International Journal of Technology Assessment in Health Care, **21:3** (2005), 1–7.

Toward a procedure for integrating moral issues in health technology assessment

Bjørn Hofmann
University of Oslo and *The Norwegian Health Services Research Centre*

Objectives: Although ethics has been on the agenda in health technology assessment (HTA) since its inception, the integration of moral issues is still not standard and is performed in a vast variety of ways. There is a need for a procedure for integrating moral issues in HTA.
Methods: Literature review of existing approaches together with application of various theories in moral philosophy and axiology are performed.
Results: The article develops a set of questions that addresses a wide range of moral issues related to the assessment and implementation of health technology. The issues include general moral issues and moral issues related to stakeholders, methodology, characteristics of technology, and to the HTA process itself. The questions form a kind of checklist for use in HTAs.
Conclusions: The presented approach for integrating moral issues in HTA has a broad theoretical foundation and has shown to be useful in practice. Integrating ethical issues in HTAs can be of great importance with respect to the dissemination of HTA results and in efficient health policy making.

Keywords: Ethics, Procedure, Moral, Science and technology studies

Health technology assessment (HTA) has been defined as a systematic study of the consequences of the (introductory or continued) use of technology in a particular context and is conceived of as a way to handle some of the major challenges in modern health-care: outcome and cost. Although ethics has been on the HTA agenda since the 1970s, many assessments have focused exclusively on "systematic reviews," and it is worth noticing that moral issues have been more explicitly treated in general technology assessments (TA) than in HTAs (10).

Although moral aspects have not become common parts of HTAs, it soon became urgent to include such issues in the assessments. One reason for this finding can be related to the characteristics of the technologies in question: that they were morally controversial, such as in vitro fertilization (IVF) and preimplantation genetic diagnosis (PGD); that they were culturally and socially challenging, such as cochlea implant; or that they were extremely expensive and would result in strenuous prioritization. Another reason for the interest in integrating moral issues in HTA is the challenge with making the results of good and thorough technology assessments acknowledged and implemented in clinical practice. Maybe parts of the dissemination problem are due to ignorance of important moral issues.

Accordingly, the role of moral aspects are acknowledged in the definition of HTA as follows (15): a) Identifying evidence, or lack of evidence, on the benefits and costs of health interventions, b) Synthesizing health research findings about the effectiveness of different health interventions, c) Evaluating the economic implications and analyzing cost and cost-effectiveness, and d) Appraising social and ethical implications of the diffusion and use of health technologies as well as their organizational implications.

In 2003, INAHTA performed a survey that showed that, of the thirty-six of the thirty-nine organizations that responded, some 47 percent included ethical issues in their

I am most grateful to Director Berit Mørland, at National Health Services Research Center, and Professor Kerstin Hagenfeldt at Karolinska Institute for useful comments and for their enthusiasm.

assessments. However, most of the agencies applied ad hoc solutions, and few systematically included ethicists in the work.

Hence, although "appraising social and ethical implication" of health technology is an explicit part of the HTA process, it is by far as systematically performed, and the methods for assessing ethical implications of health technology are relatively undeveloped (23). Moreover, it appears to be unclear what is actually meant by "appraising social and ethical implication of the diffusion and use of health technologies."

How then are we to grasp moral aspects relevant to HTA, and how are we to perform the ethical inquiry of a HTA in practice? These are the key questions of this article. Until recently, few authors had addressed these questions. Some tentative suggestions had been made, and some examples had been given (4;5;9;16). However, no consistent and coherent method has been identified.

NO METHOD?

Is it possible, then, to find an appropriate method for "appraising the social and ethical implications of the diffusion and use of health technologies"? With reference to the literature, the moral aspects are frequently viewed as an "add on" to "the real thing," that is, systematic reviews. This view has led to criticism: "Ethics is nothing but a technology to make a particular set of (potential) problems manageable and controllable" (22). Correspondingly, ethics is conceived of as being part and parcel of the effectiveness research with technology (17). Others point out that it appears to be difficult to take action based on the results of such ethical evaluations (23). Moreover, ethical approaches tend to ignore important social forces, such as professional and industrial incitements.

Reuzel et al. have suggested a combination of an interactive technology assessment and casuistry, and they apply the method to the case of cochlear implant (18). This method has also been combined with a principlist approach (23) and the principlist approach has been applied alone (14). Skorupinski and Ott have suggested a participatory and discursive approach (20), and ten Have has pointed out the need to investigate the normative influence of society on technology and not only the other way around (22).

