, the INTEGRATE-HTA project developed guidance on how to assess the effectiveness and economic, social, cultural, legal, and ethical issues of

complex health technologies; to elicit patient preferences and patient-specific moderators of treatment; to include context, setting, and implementation in the assessment of complex health technologies; to choose adequate qualitative evidence synthesis methods; and on how to integrate all these issues to a patient-centred, comprehensive assessment of complex health technologies. The guidance was applied in a case study on palliative care (Bakke Lysdahl 2016; Gerhardus 2016; Van Hoorn 2016) and showed that the key concepts and methods could provide a helpful structure for the integrated assessment and analysis of a complex health technology and for reporting clearly what had been done and why. Some experiences utilizing the INTEGRATE-HTA framework have been reported. (Bond 2017) The development of frameworks for the analysis of ethical issues in newer and challenging areas of HTA, such as in disinvestment, is nascent, but progressing.

Examples of how ethics analysis has been done (by different HTA agencies or ethicists)

The previous sections outlined a number of different approaches that have been used in ethical analyses of HTA and these approaches have been employed in practice by different HTA agencies to analyze ethical issues raised by health technologies. The Swedish Council on Health Technology Assessment (SBU) developed a context specific framework that adapted principles of the Swedish ethical platform for healthcare priority-setting (Heintz 2015). This framework relied on four aspects to consider when developing a framework for ethical analysis in HTA: (1) The use of checklists at specific stages of the HTA process; (2) The use of standpoints to provide guidance for assessment of ethical aspects such as equity, autonomy, and privacy based on laws, regulations and case rulings of agencies or courts. This also involved the use of the “need and solidarity principle” which focuses on health care resources being given to those in greater need and implies that not everyone can have their needs met in part or at all; (3) Questions to consider on how health technology is funded in particular contexts and its implications on the organization’s interests, the specific role of the organization that will adopt the framework which introduces the cost-effectiveness principle that involves choosing between different interventions an individual needs to strive for a reasonable relationship between costs and effects, measured in terms of improved health and quality of life; (4) The availability of ethics experts to assess the ethical aspects with respect to the ethical theory and argumentation. The framework also outlines the effects of the intervention on health, its compatibility with ethical norms, structural factors with ethical implications and the long-term ethical consequences.

For example, the report identified specific social aspects about the technology arising from patient interactions that are not necessarily related to clinical ethics.

While bariatric surgery has shown positive results in weight reduction in the past several years (Buchwald 2004), it is associated with high costs and a rise in health care expenditure. In addition, there is inadequate information on the psychological consequences (Pratt 2009), and this inadequacy has raised questions about the patients' autonomy such as the validity of informed consent (Madan 2007) as well as the symbolic value of the surgery and its effect on distribution of healthcare. The analysis also identified challenges to human integrity or dignity, the social conception of an individual, and the relationship between physician and patient.

The Canadian Agency for Drugs and Technologies in Health (CADTH) produced an ethical analysis of DNA mismatch repair deficiency (dMMR) testing for Lynch syndrome diagnosis among patients with colorectal cancer. This test can help to optimize chemotherapy treatment in colorectal cancer patients and diagnoses Lynch syndrome at an early stage for treatment. The ethics analysis examined issues identified in the literature as well as those identified by an analysis of the other sections of the HTA report and raised and discussed issues regarding ten "core values" that are challenged by the use of dMMR testing: patient autonomy (informed consent for both tumour and germline testing, maintaining confidentiality, etc.), maximizing benefits and minimizing harms to patients, others (burden and anxiety of testing, harm of undiagnosed or late-diagnosed cancer, etc.) and to populations, the duty to warn, distributing benefits and burdens fairly, providing excellence in health care, consistency, relational considerations, and stewarding scarce health care resources.

Current Methodological Issues in Ethics Analysis in HTA:

Two areas that are in the early stages of development are competencies for ethics analysis and quality assessment of ethical analysis. As these topics develop, they will have an important influence on how and when ethics analysis is conducted.

