# Why ethics should be part of health technology assessment

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From the heydays of HTA in the 1970s, it has been argued that ethics should be a part of HTA. Despite more than 30 years with repeated intentions, only few HTA reports include ethical analysis, and there is little agreement on methods for integrating ethics. This poses the question of why it is so important to integrate ethics in HTA? The article analyzes ten arguments for making ethics part of HTA. The validity of the arguments depend on what we mean by "integrating," "ethics," and "HTA." Some of the counterarguments explain why it has taken so long to integrate ethics in HTA and why there are so many ethical approaches. Nevertheless, some of the arguments for making ethics part of HTA appear to be compelling. Health care is a moral endeavor, and the vast potential of technology poses complex moral challenges. A thorough assessment of technology would include reflection on these moral aspects. Ethics provides such a moral reflection. Health technology is a way to improve the life of human individuals. This involves questions of what "the good life" is, and hence ethical issues. Trying to ignore such questions may inflict with the moral foundation of health care: to help people. Additionally, HTA is an evaluation, and as such also a reflection on values. Hence, there is a profound affinity between HTA and ethics. Accordingly, ethics cannot be "integrated" in HTA as ethics is already a constitutive part of HTA. However, ethics can be acknowledged and emphasized.

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From the incipiency of health technology assessment (HTA) in the 1970s, it has been argued that ethics is an integrated part of health technology assessment (5;6), and early definitions of technology assessment include ethics: "Technology assessment is comprehensive in scope, examining impacts on social, ethical, legal, and other systems . . ."(39). So do more recent definitions of HTA (14;28).

A series of traditional ethical approaches have been applied in HTA, such as principlism (1;2;49), casuistry (16), utilitarianism (economic analysis), and coherence analysis (17;29;30;38;). In addition, some methods have been developed especially for addressing ethical issues in HTA, such as interactive (participatory) HTA (40–42;45), context sensitive approach (9), eclectic approach (4), complex systems approach (11), various approaches within the framework of

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Social Shaping of Technology (SST) (10;43), and axiological approach (21;22). Working groups on ethics in INAHTA and HTAi have tried to come to agreements on methodology, and EUnetHTA has developed a core model for HTA including ethics (31;44).

Despite this, only a small fraction of HTA reports address ethical issues (13;33;35), and there is still no general agreement on how ethics should be integrated in HTA. One of the reasons for this may be that it is not clear what is meant by "integrating ethics in HTA" and that the goal with this integration is not made explicit. Hence, despite the long tradition of stating the importance of integrating ethics in HTA, there are surprisingly few explicit arguments for why this is so important. This article therefore investigates these arguments for integrating ethics in HTA: (i) Ethics can make HTA more efficient, (ii) Health technology has normative implications, (iii) Ethics is a way to integrate patients' perspective, (iv) Health technology is morally challenging, (v) Health technology is value-laden, (vi) Health interventions are moral, (vii) Core issues in HTA are normative, (viii) HTA

informs decision making (which is value-laden), (ix) HTA is evaluative ("assessment," "appraisal"), and (x) Because man creates himself by technology, and ethics is a way to reflect on this.

Closer scrutiny of these arguments can explain why it has taken so long to integrate ethics in HTA, it can elucidate why there is no standard methodology for ethics in HTA, and third, it can serve as a backdrop for the development of fruitful methods for addressing ethics in HTA.

#### ETHICS CAN MAKE HTA MORE EFFICIENT

Despite easy access to high quality HTA reports, one of the main challenges for HTA has been the dissemination of its results (36). One reason for this may be that there are important aspects of implementing health technology that are not addressed in traditional HTAs. Accordingly, integrating ethics in HTA could be a way of addressing moral and other normative issues being crucial to the dissemination of HTA results (22). Hence, one answer to the question "why integrate ethics in HTA?" could be "to make HTA more efficient". If the normative issues being crucial for the implementation of health technologies are adequately addressed, for example, by ethical analysis, then their implementation will be more effective.