A recent series of articles address the issue of how to integrate ethical inquiry into HTA (Poiesis and Praxis no. 2, 2004;6;8;10;17). Common to most of the articles is that they focus on the relationship between society and technology, and many of the contributions place themselves within a social shaping of technology (SST) framework. This framework is particularly suitable to explain the interrelationship between society and technology, where moral issues are essential in the social process of shaping technology (6). However, SST makes the integration of ethics more a "conceptual challenge" than a traditional "methodological challenge" (17), and it can be argued that it is a way to integrate HTA in the practice of SST theory rather than integrating ethics in HTA.

Hence, moral theories and theories about technology are diverse, and it appears to be impossible to find a particular moral theory or position within the science and technology studies that will provide an appropriate method for integrating moral issues in HTA. Where does this leave us? Do we have to abandon the prospect of finding a suitable procedure for integrating moral issues in HTAs al together? Is the reason why so few HTAs have taken moral issues into account that there is no method? The answer to these questions is not necessarily positive. Even if it is difficult to find a method, it might be possible to find a practical procedure to address the moral issues.

NO PROCEDURE?

Within normative ethics, it is argued extensively that we can apply (intermediate) moral principles, such as beneficence, nonmaleficence, autonomy, and justice, even if the theoretical foundation of these principles is unclear or disputed (1). Prima facie principles and rules for infringement of the principles, if necessary, represent a robust procedure for handling moral issues related to medical matters.

Although such an approach is attractive, with many advocates, it is heavily challenged and disputed. Hence, subscribing to one particular position in moral philosophy would make the procedure subject to all the objections to the position. Moreover, the technologies introduced in health care are extremely diverse, and the implementation of new technology raises a wide range of heterogeneous moral issues. Can this variety of moral challenges be managed by one particular approach in moral philosophy?

Should we thus abandon the ambition of finding a way to integrate ethical inquiry into HTA altogether? I do not think so. Even if we cannot find one procedure on the basis of a single approach in normative ethics, we may be able to find a set of questions that are relevant in handling moral issues with respect to the assessment of technology.

MORALLY RELEVANT QUESTIONS

The set of moral questions that may be relevant in the assessment of health technology are presented in Table 1. They can guide us in our practical work with highlighting the moral issues with respect to assessing new technologies and form a kind of "checklist." The questions will be discussed in some detail throughout the rest of the article.

Moral Issues

Q1. What are the morally relevant *consequences* of the implementation of the technology? This question suggests a

Table 1. Morally Relevant Questions with Respect to Assessing Health Technology

Q1	What are the morally relevant *consequences* of the implementation of the technology?
Q2	Does the implementation or use of the technology challenge patient autonomy?
Q3	Does the technology in any way violate or interfere with basic human rights?
Q4	Does the technology challenge human integrity?
Q5	Does the technology challenge human dignity?
Q6	Will there be a moral obligation related to the implementation and use of a technology?
Q7	Does the technology challenge social values and arrangements?
Q8	Does the widespread use of the technology change our conception of certain persons (e.g., with certain diseases)?
Q9	Does the technology contest religious, social, or cultural convictions?
Q10	Can the use of the technology in any way challenge relevant law?
Q11	How does the assessed technology relate to more general challenges of modern medicine?
Q12	Are there any related technologies that have turned out to be morally challenging?
Q13	Does the technology in any way challenge or change the relationship between physician and patient?
Q14	How does the implementation of the technology affect the distribution of health care?
Q15	How does the technology contribute to or challenge professional autonomy?
Q16	Can the technology harm the patient?
Q17	What patient group is the beneficiary of the technology?
Q18	Are there third-party agents involved?
Q19	What are the interests of the users of the technology?
Q20	What are the interests of the producers of technology (industry, universities)?
Q21	Are there moral challenges related to components of a technology that are relevant to the technology as such?
Q22	What is the characteristic of the technology to be assessed?
Q23	Is the symbolic value of the technology of any moral relevance?
Q24	Are there morally relevant issues related to the choice of end points in the assessment?
Q25	Are there morally relevant issues related to the selection of studies to be included in the HTA?
Q26	Are the users of the technology in the studies representative of the users that will apply it in clinical practice?
Q27	Are there morally relevant aspects with respect to the level of generalization?
Q28	Are there moral issues in research ethics that are important to the HTA?
Q29	What are the reasons that this technology is selected to be assessed?
Q30	What are the interests of the persons participating in the technology assessment?
Q31	At what time in the development of the technology is it assessed?
Q32	Are there related technologies that have or have not been assessed?
Q33	What are the moral consequences of the HTA?

