International Journal of Technology Assessment in Health Care, **27:1** (2011), 64–70.
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doi:10.1017/S0266462310001303

METHODS

Improving ethics analysis in health technology assessment

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Objectives: The aim of this study was to critically examine the current guidance for conducting ethics analysis in health technology assessment (HTA) and to offer recommendations for how to improve this practice.
Methods: MEDLINE, Philosopher's Index, and Google Scholar were searched for articles and reports using the keywords "ethics" and "health technology assessment" and related terms. Bibliographies of all relevant articles were also examined for additional references. A philosophical analysis of the existing guidance was conducted.
Results: We offer three recommendations for improving ethics analysis in HTA. First, ethical and legal issues must be clearly separated so that all policy-relevant questions that the technology raises can be considered clearly and systematically. Second, analysts must make better use of ethics theory and discuss better how particular theoretical approaches and associated analytic tools are selected to make transparent which alternative approaches were considered and why they were rejected. Third, the necessity for philosophical expertise to adequately conduct ethics analysis needs to be acknowledged.
Conclusions: To act on these recommendations for ethics analysis, we offer these three steps forward: acknowledge and use relevant expertise, further develop models for conducting and reporting ethics analyses, and make use of untapped resources in the literature.

Keywords: Health technology assessment, Ethical analysis, Bioethics, Normative ethics

Ethics is the philosophical inquiry into the nature and grounds of moral judgments and standards and rules of conduct both actual and ideal (26). In health technology assessment (HTA), an ethical issue can be identified by its potential to cause real and significant consequences for people's conception of the good and their abilities to pursue projects in the world. Because ethical issues present philosophical questions which, by definition, cannot be answered using the usual empirical techniques used in HTA, ethical issues require a separate and distinct analysis from clinical, economic, and social issues.

No matter which philosophical frameworks and tools are used, ethics analysis requires systematic reflection and reasoning about what is of fundamental importance to those developing, using, and affected by a particular technology

The authors thank members of the Institute of Health Economics (Edmonton, Alberta) and participants at the CADTH 2010 Symposium (Halifax, Nova Scotia) for constructive discussion and comments on oral presentations that led to the development of this manuscript. Both authors are responsible for the conception and design of the project and writing and revising the manuscript. Both authors approved the final version of the manuscript. Katherine Duthie's research is supported by a stipend from the Western Regional Training Centre for Health Services Research, Vancouver, British Columbia, and a grant from the Maternal-Fetal-Newborn Health, University of Alberta, Edmonton, Alberta. The authors declare no conflicts of interest.

https://doi.org/10.1017/S0266462310001303 Published online by Cambridge University Press

and moves systematically to some course of action that best reflects this importance.

The consideration of ethical issues in HTA is considered important for three reasons. First, an ethics analysis has instrumental value: HTAs are more useful for decision makers and are more transparent (13) (thus, more transferable) (28) if ethical issues are identified and addressed. Second, HTAs are value laden (22;23). Including ethics allows the HTA to better reflect the actual role of ethical issues in technology assessment. Third, because ethics are inherently part of HTA, we have a *moral duty* to ensure that ethics issues are meaningfully considered in HTA (17). Given the importance of ethics analysis in HTA, our objective in this paper is to critically examine the current guidance for ethics analysis in HTA and to offer recommendations for how to improve on its practice.

To identify HTA reports, guidance documents, methodological papers, and research papers upon which to base an assessment of the guidance available for ethics analysis in HTA, we conducted a literature search in two electronic bibliographic databases (MEDLINE and Philosopher's Index) and using Google Scholar using the keywords "ethics" and "health technology assessment" and related terms. We reviewed the references of relevant articles and searched HTA agency and organization Web sites (International Network of Agencies for Health Technology Assessment [INAHTA], Health Technology Assessment international [HTAi], European network for Health Technology Assessment [EUnetHTA]) for additional reports. All searches were restricted to English-language publications, and no date restrictions were used. We then conducted a critical philosophical examination of the relevant studies identified in this search.

Despite relative agreement in the broader HTA community about the importance of ethics analysis (6;16;17), among HTAs there are differences in the extent to which such analyses are conducted (6;16;17). The demanding models for ethics analysis discussed in the literature continue to challenge HTA producers. If nothing else, the literature shows that it is difficult to incorporate ethical analysis into HTA in a meaningful and useful way, and the ethics questions in HTAs continue to be reduced to the core questions of efficacy and cost (27).