However, there is little evidence that integrating ethics will make results from HTAs more effectively implemented in practice. It would be hard to design studies showing the outcome of integrating ethics. So, this argument for integrating ethics appears to be speculative. However, it is not more speculative than the argument for applying HTA in the first place. That is, both HTA and ethics in HTA are based on health policy decisions and not on empirical evidence of their efficiency.

Another objection against the efficiency argument is that it presupposes an instrumental conception of ethics. It reduces ethics to a normative technology (46), and a handmaiden (8). However, in the same manner as HTA cannot be reduced to a simple decision making tool for health policy matters, ethics cannot be reduced to a normative tool for increasing the efficiency of HTA.

Hence, one reason for addressing normative issues can be to avoid that HTA results are discordant with social or moral values. It could make decisions on health technology more informed, transparent, accountable, and hence, more open or sound. Other things than ethics could of course have the same effect, and there is no guarantee that ethics will reach these goals.

# HEALTH TECHNOLOGY HAS NORMATIVE IMPLICATIONS

The most obvious reason for integrating ethics is that applied technology has morally relevant consequences ("implications"). Health technology is a means that is intended

to promote a moral good, for example, absence of pain, improved health status, that is, "the good life". Assessing the risks and benefits of health interventions presupposes evaluations of what is morally good. This gives ethics, being the *logos* of the good life, a natural place in HTA.

However, this seems to presuppose a consequentialist framework, which is at the core of economic analysis, but not necessarily of ethics. The moral implications of a health technology may reach beyond strict utilitarian calculus. Moreover, they could easily and more appropriately be handled outside a HTA setting (especially if appraisal is not a part of HTA). Furthermore, implementing health technology has other normative implications than those being addressed by ethics, such as social, legal, organizational, and political implications. For example, introducing patient payments for mammography screening on basis of high cost per gained health benefit revealed by HTA could be politically devastating (in systems with universal health coverage). If ethics should be integrated due to the ethical implications of HTA, why should we not integrate political analysis as well? Health technology has many implications, for example, legal, political, constitutional, professional (status) and heuristic. So if HTA should address all the normative implications of a health technology, then there is no reason only to address social, ethical and legal implications. Political implications appear to be far more pressing for decision makers than other normative issues. Hence, political analysis, organization theory, history, and anthropology should be integrated in HTA as well.

Nevertheless, the "normative implication argument" appears to carry some weight: "new medical technologies' purposes and effects must be judged for their moral, social or political value before technology assessment information can inform decision in a meaningful way." (15) The normative implications are sweeping, and include challenges with endpoint definitions, classification of disease entities, rationing, prioritization, stigmatization of patient groups, medicalization, and defensive medicine. It involves cultural and societal values such as linguistic identity (deaf community), research ethics (ways of gaining knowledge), and implications for legal and political systems (challenges with consumer liability) (32). Ethics is one way to address normative implications of health technology.

## ETHICS IS A WAY TO INTEGRATE PATIENTS' PERSPECTIVE

More specific than addressing the normative implications of health technology, ethics can highlight patients' perspectives (1) and community views (8). As HTA can be seen as a decision-making tool in health policy making, vulnerable groups need voicing, and ethics may be one way of doing this. Other disciplines, such as anthropology, sociology, science and technology studies (STS), may of course be suitable to address patients' and communities' perspectives as well. The

important point is that ethics can contribute in highlighting important perspectives.

## HEALTH TECHNOLOGY IS MORALLY CHALLENGING

History shows that technology can challenge basic moral principles (autonomy, integrity, dignity, beneficence, justice), basic human rights, and crucial moral conceptions (moral status), and that safety issues can be morally challenging. Controversial technology have called for ethical analysis, for example, genetic testing, IVF, PGD. Hence, one reason for integrating ethics in HTA would be because new health technology are morally challenging.

However, most health technologies are not morally challenging, and need no ethical analysis (17). Ethical analyses have been applied for particularly controversial technologies such as cochlea implants, assistive reproductive methods, and genetic tests. It could also be argued that these technologies pose general moral issues, such as how to respect sign language communities, how far we should go in shaping human embryos, and how we should handle predictive knowledge, respectively. They are not technology specific, but are made topical by the technology (21). With regards to diagnostic ultrasound machines, statins, and bypass surgery, there appears to be little disagreement.