HTA, health technology assessment.

series of related questions. What are the risk and the benefit for the particular patient (group) with respect to the application of this technology? The "consequences" of technology have to be given a wide interpretation. A morally relevant consequence of a diagnostic test is, for example, false-positive and false-negative test results and whether the test discloses information that may harm the flourishing of the person.

Q2. Does the implementation or use of the technology challenge patient autonomy? Many technologies can alter a person's self-determination. Drugs for sedation and surgical treatment of severely ill cancer patients are examples where patient autonomy may be challenged. IVF, pregnancy not delivered (PND), and PGD are technologies that may extend patient autonomy.

Q2 May be complemented by questions such as Q3–Q5.

Q3. Does the technology in any way violate or interfere with basic human rights?

Q4. Does the technology challenge human integrity?

Q5. Does the technology challenge human dignity? Technology for tracking patients with Alzheimer's disease is but one example.

Q6. Will there be a moral obligation related to the implementation and use of a technology? The question relates to the debate on "the imperative of possibility" (11). If something becomes possible, it soon is conceived of as imperative. This development can be challenging, for example, if a diagnostic technology is implemented without existing therapeutic means. Correspondingly, if a woman refuses to participate in the mammography screening program and gets breast cancer, she may face claims such as "it's your own fault."

Q7. Does the technology challenge social values and arrangements? Some technologies may influence social structures or values. Does the technology address certain subgroups, or does it change the social status of certain conditions? For example, technological tests for "fibromyalgia" or "chronic fatigue syndrome" would dramatically change the status of such conditions. A related question is:

Q8. Does the widespread use of the technology change our conception of certain persons (e.g., with certain diseases)? Technologies making it possible to screen for certain conditions, such as Down's syndrome, may change esteem of persons with these conditions.

Q9. Does the technology contest religious, social, or cultural convictions? Some technologies tend to contest convictions of groups in society. Contraception is opposed by the Catholic Church, and Jehovah's Witnesses abstain from blood transfusion. Less obvious are cases where communities refuse certain technologies because they interfere with the foundations of the community, such as deafness and smallness.

Q10. Can the use of the technology challenge relevant law? The introduction of new technology frequently results in changing existing laws. The introduction of new methods for fetal diagnostics or stem cell therapy has resulted in a change in law in many countries.

Q11. How does the assessed technology relate to more general challenges to modern medicine? How does the technology influence overall outcome measures? Does it increase sensitivity or lower the treatment threshold for a certain condition (7)? Does it change our conception of disease (13)? For example, IVF turned a social matter (childlessness) into a medical one (infertility), and by identifying its cause (male/female), distributed guilt. Is the technology subject to critique of medicalization, overdiagnosis, or overtreatment?

Q12. Have related technologies turned out to be morally challenging? It is extremely hard to foresee all implications of a technology. However, relating new technologies to existing technologies may be helpful. The moral challenges with positron emission tomography are probably related to those with magnetic resonance imaging and computed tomography.

Q13. Does the technology challenge or change the relationship between physician and patient? The use of telemedicine in psychiatry turned out to increase the patient's power (leaving the camera when uneasy). Conversely, technologies can increase the power of the physician. A related question to Q13 is whether the technology challenges the patients' trust in health care.

Q14. How does the implementation of the technology affect the distribution of health care? Many technologies imply substantial costs, sometimes covered with resources from other areas. Who will gain, and who will loose? Is the prioritization explicit or implicit?

Q15. How does the technology contribute to or challenge professional autonomy? In the same manner as with patients, technologies can alter or challenge the autonomy of the professionals. Implementing HTA results tends to be very difficult with technologies that reduce professional autonomy.

Q16. Can the technology harm the patient? New technology is highly potent for good and for bad. Explicitly addressing the potential harms is of moral import.

Questions with Respect to Stakeholders:

Q17. What patient group is the beneficiary of the technology? Are there morally relevant aspects with respect to the patient group that the technology is to be used for (e.g., socioeconomic aspects)? Are particular patient interest groups involved (19)?

Q18. Are there third-party agents involved? Many modern technologies pose moral challenges because they involve third parties, for example, organ donors, biobank contributors, proxies, surrogacy (egg donation), and family members (diagnostic tests).

Q19. What are the interests of the users of the technology? Is the technology of any relevance for the professional identity? Does it contribute to establishing a new specialty?

