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# Ethics and health technology assessment: Handmaiden and/or critic?

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# Ethics and health technology assessment: Handmaiden and/or critic?

## Abstract

**Objectives:** This study examines the content and role of ethical analysis in health technology assessment (HTA) and horizon scanning publications. It proposes that ethical analysis in HTA is of at least two different types: an ethics of HTA and an ethics in HTA. **Methods:** I examine the critical differences between these approaches through the examples of the analysis of genetic screening for breast cancer and home blood glucose testing in diabetes. I then argue that, although both approaches subscribe to similar views concerning HTA and ethics, they use different theoretical and methodological traditions to interpret and explain them.

**Results and Conclusions:** I conclude by suggesting that we need the interpretive insights of both these approaches, taken together, to explain why ethics has not been able yet to contribute fully to HTA and to demonstrate the scope and complexity of ethical work in this domain.

## Keywords

ethics, health, critic?, technology, assessment:, handmaiden, and/or

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# Ethics and health technology assessment: Handmaiden and/or critic?

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**Objectives:** This study examines the content and role of ethical analysis in health technology assessment (HTA) and horizon scanning publications. It proposes that ethical analysis in HTA is of at least two different types: an ethics *of* HTA and an ethics *in* HTA.

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**Keywords:** Ethics, Social analysis, Procedure, Science and technology study

This study examines the role and content of ethics in health technology assessment (HTA) and horizon scanning publications. Most HTA methodologists agree that ethics has a very important role to play in HTA (1;15). Ethical analysis has contributed significantly to health technology assessment in at least two ways: (i) enhanced recognition of the value-laden nature of HTA; and (ii) recognition of the role of public and community consultation about new technologies.

Yet, despite its importance, ethical analysis has not been fully integrated into health technology assessment reports (2). A recent international review of HTA noted that over half the organizations undertaking technology assessment professed to include ethical, legal, and social assessment in their analyses (19). However, these analyses are often rudimentary and poorly informed by recent work in social and ethical theory and practice, and they rarely incorporate the findings of studies of community views (24;25;26). Where ethicists do contribute to the work of HTA units, there is not always a clear understanding of the nature of the contribution they make (17).

This study explores why this finding is so. I will develop my argument by laying out two roles that ethics currently

fills with respect to HTA: the handmaiden role of ethics *in* technology assessment and the critical role of ethics *of* technology assessment. I will then suggest that we need the interpretive insights of both these approaches, taken together, to explain why ethical analysis is yet to realize its full potential with respect to HTA and to demonstrate the scope and complexity of ethical work in this domain.

## ETHICS *IN* AND ETHICS *OF* HTA

In 1970, Eliot Freidson, drawing on Robert Straus, popularized a now famous distinction between “sociology of medicine” and “sociology in medicine” (7). Paraphrasing Straus and Freidson’s distinction, one can describe the relationship between ethics and HTA in two ways:

Ethics *in* technology assessment consists of collaborative research or teaching, often involving the integration of concepts, techniques, and personnel from many disciplines. It takes as its object of interest the analysis of ethical problems as they arise within the context of new technologies.

... the ethics of technology assessment is concerned with studying such factors as the organizational structure, role relationships, value systems, rituals, and functions of HTA as a system of *behavior* and ... this type of activity has generally been carried out by persons operating from independent positions outside the formal HTA setting.

On the one hand, the ethicist is collaborating with the HTA specialist in trying to help her in the performance of her research functions; on the other, she stands apart and studies HTA as an institution or ethical system, challenging assumptions about what counts as ethically legitimate in HTA activities and in the technological world that HTA represents.

The typology proposed here brings together a range of suggestions from other scholars. For example, Ashcroft distinguishes between “thin” and “thick” accounts of the relationship between ethics and HTA (1); and several papers in volume 2 of *Poiesis and Praxis* describe both the “social shaping of technology (SST)” view of ethics in HTA and the “conventional” approach to ethics in HTA (5;8;11;12;17;24;26).