Accordingly, the possibility of creating human beings with the same genetic characteristics is controversial even without the cloning technology. It is morally challenging even without any knowledge about its effectiveness, and thus, before there can be any HTA of the conventional type. That is, HTA is irrelevant for the assessment of morally challenging technologies.

Nevertheless, it can be difficult to anticipate which technology will be controversial, and in which social context (20). Reflection on how morally challenging a technology may become appears to be of some value to HTA (33).

### **HEALTH TECHNOLOGY IS VALUE-LADEN**

Technology is defined by its purpose, which is given by values (21;23;48). The goals and values of health technology are as follows: knowledge about disease and prognosis, surveillance of health behaviors and states, intervention, extended life expectancy, risk reduction, protection, autonomy, mobility and information (34). Values constitute the framing of the problems that technology are to solve as well as its' solutions (i.e., technology).

Hence, there are normative assumptions underlying health technology (18), and one reason for integrating ethics is that technology is value-laden. According to standard definition in an HTA context, health technology is "[a]ny intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes the pharmaceuticals, devices, procedures,

and organizational systems used in health care." (26) and it is defined as "the drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided." (50). So, technology is given by its purposes (promoting health, preventing disease) and its systems (procedures and organizations), which are given by values, making ethics, or at least axiology, relevant for addressing evaluative issues related to technology.

However, not all values related to a given technology are essential to the technology. The high status of advanced imaging technology is not only due to its inherent value (its purpose), but also because we ascribe values to this kind of high-tech. However, some values appear to be inseparably related to technology (21), and even value ascription calls for attention and analysis.

Yet another argument is that although ethics is not necessary to address the question of whether a technology is efficacious, effective and efficient, it is crucial to answer the question of whether it is right or not to implement and use the technology. Although this is relevant for health technology appraisal, it is not for assessment, where the issue of whether it is right or not to implement a technology is declared to be beyond its scope. Accordingly, there would be no need for integrating ethics. Whether it is possible to maintain such a "value-free" HTA is contestable. The aim of any HTA, purist or not, is to assess whether a technology has a beneficial outcome, that is, a good purpose.

However, assessing the purposive value-ladenness of technology may prove insufficient, as technology may find unintended and surprising applications. For example, services developed for diagnosing somatic diseases in patients are used also for treating mental conditions in patients (anxiety), to confirm health, and (sometimes) relieve professional uncertainty and fear of litigation. Such essential but elusive normative phenomena are difficult to address, but there are branches of ethics that try to deal with value ascription, for example, in terms of covert interests and technology's status. HTA intends to address the indirect and unintended impacts or consequences of interventions, and ethics can offer a framework for doing so (24).

#### **HEALTH INTERVENTIONS ARE MORAL**

Although the idea that technology is value-laden is unfamiliar and alien to many scientists, they will accept that other health interventions, such as nonsmoking campaigns, are value-laden. Even agencies working in the purist end of HTA assess socially oriented health services, for example, assessments of educational programs and behavioral aspects in the population, such as the influence of co-sleeping on cot death. Hence, as such health interventions appear to be more obviously related to moral issues, it becomes more reasonable to integrate ethics.

Correspondingly many technologies become socially interfering, as they involve large population groups or intervene in peoples' private life. This makes it easier to recognize that moral issues play an important role in assessing whether the health technology in question is good or bad. Moreover, it becomes obvious from various discussions, for example, on enzyme replacement treatment, beta interferon and herceptin, that economic evaluation is not sufficient to take all relevant normative issues into account.

A more general version of the same argument is that ethics has a natural place in HTA because actions in health care have a moral end, that is, to help people, as well as a moral premise (consent). Hence, all means in health care are part of a moral activity and have moral relevance. Ethics can be seen as a natural part of assessing any moral activity and its means.