There is a gap, then, between the development of methods and guidelines for assessing clinical and cost-effectiveness and those for ethical issues (9). In response to this gap in methodology and practice of ethics analysis in HTA, two international HTA networks convened working groups to develop guidance. In 2005, the INAHTA Ethics Working Group released its report on handling ethical issues (15). In 2008, EUnetHTA released the Core Model for HTA for medical and surgical interventions (8), which includes a detailed module on ethics analysis. The INAHTA and EUnetHTA guidance suggests that ethics analysis in HTAs improves HTA overall by making them more *comprehensive*, *transparent* (and therefore *transferable*), and ultimately, more *useful* to HTA users (8;15).

However, the conduct of an adequate ethics analysis of the kind recommended in the EUnetHTA and INAHTA documents and in related and similar publications (4;23) is hampered by three weaknesses: (i) the view that ethical issues are coextensive with legal and social issues, (ii) poor use of ethics theory, and (iii) the belief that ethics expertise is neither necessary nor sufficient to conduct an ethics analysis. Addressing these weaknesses requires a clear distinction between ethical and legal issues, the reflective and reasoned use of good ethics theory, and the specific expertise required to conduct an ethics analysis.

CLEARLY DISTINGUISHING BETWEEN ETHICS AND LAW

The HTA literature shows a problematic tendency to group ethical and legal issues together (22). It is important to consider ethical and legal issues separately for two reasons. First, law and ethics are separate concepts and processes. Law can be ethically contentious or defective, and moral rights can fail to be incorporated into law, or be incorporated inadequately (2). Second, law and ethics entail separate analytic systems that generate distinct conclusions.

A consequence of combining ethical and legal issues is illustrated by a recent Canadian HTA (10) on the reuse of single-use medical devices. Despite its goal to address the "legal and ethical questions," the analysis is primarily legal. Typical issues in ethics, for example, informed consent, are reduced to their status in law, in this case "legally valid informed consent." The report gives priority to legal analysis, explaining that ethical principles will guide decision making in the "absence of clear regulation and legal precedents." The report then focuses on matters that carry ample legal regulation and precedent, effectively ignoring several ethically relevant issues including considerations of fairness, safety, duties of care for particular populations, obligations to non-patient populations, impacts on system sustainability, and the environment.

Combining (and, worse, conflating) ethical and legal issues is also problematic because the ethical issues persist despite an absence of ethical assessment. As a result, an HTA without an ethics analysis fails to identify and address all policy-relevant questions that the technology raises. A clear and separate discussion of ethical issues best ensures that the HTA achieves the purposes of ethics analyses in HTA (comprehensiveness, transparency, transferability, and usefulness) by requiring that the relevant ethical issues are given their due consideration in a systematic way that can easily be reviewed or communicated (13).

BETTER USE OF ETHICS THEORY

The literature on HTA and ethics is impeded by poor or incomplete use of ethics theory. Three related problems

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contribute to this weakness: First, the literature frequently endorses an eclectic use of moral theory to guide ethical reflection and analysis. Second, discussions of the use of ethics theory lack detail about the assumptions, implications, and applications of each theoretical approach. Third, many of the proposed strategies for ethics analysis do not generate sufficient direction for HTA end-users.

Eschewing Unsystematic Eclecticism

"Eclecticism," in philosophical contexts, refers to a theoretical approach that draws ideas from a variety of different philosophical theories and traditions. There is a trend in the HTA literature to promote the use of eclectic approaches to ethics analyses in HTA (8;11;13;23). The EUnetHTA Core Model endorses an unsystematic eclectic approach explicitly, describing at least six different methods stemming from divergent theoretical areas, any combination of which HTA producers are encouraged to use in their ethics analysis.

Other authors on HTA and ethics have defended the use of an eclectic approach on the grounds that it provides analyses that are "typically a more comprehensive evaluation of ethical reasoning behind and consequences of various courses of action than is possible with only one analytic method" (11). Still others have contended that such an approach avoids being vulnerable to the objections to any single method (13). Despite their putative appeal, eclectic approaches pose two major problems. First, they can result in the choice of ethical approaches that carry conflicting philosophical assumptions. Second, and perhaps more problematically, with its inattention to theory, eclecticism is vulnerable to resulting in unsystematic approaches to ethics in HTA, unless the various pieces of divergent theory are united within a single logically coherent system.

