# INAHTA's Working Group on Handling Ethical Issues

# Final report

## INAHTA Ethics Working Group

## June 2005

## Members of writing group

Svend Andersen, Centre for Bioethics (representing DACEHTA), Denmark

Lorraine Caron, AÉTMIS, Canada

Ghislaine Cleret de Langavant, AÉTMIS, Canada

Wybo Dondorp, GR, The Netherlands

John Gabbay, NCCHTA, UK

Kerstin Hagenfeldt (Chair), SBU, Sweden

Christa Harstall, AHFMR, Canada

Bjørn Hofmann, SMM, Norway

Marta Lopez-Argumedo, OSTEBA, Spain

Hussein Noorani, CCOHTA, Canada

# TABLE OF CONTENTS

# Terms of Reference

The results of a 2003 survey among INAHTA organizations on ethical issues revealed some differences with respect to how the ethical issues are dealt with as part of the Health Technology Assessment (HTA) process. These differences have to be taken into account.

The most important part of ethics in HTA has to do with the consequences of applying the technology to be assessed. However, there are also ethical questions related to the HTA analysis itself, including the starting point of choice of an area to be looked at.

The ethics working group was asked to address the following questions:

1. Can there be a procedure for handling ethical issues concerning technologies being assessed?

2. If yes, what would such a procedure look like?

3. If no, why not and what else can be done to assure good quality of the assessment of the ethical aspects of a technology?

4. What kind of ethical issues and questions are relevant with respect to a given technology?

   - Consequences

   - Duties

   - Relevant law

   - Human rights

   - Ethical principles (beneficence, non-malfeasance, justice, autonomy)

5. How far should HTA go in:

   a) Displaying values involved in the HTA-process itself?

   b) Highlighting relationships between knowledge and norms?

   c) Making recommendations with respect to ethical issues?

6. What is the relevance of addressing ethical issues with respect to achieving a successful dissemination?

   a) With respect to professionals?

   b) With respect to health policy?

7. What kinds of methods might be used to tackle these kinds of issues in an HTA and how might INAHTA help to assist with appropriate methodologies and quality checks?

8. What can be done to find or develop skills that would be required by HTA agencies undertaking ethical analyses?

The group is expected to prepare an interim report for the Annual meeting in Krakow (June 2004) which should be finalized for the 2005 meeting.

# PREAMBLE

This report is the result of work completed during 2004–2005. The method of work has been e-mail correspondence. It is important to know it is not the vision of one individual, nor that of a consensual process, nor that of individually authored discrete contributions. Moreover, this is a work in progress that could be greatly improved if INAHTA helped by sponsoring ethics panel and practical workshops (like the ones we are doing at HTAi 2005) so that we could enrich and refine our position.

# INTRODUCTION

The most important part of ethics in HTA has to do with the *actual consequences* of applying the technology to be assessed. There are also ethical questions, however, related to the HTA analysis itself*, including the starting point of choice of an area to be looked upon.* The consequences of HTA analyses may be understood in different ways. They could refer to the potential uses that could be made of these HTA results which include an ethical perspective – i.e. the relevance of HTA assessments for making and, in some cases, justifying decisions. Another interpretation of *"consequences"* could be the actual ethical implications of an HTA appraisal, assuming the recommendations are implemented. Still another meaning could be the implications of the extent to which ethics is integrated in the evaluative process itself.

The moral issues related to the *actual consequences* resulting from an HTA analysis may be quite different, whether the ethical analysis is considered to be an "adjunct" to the assessment or whether it is an integral part of the assessment/appraisal procedure. If ethical dimensions are not examined early in the evaluation process, it not only reduces the potential for informed decision-making but it also runs the risk that the results of the evaluation may be more readily used to justify the position of stakeholders (politicians, caregivers, patient groups) on the adoption, diffusion, or reimbursement of a particular technology.

The ethical issues have to be analyzed, keeping in mind whether the HTA results are to be used as a basis for recommendations/guidelines. HTAs are never totally free from being morally normative. But, should they also include recommendations on moral norms? This may differ with regard to specific terms of reference of HTA organizations. The fact that recommendations may include the consideration of ethical dimensions of the technology does not mean that the recommendations are directly relative to ethical norms. Nor, conversely, does the lack of explicit moral considerations mean that the results have no ethical dimension. Values are indeed a part of the evaluative process. It is best to be as transparent as possible concerning moral positions and choices such that the decision-makers may distance themselves from these positions if they don't share them, while still using the essence of the recommendations (Blancquaert, Cleret de Langavant, Bouchard 2002).