Q20. What are the interests of the producers of technology (industry, universities)? It is quite obvious that developers and producers have interests in promoting their technologies (3), which frequently influence their distribution and use. At a point, this influence also becomes morally relevant and should be taken into account in HTAs.

Questions Related to Technology

Q21. Are there moral challenges related to components of a technology that are relevant to the technology as such? For example, intracytoplasmic sperm injection (ICSI) relates to IVF, and the ethical issues of IVF are relevant to the evaluation of ICSI (12). Assessing the moral issues with respect to PGD can include an assessment of the moral issues of IVF and PND (14).

Q22. What is the characteristic of the technology to be assessed? Technology is characterized by its end (function, purpose) and as such is related to values (13). Sometimes it is important to highlight these values, as they are of moral relevance. The possibilities technology provides advance responsibilities. Implementing tests makes the health-care system responsible when such tests are not performed or when they fail.

Q23. Is the symbolic value of the technology of any moral relevance? Technology tends to have status, and this status differs among patients, professionals, producers, and policy-makers. This difference can influence the production, promotion, and assessment of technology.

Moral Aspects of Methodological Choices

Q24. Are there morally relevant issues related to the choice of end points in the assessment? The choice of end points is a matter of value. What if increased life expectancy results in reduced life quality or reduced morbidity results in lower functional status? Should diagnostic technologies be evaluated on behalf of treatment outcomes or with respect to diagnostic accuracy or diagnostic impact? These methodological questions are of moral relevance.

Q25. Are there morally relevant issues related to the selection of studies to be included in the HTA? The quality of the studies and the level of evidence that is required to include them in an HTA is an issue of moral relevance. What is the foundation of methodological norms such as including mainly meta-analysis and randomized control trials? What if the result from a meta-analysis becomes statistically significant if a "borderline study" is included? What if the (meta) analysis shows that a technology appears to have an effect that is not statistically significant, but where there are no other alternatives to help people with a particular disease?

Q26. Are the users of the technology in the studies representative of the users that will apply it in clinical practice? It is well known that studies performed by "enthusiasts" show different results than those performed by others (2) and that the results of experts can be quite different from those of "novices". If the technology is to be used in a context different from the one where it has been tested, we may end with doing more harm than good.

Q27. Are there morally relevant aspects with respect to the level of generalization? Is the patient group this technology is tested with representative for the group that is addressed in the HTA? That is, is it representative for the patient group it will be used for in practice (external validity)? In other words, is there a bias toward assessing internal validity?

Q28. Are there moral issues in research ethics that are important to the HTA? Should ethics be included in the checklist of systematic reviews, and what issues should count (24)? Should "scientifically sound" studies that have not passed a research ethics committee or institutional review boards and that "do not raise significant ethical issues" be excluded from HTAs? Who should be included in the control group, and what treatment should they have (21)? Many clinical trials do not report details of ethical issues such as financial support, conflict of interest, justification of sample size, and publication biases. Therefore, issues in research ethics may be of great relevance to HTA (24).

Questions Related to Technology Assessment

Q29. What are the reasons that this technology is selected to be assessed? Are there particular interests that make this technology subject to assessment (costs, expectations, pressure from interest groups). Is this of moral significance? Furthermore, with established technology that has not been properly assessed: what is the reason for the lack of assessment? Is there fear of presenting unpopular results? Is there a bias toward assessing technologies that have documented effect, such as pharmaceutical products?

Q30. What are the interests of the persons participating in the technology assessment? HTA experts take part in public debate, they are paid by organizations that live from HTAs, and HTAs are paid by agencies that have certain interests. It is naïve to believe that this interconnection is of no importance to the HTA process, and it can be crucial to be open about such matters.

Q31. At what time in the development of the technology is it assessed? Technologies assessed "too early" may show a negative result, and technologies assessed "too late" may not be as useful to many patients as it could.

Q32. Are there related technologies that have or have not been assessed? Assessment of a new technology in the field where there is no tradition for assessment may seem unjust to the professionals in the field.

Q33. What are the moral consequences of the HTA? Who will (not) get access to the new technology, as a result of the recommendations of the HTA? What are the consequences with respect to rationing? What is the role of the economic models that are applied in the calculations of cost-effectiveness? (How relevant and reasonable are they, what consequences do they have?) The debate on β-interferon in England and Wales tends to demonstrate this. See also Q14.