Approaches that do not engage adequately with theory, like the one recommended in the EUnetHTA core model, seem less likely to produce the benefits that ethics analysis is thought to bring to HTA. Such an approach is unlikely to produce transparent HTAs because an unguided application and interpretation of moral theory greatly reduces the chances for logical and clear record keeping and reporting. An eclectic approach may enable comprehensiveness by providing several strategies for uncovering ethical issues, but it does not show how they can be systematically addressed. The usefulness of an HTA that uses this approach will depend greatly on how the individual HTA producers record the process and analyze the results. Without systematic guidance, HTA producers would need to rely heavily on their own resources and discipline to generate useful ethics discussions in their HTA report.

Better Discussion of Which Methods to Use, Why, and How

Most HTA reports fail to describe how the chosen theoretical approach and associated analytic tool was selected for the ethics analysis. If the absence of such a description is due to a lack of active consideration on the part of HTA producers, this creates several problems. First, the analytic tool often determines which ethical issues related to a particular technology end up being the focus of the analysis. Without considering other approaches, HTA producers risk overlooking an issue that is significant for the technology under consideration. Such an omission puts the comprehensiveness of the analysis at risk. Furthermore, a failure to acknowledge and explain the decision about which theoretical approach to take and why limits HTA producers' capacity to provide a transparent account of the assessment.

Second, the usefulness of the ethics analysis tool varies with the nature of the technology and with the context in which it is being applied. A clear consideration of the tools in a specific context is required to understand the ways in which a particular approach (even an eclectic one) maps onto the technology and the HTA environment (17). Third, a failure to discuss how a particular ethics approach was selected eliminates the possibility of discussion about the consideration and rejection of alternative approaches. In the process of an HTA, even a brief discussion of which methods were considered and why the chosen methods were selected adds transparency to the process.

Failure to Provide Ethical Direction

The extent to which an ethics analysis renders an HTA more useful depends in part on the HTA user's context. To a government policy maker, a report is useful when it uses clear language and provides succinct information that is relevant to the policy-maker's context. Moreover, the useful report does as much work as possible, providing analysis and basic direction that the advisor can easily include in communication documents for other decision makers within the organization.

The HTA literature fails to direct HTA producers to analyze ethical issues in a way that generates this basic direction. In fact, some literature remains silent about the necessity of doing an ethics *analysis* at all (11;13). Raising ethical issues without analysis results in a cataloguing of issues. An HTA report that simply lists the relevant ethical issues requires end users to do the additional work of weighing issues, prioritizing underlying values, and identifying points of contention to fully understand the ethical implications of the technology. Guidance that fails to provide even minimal instruction on how to analyze ethical issues (as is the case with the dominant eclectic approach in the HTA literature) results in HTAs that are unlikely to achieve the expressed goal of usefulness for HTA users.

DEVALUING ETHICAL EXPERTISE

HTAs that include an ethics analysis seldom indicate whether authors with ethical expertise were involved. When expert involvement is indicated, their contributions are typically not well described (6). Surprisingly, neither the EUnetHTA Core

https://doi.org/10.1017/S0266462310001303 Published online by Cambridge University Press

Model nor the INAHTA handbook provide guidance about the relevant expertise that ought to be used.

Following Weinstein (29), we consider ethics expertise to be a capacity to provide strong justifications for claims in a domain (epistemic expertise). Characterizing expertise in this way makes it clear that we are talking about people with a particular knowledge of methods of argumentation and justification, that is, *methodological* expertise in ethics. Our examination of the HTA literature indicates that the apparent lack of discussion of expertise is the result of either the belief that there is no expertise for conducting ethics analysis or the belief that, even if there is such expertise, it is not necessary or helpful. Both these beliefs, we believe, are unwarranted.

There Is no Expertise, so None Is Required

The belief that no expertise is required for conducting ethics analysis rests on the assumption that the subject matter of ethics analysis resists the development of expertise or that a lack of consensus regarding a philosophical approach suggests there is no real or useful expertise.

The belief that the subject matter of ethics analysis precludes the development of specific expertise may be based on the ambiguity of "expertise" or on the failure to recognize the distinctly philosophical nature of the questions being asked and of the approaches being advocated. For example, Saarni et al. (23) appear to reject a place for ethics expertise, claiming that all that is necessary for an adequate ethics analysis is a broad literature search and the inclusion of relevant "stakeholders." However, both the INAHTA and EUnetHTA approaches acknowledge ethics expertise. The Core Model specifies the need for "philosophical analysis of the logic and coherence of the argumentation" (8). And the use of wide reflective equilibrium, another recommended approach, requires *philosophical* arguments to bring out the relative strengths and weaknesses of the alternative sets of principles (or competing moral conceptions) (5). The role of ethics expertise and the philosophic dimension of the questions are clear.