Each of these two approaches leads the ethicist to ask particular kinds of questions and to ignore others. The ethicist working in HTA is concerned primarily with how new technologies are *used*, in initial trials and/or in later evaluation of the technology (25). For example, the ethicist working in HTA may carry out an ethical analysis of randomized controlled trials; here, he or she will assess informed consent protocols for clinical trials, benefits and burdens for trial participants, randomization, stoppage rules for clinical trials, and the possibility of coercive practices. Alternatively, the ethicist working in HTA may focus on the likely impact of introducing a new technology. The ethical issues here will concern, for example, the likelihood of equitable access to the new technology, issues associated with explaining the technology to patients, the ethical significance of differing sensitivities and specificities of tests, and the possibility of extending the technology to new groups of patients.

An ethicist of HTA approaches new technologies in a rather different way and asks different questions. Vos, for example, indicates the types of questions an ethicist of HTA will ask:

- How does medical technology transform disease concepts and the way the body is conceptualized in modern medicine?
- How does the (daily) use of medical technology by patients shape their views on disease, illness, and the body?
- What are the relationships between technology and care (especially in chronic diseases)?
- What implications should answers to these questions, albeit in a provisional way, have for the evaluation of medical technology (see 28, pages 2–3)?

Clearly, these two approaches can lead ethicists in two rather different directions. In the following two sections, I offer two examples of recent innovations in medicine—genetic screen-

ing for breast cancer and blood glucose self-monitoring—to examine the differences between ethics in and ethics of HTA approaches to these technologies.

## GENETIC SCREENING FOR BREAST CANCER

In 1999, the Canadian Coordinating Office for Health Technology Assessment produced a report on predictive genetic testing for breast and prostate cancer (16). The aim of the report was to

“[provide] the information necessary to understand the scientific advances in these areas [predictive genetic testing for breast and prostate cancer] and to appreciate their broader implications when applied to clinical practice as a means of improving detection, treatment, and ultimately prevention of breast and prostate cancer” (see 16, page 1).

The report identifies a range of issues of ethical significance that are typical of the ethics in HTA approach. First, the report notes that informed consent is crucial when predictive genetic screening is contemplated. Consent information needs to emphasize the

“voluntary and optional nature of testing as well as the potential benefits including the accuracy of current diagnostic techniques, the fact that test results cannot provide definitive information about whether or when cancer will develop ... and limitations in conventional options for screening and treatment” (see 16, page 28).

The information needs to be understandable, and providers of information need to bear in mind possible risks (anxiety, stigmatization, discrimination, and, for genetic information, misidentified paternity) as well as the potential for DNA banking. The rest of the section focuses on empirical studies of consent to genetic testing and the authors end by noting that “the impact of the consent process on decision making for genetic testing is not clear to date” (16).

The second issue of importance concerns privacy and confidentiality. Noorani and McGahan state that genetic information is unlike other health information in that it is both, on the one hand, personal and private and, on the other, familial and nonindividual (see 16, page 30). They suggest that health professionals may have an obligation to warn at-risk family members so that these people can adopt early monitoring and prophylactic treatment if necessary and so they can make informed reproductive choices. Despite this recommendation, they also recognize that learning unwanted genetic information can be harmful; for example, if a patient learns that she is BRCA1-positive and, therefore, has an 85 percent chance of developing breast cancer in her lifetime, this finding has consequences for her sisters and their risk of developing breast cancer, whether they wish to know that risk or not.

Lisa Parker takes a quite different approach to the same issue of genetic screening for breast cancer susceptibility (18). Parker describes her work as “critical bioethics,” a term that might equally well be used to describe an ethics *of* HTA approach. Parker begins by suggesting that an ethical analysis of genetic screening for breast cancer needs to acknowledge the role that genetic screening for breast cancer susceptibility can play in shaping our values about and response to all types of breast cancer. The huge amounts of money spent on the Human Genome Project, the public perception that we are being successful in locating genes for all kinds of diseases, together with publicity about testing for the BRCA1 gene, increases the likelihood that breast cancer will be labeled as a genetic disease; through this process, all breast cancers become “synonymous with genetically-linked breast cancer” (see 18, page 320). The geneticization of breast cancer is hazardous for two reasons. First, it may skew the provision of funding for research, diagnosis, and treatment of breast cancer. Second, it may increase the prevalence of simplistic social perceptions of breast cancer (see 18, page 321).