Exclusiveness and Exhaustiveness

It should be quite clear that the questions presented here are neither exclusive nor exhaustive. The questions are interrelated. For example, Q23 is related to Q15 and Q19, and Q29 is related to Q18, Q19, and Q20.

Furthermore, the questions are not exhaustive. There will always be moral questions that have to be added, depending on the specific technology or its particular use. This is because the questions are not customized to particular technologies. They are general questions framed at moral issues related to health technology and the HTA process. Moreover, the questions also cover a wider range of (normative) moral theory. For example, Q1 bears on a consequentialist approach; Q3–Q6 and Q8 relate to deontological ethics; Q2, Q14, and Q16 relate to a principlist stance (1); Q9 bears on SST theories; Q11 relates to critical theory; Q12 connects to casuistry; Q13 relates to virtue ethics; and so on. In this way, the collection of questions is eclectic. However, this is exactly the point, not making them subject to a particular moral theory and its shortcomings.

Correspondingly, the HTA agencies differ with respect to their purpose and their product. Some only commission assessments, others perform the assessments themselves. Some only provide the background information for the decisions; others develop recommendations and guidelines. The selection and emphasis of the questions may be different, depending on the task and strategy of the agency. Correspondingly, all the questions above are not relevant in every assessment, and not all moral issues have to be dealt with explicitly (8). However, it is believed that the questions present an overall framework that can be useful for addressing the ethical issues in HTAs.

How Can We Ensure the Quality of the Ethical Inquiry?

The ethicist's answer to the quality question is to get hold of a good ethicist. However, an academically well-written ethical analysis may be completely incomprehensible to non-ethicists and have no impact on the practical implementation of the technology. An open communication between professionals, HTA personnel, ethicists, and patient groups appears to be important for good, relevant, and integrated ethical inquiries.

Moreover, the context for assessing the moral implications of a technology varies according to clinical practices and moral traditions. Hence, one assessment performed in one context may be irrelevant to another. PGD is highly controversial in some countries but not in others. Hence, there will be no "objective" ethical inquiry in HTA.

However, we may still discuss the goodness of an inquiry. An assessment that spells out the relevant moral aspects related to a technology and makes it easy for the reader to get hold of the moral complexity will be better than one that does not.

Why Include Moral Issues in HTAs?

At the end of this article, it appears to be appropriate to underscore the reason why it is important to integrate moral issues in HTAs in the first place. First, the point with integrating moral issues in HTAs is to address important aspects other than outcome and costs. Health technology shares the overall (moral) end of health care, to help people, making HTA a moral endeavour and giving moral issues a natural place.

Second, outcome and cost assessments are performed by experts in an expert language. They often communicate badly in the public sphere where many of the issues about technology are debated. Moral issues, on the other hand, concern common subjects in ordinary language and tend to work well in the public debate.

Third, the questions presented here concern a wide range of moral issues, also issues related to the basis, method, and results of the HTA process itself. This approach may make HTA more transparent, open, and acknowledged.

Fourth, integrating moral issues, it is hoped, can lead to well-founded decisions and success in implementing the results of HTAs. Dissemination of the results and decisions made from HTAs still is a great challenge. Integrating a broader range of value issues than just outcome and costs potentially can contribute to reduce the dissemination problem.

The approach presented here is not a method, and it does not satisfy strong criteria for being a procedure. Moreover, it does not qualify as a moral theory and is subject to criticism of being too subject to HTA ideology. However, the collection of questions is only meant to be a starting point for a practicable approach to integrate moral issues in HTAs. It offers no revolution of HTA as such, it is not an application of a particular STS theory, and it is not an implementation of specific moral theories in the field of health technology assessment. Neither does it intend to make methodological issues of HTA or systematic reviews part of value theory. However, it has turned out to be helpful checklist in the practical assessment of a wide range of health technologies, and it is hoped that it can be useful to others as well.

POLICY IMPLICATIONS

Integrating ethical issues in HTAs can be of great import to the dissemination of HTA results, ease decision making, and be useful for health policy making.

CONTACT INFORMATION

Bjørn Hofmann, Adjunct Professor (b.m.hofmann@medisin.uio.no), Section for Medical Ethics, University of Oslo, P.O. Box 1130, Blindern, N-0318, Oslo, Norway; Consultant, The Norwegian Health Services Research Centre, Box 7004 St. Olavs plass, N-0130 Oslo, Norway

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QUERIES TO THE AUTHOR

Q1. Provide academic degree.

Q2. Per journal style, please provide names of authors.