#### **CORE ISSUES IN HTA ARE NORMATIVE**

Core issues in HTA, such as safety, efficacy, effectiveness, and efficiency, raise moral issues: how do we define safety, how do we measure efficacy, what criteria should we apply to assess effectiveness, which models should we use when analyzing efficiency? Where we set the limits for safety, efficacy, and statistical significance are normative issues as well as criteria for study design and quality of evidence. There tends to be an implicit normativity in evidence-based medicine (37), and ethics is needed to uncover and analyze it.

Ethics can unravel subtle normative premises, for example, the important distinction between "output" or "effect" and "benefit" (47), which may be covert and can be harmful if not addressed. Hence, ethics can be important in making end points explicit (51).

It may be argued that even though HTA follows certain norms (e.g., norms of evidence) there is no need for reflection on these norms, as long as they are fixed. Within a defined regime of safety, efficacy, effectiveness, and efficiency, where the inclusion/exclusion criteria for sources of evidence and the hierarchy of study designs is given, reflection on such values is not needed.

This may miss the point of HTA, as HTA is most needed in controversial cases. What makes the question of whether enzyme replacement therapy is a good or a bad thing controversial is the unsettled questions of end points, models, and quality of evidence. Hence, for the most important HTAs the normative premises of HTA methodology are questioned, and normative reflection, such as ethics, can be fruitful.

#### HTA INFORMS DECISION MAKING

The main purpose of HTA is to inform decision making in health care (24) This is a normative issue because the end of health care is moral (to help people), assessment of its means as well as the means themselves are normative (through their purposes), but also because decision making has norms of

its own, such as political (re-election) and organizational (bureaucratic efficiency).

Ethics can reflect on such issues and could also close the gap between parliamentary technology assessment (PTA) and HTA (19). HTA has been dominated by a "clinical perspective" and lacked the "societal perspective" of PTA, which appears to be highly relevant in decision making. Addressing the normativity of decision making would also make HTA more in accordance with the process of implementing technology in practice: involving social (re)negotiation, (re)positioning of actors, interactive definition and resolution of technology, and it would address the heterogeneity of technology.

Although this argument may have some validity in an appraisal context, it does not in a purist assessment context, as it contests HTA's scientific aspirations and challenges its methodological bedrock.

However, this (counter)argument ignores the context and purpose of HTA. As argued extensively: "HTA agencies have a professional responsibility to provide policy makers with comprehensive assessments that highlight and integrate discussions of the associated social and ethical challenges." (33).

#### HTA IS EVALUATIVE

HTA originates from normative worries over the unrestrained implementation of new technologies into healthcare practice (47). Its objective is to arrive at values of merit of technologies (51). Semantically both "assessment" and "appraisal" mean to judge or classify something with respect to its worth. "HTA is the systematic evaluation of properties, effects or other impacts of health care interventions" (24). Values are part of the evaluative process (7), that is both assessment and appraisal. This makes methods for reflecting on norms and values, such as ethics, relevant. HTA is in the evaluation business, that is, in the same business as ethics.

Against this one could argue that there are many types of values, and that the kinds of values in HTA and ethics are different, that is, scientific or clinical values versus moral values respectively. The goals, methods, and modes of rationality of HTA and ethics are categorically dissimilar. HTA has a stringent normative (methodological) basis that is incompatible with ethics and that is hard to change to make integration possible.

However, as argued before, HTA, as health care, has a moral goal: to help people. Any evaluation in HTA has to reflect this. Ethics may be a way to do so. Moreover the development and implementation of new health technologies are associated with many kinds of values: individual, clinical, (health) professional, economic, managerial, commercial, political, and social. Evaluations of health technologies that ignore such values appear to be blind.

## BECAUSE WE CREATE OURSELVES BY TECHNOLOGY

No single factor seems to have changed the life of man the last 100 years more than technology. Our professional identity is based on technology, and technology shapes our views of disease, illness, and the body (52). The modern man is dependent on and shaped by the technology she creates (12;25). In particular, technology invents disease and its remedies (21). Accordingly, analytical perspectives that address this profound role of technology should be welcomed in the assessment of technology in a field so crucial to human beings as health care.