Parker’s second observation is that breast cancer occupies a distinctive place in Western societies, for the organ affected in breast cancer has particular social significance. The iconic value of breasts in Western societies means that any assault to this organ can become an assault on our values and beliefs about women and their role. Because of this, Parker thinks that the interpretation of “facts” about breast cancer becomes inevitably entwined with social, political, and cultural values about breast cancer.

Parker also argues that the language we use to describe breast cancer shapes, and is shaped by, our beliefs about disease more generally. For example, applying the label of “epidemic” to breast cancer constructs this disease as “on the rise, spreading, or out of control” (see 18, page 323) and defines those who acquire the disease as somehow responsible. Communities historically have responded to epidemics by blaming those who carry the disease both for their own illness and for the risk they create for other, hitherto unaffected, members of society (21). The development of genetic screening tests, therefore, increases the risk that society will label as socially irresponsible and deviant those who do not wish to know their breast cancer risk or, even worse, know they are BRCA1-positive but choose to do nothing about it.

## BLOOD GLUCOSE SELF-MONITORING AND DIABETES MANAGEMENT

My second example directs our attention away from a controversial technology and toward a much more mundane device. The role of the blood glucose-monitoring device in people with diabetes is to help keep blood glucose values within normal limits. Patients can do this by self-monitoring, the results of which are reviewed with a clinician who, through the patient, can acquire a picture of the level of glycemic control.

For the ethicist working in HTA, there appears to be very little ethical significance in this technology. The ethical questions, if any are considered at all, may address issues such as the risks and harms affecting the user, the voluntariness of consent to use the new device, and the extent to which the device is available to people across geographic and socioeconomic divides. Such questions seem almost trivial, and it is not surprising that several recent health technology assessments of devices used to monitor blood glucose have contained no consideration of any ethical issues at all (4;10).

However, an ethics *of* HTA approach suggests a rather different picture. Anne Marie Mol’s account of the social and ethical implications of home-based monitoring of blood glucose shows how the miniature blood glucose monitor is not merely a device that “passively register[s] the facts” (see 14, page 9). Rather, it actively intervenes in the patient’s life in three ways: it alters what counts as normal, it changes patients’ relationships with their bodily sensations, and it shifts the ownership of the suffering associated with the disease (14).

First, the availability of self-monitoring of blood glucose has changed how normality is defined. Until its advent, the moments in time when blood glucose could be measured were limited to those times when patients came into the hospital or clinic and had their blood glucose monitored. Where once the target of treatment was the blood glucose level registered while the patient was in the hospital or clinic, now the target is the patient’s blood glucose levels measured over the entire day, everyday. With more extensive monitoring, tighter control is possible. What is acceptable now as a “normal” blood glucose for a diabetic is defined far more narrowly than it once was. This tighter control becomes even more pronounced when patients begin to self-regulate and fine-tune their insulin, exercise, or sugar intake to reflect their measured blood glucose. “The diagnostic device made to *detect* abnormal blood sugars *alters* what counts as abnormal” (see 14, page 19).

Regular blood glucose measurement also changes how patients respond to their bodies. Patients know there is a correlation between abnormal blood sugars and symptoms. However, because sensations are not a perfect indication of glucose levels, patients who think that their blood sugar level is dropping are advised to measure the levels with the machine *before* they do anything. Thus, this diagnostic device undermines patients’ reliance on their own bodily awareness:

“by being put in the position of correcting *subjective sensations* with *objective findings* they end up eroding the subjective sensations, or at least, by making them of little relevance in the daily management of (chronic) diseases” (see 14, page 15).

Ironically, as well as undermining sensation, the device can also augment it, as patients learn to feel “hypoglycemic” rather than “dizzy” or “light headed.”

Finally, self-monitoring of blood glucose provides patients with greater freedom, from professionals and in their daily lives. Where once patients were required to eat at certain hours, sleep regularly, and do about the same amount of exercise each day, now they can vary these activities if they know how to moderate their therapy. However, freedom comes at a price. Professional oversight cannot be thrown to the wind; patients must replace it with their own internal monitoring. Their own blood sugar takes over as the master whom they must obey or ignore. That takeover brings with it new moral demands: where once suffering could be ascribed to the disease, now failure to deal with the disease is the cause for suffering (see 14, page 21). Through the apparently noncontroversial example of blood glucose self-monitoring, Mol shows how one medical device can shape patients' and doctors' views of disease, illness, and the body, and alter the locus of moral responsibility.