Skepticism about the existence of ethical expertise and the difficulty of finding relevant experts have been advanced as reasons for why ethics analysis has not been successfully integrated into HTA (Hofmann 2014; ten Have 2004). Ethicists and philosophers are normally not trained in evidence-based-medicine, HTA, or health policy decision-making processes, while HTA experts are rarely trained in ethics (Hofmann 2015).

The questions of who possesses the relevant expertise for conducting ethics analysis in HTA and which qualifications are necessary are important and are the subject of discussions in the international ethics in HTA community (Hofmann 2015). Some HTA researchers have proposed that conducting these analyses demands a reasonable amount of knowledge of ethical theories and principles and at a minimum, competent researchers in this area should be familiar with approaches in clinical ethics and moral philosophy (Bond 2014). Regardless, philosophical expertise is only one aspect of competency for conducting sound ethics analysis in an HTA.

One recent attempt to articulate and clarify the relevant dimensions of competency for conducting ethics analysis in HTA describes three main domains: knowledge, skills, and attitudes (Sacchini and Refolo 2018). Knowledge covers both the basic knowledge of typical HTA content, comprising an understanding of scientific concepts in epidemiology and health economics as well as a general understanding of the theories and approaches of moral philosophy (e.g.: utilitarianism, casuistry, egalitarianism) and common bioethical issues (e.g.: self-determination, privacy, autonomy, informed consent, etc.). Advanced knowledge includes an understanding of specific debates about ethics in HTA, methods of ethics for HTA, and health law and policy.

The domain of skills includes abilities in ethical assessment (clearly articulating ethical concerns and distinguishing them from overlapping issues, identifying relevant beliefs and values, and gathering relevant information), HTA process (communicating and collaborating effectively, identifying and resolving potential conflicts of interest, and identifying who needs to be involved in consultations), and interpersonal skills (facilitating communication, educating others about the existence of the ethical domain, and eliciting the moral views of various stakeholders). The attitudes deemed important include integrity, prudence, courage, open-mindedness, and respect for multiculturalism. Defining and agreeing on the core competencies required for good quality ethics analysis remains to be done.

Quality assessment of ethics analysis is still nascent and there do not currently exist any broadly accepted tools or checklists for conducting this quality assessment as there are for assessing the strength of primary empirical studies, systematic reviews, and economic evaluations (Scott et al 2014). The development of a quality assessment tool for ethics analysis is thought to be desirable for a number of reasons.

It would increase the transparency and readability of ethics analyses; it could help to assess the transferability of ethics analyses across jurisdictions; and it would provide a common vocabulary and means of structuring communication among members of an HTA team.

Members of the HTAi Interest Group on Ethics in HTA have published two articles (Scott et al 2014; Scott et al 2016) describing a tool they have developed for quality analysis that provides guidance on assessing both the content of the argument of an analysis as well as the applicability of the results and potential sources of bias. The Q-SEA (Quality Standards for Ethics Analysis) checklist divides the quality criteria into those bearing on internal or process features of the analysis and external or output features. The process domain includes ratings of the reporting and conduct of the research question, the literature search, description of the perspective, and the ethics framework employed. The output domain aims to rate the reporting and conduct of completeness of the analysis, identified sources of bias, policy implications, conceptual clarification, and identification of conflicting values (Scott 2016). While the Q-SEA tool has good face validity, it has yet to be formally validated and its feasibility and utility as a quality assessment tool for ethics analysis within HTA remain to be assessed.

Concluding Remarks

HTA is a moral enterprise and making explicit the many value judgments involved in designing, conducting, and interpreting the results of an HTA is essential to decision-makers to make reasonable, fair, and sound decisions at multiple levels (clinical, institutional, and ministerial). The newcomer to HTA is an area with challenging issues, partially unresolved, but which is essential to consider. At least identify ethical issues relevant to an HTA, if necessary with referral to others for resolution. While many methods exist for analyzing ethical issues in HTA, there are more methods than actual analyses and HTA agencies face a number of conceptual and operational challenges in advancing this important work. Articulating who can do this work and what it looks like to do this work well is an important next step in facilitating the conduct and uptake of ethics analysis.

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