This argument makes no sense to people conceiving of technology as a value-neutral tool to external values. According to such conceptions, evaluative issues can and should be addressed independent of the assessment of technology, neatly maintaining the is-ought-distinction. However, as previous arguments indicate, it has become increasingly difficult to defend the value-neutral-stance on technology.

#### THE ANSWER IS CONTEXTUAL

The previous answers to the question of why ethics should be part of HTA are not exhaustive. A series of trivial answers have been omitted, for example, that we should integrate ethics because the founding fathers of HTA have said so (6;33;39), because policy makers want it, or because ethicists with some influence have shown interest in HTA. Such answers are of course not irrelevant, but (personal) *motivations* are beyond the scope of this article, which has focused on *arguments* for making ethics part of HTA.

The analysis also reveals that the arguments for ethics' place in HTA vary in quality and are contextual. It depends on the aim of HTA: whether the aim is assessment, as basis for decision, or whether it is appraisal, guidelines, or regulation. It also depends on what is meant with "integration of ethics in HTA" (27): whether one has an instrumental approach, wants to integrate or exhibit normative thinking in HTA, or whether one wants to integrate awareness of values (axiology) or promote critical thinking (3;8;22). To reduce complexity I have not differentiated between these meanings explicitly, and discussed the issue of making "ethics part of HTA" in general. Moreover, the answer to the question of why we should make ethics part of HTA also depends on the type of technology: if the technology is minimally challenging, for example, a new type of thermometer, if it is not morally challenging (in itself), but with morally challenging consequences (e.g., with respect to resource allocation), or if it is conceptually challenging (e.g., with regards to the conception of disease, body, patient, social group or self).

Correspondingly the answers depend on the kind of ethics we have in mind and its role: if it is addressing morally challenging questions in clinical application of technology, in the implementation of technology, in knowledge formation (research ethics), related to HTA-process (assessment, appraisal), addressing morally challenging issues of the decision process, changing the way HTA is performed, or in framing the problem for which technology is seen as a solution. They also hinge on whether "ethics" means bioethics, normative ethics, sociology, anthropology or science and technology studies (3).

Accordingly, the answer also depends on to whom the question is important: health care professionals, the public, patient advocacy groups, health policy makers, or decision makers. Nevertheless, ethics has a role in HTA as HTA shares the normative foundation of health care: to improve the health (i.e., the good life) of individuals in society.

#### NOT INTEGRATING BUT EMPHASIZING

Hence, one lesson that can be learned from this analysis is that the arguments for "integrating ethics in HTA" strongly depend on what is meant by "integrating," "ethics," and "HTA." Another one is that there are relevant counterarguments to making ethics part of HTA that should not be ignored, and that can explain why it has taken so long to make it happen. The analysis also shows that the question of ethics' role in HTA is a question of HTA's identity, that is, what HTA is and what it should be. Accordingly, ethics may be conceived of as a threat to HTA or as a catalyst and a means for reflection and development.

Despite relevant counterarguments, there are some compelling arguments for ethics being part of HTA. Health care is a moral endeavor, and ethics provides a reflection on this moral endeavor. Technology enhances the moral challenges in health care, and assessing technology without addressing moral issues appears to miss important aspects of technology in health care.

Moreover, health technology is a way to improve the life of human individuals. This involves questions of what a good life is (and hence ethical issues). Trying to disregard such questions, or to reduce them to professional issues, may lead to conflicts with the moral foundation of health care: to help people.

Furthermore, HTA is an *evaluation*, and such reflection on values, which is at the core of ethics. Although professional, methodological and heuristic values are most apparent and dominating, the HTA enterprise is based on moral values and the goal of making people's life better. Trying to escape this affinity between ethics and HTA (assessment or appraisal) can cause serious challenges: values inevitably follow any attempts to help people.

Accordingly, there is a profound affinity between HTA and ethics, and HTA cannot easily free itself from dealing with moral values (behind its professional and methodological values). Correspondingly, ethics cannot be "integrated" in HTA. Ethics is already constitutive part of HTA, but it can be addressed, made explicit and emphasized.

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