### CONCEPTUAL FOUNDATIONS FOR ETHICS IN AND ETHICS OF HTA

The examples given above clearly show the differences between ethical analyses carried out within and outside the folds of health technology assessment. However, what the examples do not make clear are the conceptual foundations for these differences. In this section, I will explore these foundations, beginning with three statements on which ethicists working in and outside HTA would agree: (i) HTA must have an ethical component, (ii) community and public consultation is essential to HTA, and (iii) it has been difficult to integrate ethical analysis into health technology assessments. I will show that, although ethicists in and of HTA agree on these statements, they use different theoretical and methodological traditions to interpret and explain them.

#### HTA Must Have an Ethical Component

Both the ethics in and ethics of HTA approaches grant that HTA must have an ethical component. However, the two approaches regard the place of ethics in HTA in different ways. The ethicist working *in* HTA believes that the ethical or evaluative components of a new technology can be identified and separated out from the strictly technical or empirical analysis (26). In this approach, HTA is conceptualized as a two-phase process in which the first phase involves assessing the technology for safety and efficacy and the second evaluating the wider social and ethical impact of the technology (25).

At least three things follow from characterizing the relationship between ethics and HTA in this way. First, this approach sets HTA outside of society and culture, constructing it instead as an activity that occurs before the social world. The primary role for ethical analysis and critique here is as an addition at the end of the assessment process.

Second, the disciplinary home for the ethicist working *in* HTA is traditional analytical philosophy. The ethical methodology most suited to this approach is principlist: it applies

principles to moral problems in a rigorous and deductivist manner (3;9;27). The principlist approach to ethics—with its mantra of autonomy, beneficence, nonmaleficence, and justice—is ideally suited, for it offers a series of general questions that can be asked of any situation and any technology.

Third, consistent with this principlist approach, ethics in HTA tends to be preoccupied with the interests, rights, and autonomy of individuals. It explores, for example, whether *individuals* understand the implications of new technologies, whether their consent to participate in trials is coerced, whether the false-positive rate of a new screening test will have some bearing on the disease and health experiences of individuals screened. Where the technology raises broader questions, these questions are addressed primarily as they affect individuals. When the introduction of new technologies leads to consideration of the allocation of resources, the primary question becomes not whether the technology itself is distributed fairly, but rather whether access to the technology is equitable for all individuals.

The ethics *of* HTA approach casts the relationship between ethics and HTA in a different light. It regards HTA as a normative discipline itself, subject to the same norms and values as the technologies it addresses. So, for example, the ethicist of HTA argues that presenting the survival rates associated with the use of a technology suggests that life itself is of preeminent value (see 20, page 249), whereas using quality of life measures suggests that not all life is to be equally valued. More fundamentally, the ethicist of HTA regards the methods of technology assessment with the same critical eye with which she regards new technologies: the methods themselves are impregnated with a particular value set, one which privileges certain kinds of knowledge and certain professional groups over others (1).

The ethics of HTA draws on a diverse disciplinary and methodology base to carry out its work. Ashcroft suggests that there are at least three strands in the ethics of HTA (1). First, there are the theoretical critiques of technology in the works of Heidegger, Marx, Adorno, Foucault, and others. These abstract and sweeping assessments of the place of technology in society seem far removed from the practical world of HTA, and they appear to have relatively little analytical and practical value for HTA. Second, there are sociological accounts of specific technologies and contexts, which emphasize the value-laden nature of all technologies and technology assessments. Finally, there are studies of technology and democracy: scholars working in several fields, specifically in Marxist, Foucauldian, and Habermassian frameworks, emphasize the challenge that technology continues to offer democracy (1).