The belief has also been expressed that the lack of consensus among moral philosophers regarding potential approaches indicates the impossibility of expertise (23). To philosophers, the kind of disagreement over approaches highlighted in the HTA literature is considered philosophically healthy and not, as is suggested, a reason for resignation. Furthermore, it is unclear why it might be thought that philosophers ought to agree that one theory or set of concepts is sufficient to understand and appreciate the ethical import of a particular technology.

Expertise May Exist, but It Is not Necessary or Helpful

Even when it is acknowledged that the questions being asked are philosophical in nature and presuppose philosophical expertise, the belief that such expertise is not necessary to conduct an ethics analysis has been stated explicitly by some of the authors of the EUnetHTA core model (23). This belief leads to the equally contentious assertion that the eclectic method of the EUnetHTA core model offers a tool that is usable by HTA organizations, regardless of their methodological expertise (23). Underlying this belief is one or more of the following assumptions: (i) the nature of an ethics analysis suggests that there ought to be methods for the nonphilosopher; (ii) some ethics analyses might require philosophical expertise, but not all do; (iii) the methods and vocabulary of professional philosophers would make the results of an ethics analysis incomprehensible to the intended audience of the HTA; and (iv) experts in other disciplines can easily learn the tools and methods required to conduct an adequate ethics analysis.

(i) The claim that ethics analysis can be conducted without a professional ethicist (23) is supported by the rather bewildering claim that there ought to be methods for ethics analysis that are applicable for nonphilosophers. Epidemiologists, statisticians, economists, and lawyers are not required to produce methods for nonexperts, so it is unclear why this demand should apply uniquely to moral philosophers. The demand that there be such methods is perhaps based on the erroneous belief that the apparent simplicity or ordinariness of philosophical questions entails equally simplistic or quotidian methods.

(ii) There is the belief that expertise and ethics analysis, in general, are most appropriate for obviously morally contentious technologies (12) with the implication that expertise is not required for all ethics analyses. This belief undercuts the original motivation for conducting ethics analysis: Analysis is required because the values implicit in and related to the adoption of a technology and that may challenge our ethical norms are not easily recognized. The ability to make these values explicit and to articulate and respond to such challenges requires a knowledge of philosophical approaches, concepts, and arguments.

(iii) Some authors have expressed the view that, even if professional philosophers were to become involved, ethicists' professional vocabulary would only hinder the use of ethics analysis (13). This assumes, without justification, that ethicists cannot discuss ethical issues in a way that is clear to the nonexpert. Every expert involved in HTA, without question, makes use of a specialized vocabulary to conduct her respective analysis, yet is still expected to write in a way that is accessible to the nonexpert. As with (i) above, it is unclear why a problem that logically applies to all experts involved in an HTA is restricted to ethicists.

(iv) The conduct of ethics analysis in HTAs and the literature discussing ethics analysis suggest that experts in other disciplines can easily learn the methods required to conduct an adequate ethics analysis. Possible reasons for this belief include the lack of obvious technical apparatus in philosophy and the erroneous assumption that doing philosophy well does not require special training or aptitude (2). The depth

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of the ethical questions confronting researchers is hidden, as it is in many philosophical questions, by their apparently ordinary nature and by the relative stability of the intellectual landscape within which researchers work (11). But we see these facts providing still more reason for needing ethics expertise in this area and not as a reason for championing the view that the relevant knowledge and skills can be picked up along the way.

STEPS FORWARD

Based on the three improvements argued for above (clearly separating ethical and legal issues, better use of ethics theory, and acknowledging and using relevant expertise), we suggest the following three steps toward improving ethics analysis.

Expertise

Acknowledging and using appropriate expertise will help to ensure that an adequate ethics analysis is conducted. A common, although erroneous, assumption is that because a subject matter requires philosophical analysis, empirical evidence, for example, the work of clinical investigators, sociologists, and anthropologists, is not important. Good ethics begins with good facts, although the extent that empirical work should be used to inform an analysis of ethical issues is a matter of debate among philosophers (20;24) and other researchers (25). Answering practical ethical questions, such as the ones raised by HTA, requires both philosophical and nonphilosophical reasoning; however, exactly how the answers to nonphilosophical questions are to be woven into answering ethical questions is part of ethical reasoning and, thus, falls within the domain of moral philosophy (2).