#### Community Consultation Has an Important Role to Play in HTA

The point above brings to the fore a second area of difference between the ethics of HTA and ethics in HTA

approaches, related to the relationship between HTA and community consultation. Both ethics in and ethics of HTA argue for an enhanced role for community consultation processes in technology assessment. However, they treat the process and outcomes of these consultations quite differently.

Ethicists working *in* HTA may include findings from community consultations, where these are available, in their ethical assessments, and/or they may suggest that dissemination of a new technology needs to be accompanied by attempts to engage communities in discussion about the technology (22). Community consultations chiefly play an ancillary role here, providing data that can be used to supplement technical decisions about the acceptability of a technology. Ethicists working in this vein will ask questions such as, What are the likely social costs and benefits of introducing this new technology? What do we know about people's beliefs and attitudes to this technology?

Ethicists *of* HTA interpret the need for community consultation quite differently. The reason one seeks to engage the broader community in discussion of a new technology is to create an environment for democratic deliberation. In such deliberation, expert technical opinion on the technology (as presented in a health technology assessment report) is just that: one opinion among a range of opinions in a debate that is acknowledged as political rather than technical (1).

### It Is Difficult to Integrate Ethical Analysis into Health Technology Assessments

Both ethicists *in* and ethicists *of* HTA agree that the integration of ethical assessments into health technology assessments has not always been particularly successful. However, each offers different reasons for the lack of success (20).

For the ethicist working *in* HTA, the problems with integrating ethics into HTA are methodological and procedural ones. The processes of HTA are such that it is difficult to imagine how one can incorporate ethics assessment into the work of a health technology assessment unit. For example, technology assessments, particularly Horizon Scanning or early warning systems, are rapid-response assessments that require the ethicist to respond quickly to the call for commentary and feedback. When one adds to this the fact that the request for ethics commentary usually occurs toward the end of the preparation of a report, it is not surprising that the ethicist working *in* HTA believes the task of integrating their contribution into HTA to be a procedurally difficult one.

By contrast, for the ethicist *of* HTA, the integration problem is a conceptual one. Because the ethics of HTA evaluates health assessment just as much as it evaluates the technology itself, critiquing a technology also calls into question the social and cultural environment that sustains it. The disciplinary base and methods adopted by HTA methodologists—epidemiology, economics, systematic reviews, meta-analyses—are just as much the object of this ethicist's research as the technology itself is.

## CONCLUSIONS

The ethics *in* and *of* HTA approaches are different. Yet, both are important for ethical work in health technology assessment, not least because the two approaches together provide a more comprehensive explanation for why ethics has not yet reached its full potential in HTA. An ethics *in* HTA approach can produce ethical analyses that are uncritical of their HTA subject matter, narrow in their focus, and have relatively little to add to assessments when technologies are noncontroversial. By contrast, an ethics *of* HTA approach, with its wide ranging and critical perspectives, may be less palatable to policy makers, clinicians, and the medical technology industry, resulting in abstract and general critiques that are of less practical value to HTA methodologists.

This account of ethics in and of HTA suggests a tidy distinction between the two endeavors, but the distinction, in practice, is far from tidy. Ethical work in HTA in fact encompasses a plethora of approaches and a good deal of self-analysis (6;13;23;27;28;29). What Fox notes in her analysis of the wide range of perspectives in healthcare ethics generally might equally be ascribed, more narrowly, to ethical work in HTA:

Casualty, virtue ethics, narrative ethics, hermeneutics, and phenomenology are all being advanced as philosophical systems. Proposals to elevate the values of caring, solidarity, reciprocity, trust, and love above the principles of autonomy, beneficence, nonmaleficence, and justice are repeatedly set forth. Enjoiners to incorporate feminist, literary, religious, social scientific, contextualist, relational, subcultural and cross-cultural perspectives and interpretations more fully . . . proliferate (see 6, page 57).

Rather than trying to allocate these perspectives to either ethics in or ethics of HTA, it makes more sense to celebrate the diversity of perspectives available to ethicists and to acknowledge that the boundary between the two approaches is a permeable one. Many ethicists work well with both kinds of subject matter, and we should encourage them to do so. As demonstrated above, we need to foster this richness in ethical work if we are to display the broad, complex, and multifaceted contributions that ethics can make to HTA.

## CONTACT INFORMATION

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