We have been asked what difference there may be between an ethics analysis conducted by someone with ethics expertise and someone without such expertise. The question appears to assume that one can talk meaningfully about differences between clinical and economic evaluations conducted by experts and nonexperts but that any such differences diminish or disappear for ethics analysis. Our opinion is that someone with expert knowledge and skills in any area is more likely to provide an adequate analysis and to present the results in such a way that they are useful to the reader than is someone without such expertise. Because a trained ethicist can draw on many conceptual tools and has a broad knowledge of the potential issues, the differences would likely be parallel to those in other disciplines involved in HTA: The use of expertise allows for a broader and deeper (richer) analysis and makes it more likely that the results will be valid and useful.

We would be remiss if we did not recognize the limitations of organizational capacity to do ethics analyses in HTAs. Procuring staff with expertise in ethics issues is often a great challenge, especially when resources are scarce (18). It would likely be beneficial if HTA producers became more familiar with ethics analyses and qualitative methods to conduct primary research to address ethical issues. However, it is essential that ethicists be recruited into agencies (either permanently or on a contract basis) (15;17). We acknowledge that ethicists may be difficult to identify. HTA producers might first look to professional bioethics and ethics associations to begin to develop future contacts. We hope our argument serves as a call to both HTA organizations and ethicists to work together to promote a culture that rises to the challenge of integrating ethics analysis in HTAs.

Guidelines for Conduct and Reporting and Methodological Quality

The EUnetHTA report on best practices in HTA states that HTAs must provide a detailed, reproducible, and transparent description of the scientific methods (3). The INAHTA and EUnetHTA models are a similar step in this direction for ethics analysis. There are a variety of methods used to conduct and report on ethics analysis; however, there is little reason to think that reporting cannot be standardized in a manner similar to systematic reviews (19) and economic evaluations (7). Such reporting emphasizes transparent description and a detailed protocol; it does not prohibit the flexibility of methods and judgment required to conduct ethics analysis. If ethics analysis is not conducted or is restricted in some way (e.g., by focusing exclusively on the impact of the technology on patient autonomy or on the patient-caregiver/health professional relationship) this should be explained and justified.

To help end users make use of the results of ethics analysis, analysts should collaborate to develop methods to evaluate the appropriateness and strength of ethics analysis. Presently, the best that can be done is to have the relevant expertise involved in peer review of the protocol and report.

Untapped Resources

Review of the literature suggests that many of the issues of ethics in HTA have been discussed in other, largely untapped, areas. We encourage researchers to look to this literature. Examples of such resources include discussions of expertise (2;29) and the moral authority of consensus decisions (21) in the bioethics literature and debates about technological determinism (1;14) in bioethics and philosophy of technology. Examining issues with analogous technologies is one important way of identifying and exploring ethical issues, so an awareness of areas that discuss similar issues is particularly important.

CONCLUSIONS

Commentators in the HTA community have suggested that ethics analysis in HTA improves HTAs overall by making them more *comprehensive*, *transparent* (and, therefore, *transferable*), and ultimately, more *useful* to HTA users. We have argued that these benefits are unlikely to be realized

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with the current guidance and practice of ethics analysis in HTA. We have noted three weaknesses in the current literature: (i) the common view that ethical issues are coextensive with legal and social issues; (ii) generally poor use of ethics theory; and (iii) the belief that ethics expertise is neither necessary nor helpful to conduct an ethics analysis. We offer three recommendations to improve ethics analysis in HTA. First, ethical and legal issues must be clearly separated so that all policy-relevant questions that the technology raises can be considered clearly and systematically. Second, analysts must make better use of ethics theory and discuss better how particular theoretical approaches and associated analytic tools are selected to make transparent which alternative approaches were considered and why they were selected or rejected. Third, the necessity of philosophical expertise to adequately conduct ethics analysis needs to be acknowledged. To act on these recommendations for ethics analysis, we offer these three steps forward: acknowledge and use relevant expertise, further develop models for conducting and reporting ethics analyses, and make use of untapped resources in the literature.

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CONFLICT OF INTEREST

Both authors report having no potential conflicts of interest.

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