The *starting point* of an area to be looked upon – the prioritization of technologies to be assessed – has several ethical implications. Both identification and the final selection of areas for HTA are of ethical concern to stakeholders, such as patient groups, professionals, health care administrators, and politicians. To make the implicit ethical standpoint clear, the process has to be *explicit, systematic, and transparent* (Oortwijn 2000). There could be a risk of distorting priorities if all stakeholders were to be involved at the early stage of prioritization of the topics. Policy makers and politicians have their own reasons for interfering with the process. Scientists as well as patient organizations are needed, but can be in league with, and supported by, industry. Transparency, therefore, is of uttermost importance.

Important ethical questions that have to be dealt with in the prioritization process as suggested by Hofmann (Hofmann 2005) (see Appendix 1 A) are:

- What are the reasons that this technology is selected to be assessed?

- At what stage in development of the technology is it assessed?

- Are there related technologies that have not been assessed?

Early involvement of stakeholders in the prioritization process, e.g. paying attention to their concerns for societal relevance or their interest in cost-effectiveness, necessitate a balance between these views - a balance that needs to be based on ethical enquires. Such a balance could be beneficial for dissemination and implementation of the results of the specific HTA (see Question 6).

# QUESTION 1–3 – CAN THERE BE A PROCEDURE FOR HANDLING ETHICAL ISSUES CONCERNING TECHNOLOGIES BEING ASSESSED?

If yes, what would such a procedure look like?
If not, why not, and what else can be done to assure good quality of the assessment of <u>the ethical aspects of a technology</u>

The question of whether there can be a procedure for handling "ethical issues concerning technologies being assessed" can be addressed in many ways, e.g. 1) the moral consequences of HTA (itself); 2) the consequences of implementing a technology in the health care system; and 3) the development of a technology (in relation to the health care system). We believe that the first approach is too narrow because there tends to be many important moral aspects of a new technology that are not addressed if one only inquires about the HTA methodology. There is fair agreement that an ethical analysis should address the consequences of implementing a technology in the health care system (2) and some agreement that it should address the development of a technology (3).

Before starting to answer the question in the terms of reference, it may be useful to assess what one aims to do when conducting an evaluation (to which one may chose to integrate or not integrate an ethical analysis). HTA is conducted to assist decision making, be that at the policy, institutional (meso), or practice levels (micro). Some in the field are of the opinion that only "the evidence" should be presented to decision makers (assessment) without contextualisation or recommendations (appraisal). In many HTA organizations, there is a strong opinion that informed decision-making is promoted by contextualization and formulation of recommendations based on the evidence in context. This difference in perspective may explain, in part, the varying interpretations of what it means to "handle ethical issues". A synthesis or a description of what has been said in the ethics and social science literature without relating it in any way to the technology at hand or to its use in context, may fail to promote the taking into account of its ethical implications in decision-making because it is not integrated into the evaluation itself. To be relevant to decision-making, the conclusions of an evaluation need not only be valid but usable – i.e. they need to respond to the question: "What do these conclusions mean for me in my particular decision-making situation?" However, this does not preclude the view held by other HTA agencies that such a contextualized, usable ethical analysis might be presented at the appraisal stage alongside an assessment that does not include explicit ethical analysis. We must therefore explore further what might be the advantages and disadvantages of including ethical analysis in the actual assessment.

One argument against such an approach might be that the integration of an ethical analysis within the evaluation might not mean that one is doing ethics in a normative fashion. Here we deal with a complex issue. Ethics is reflexive in nature and need not be normative; one can do an analysis purely within so-called descriptive ethics. But if it is requested, the analysis can also have a character, contributing to the formulation of recommendations.

Recommendations need not necessarily concern ethical questions specifically. However, in the formulation of recommendations it is clear that the values of the evaluator and the ethical analysis conducted within the evaluation have an influence. In such situations it is crucial that the evaluator be as transparent as possible as to the ethical stance taken and his values, such that the decision-maker may distance

himself from the recommendations if he does not share the evaluators values, while still being able to use the material from which the recommendations are based.

The frequent non-consideration of ethical and social considerations within HTA evaluations has been the source of much criticism. Recently, several authors have proposed different approaches to integrate ethical reflection in assessments, in relation to the perceived role of ethics in HTA. The contribution of ethics to HTA is seen to be at various levels, ranging from the unearthing of values involved in the framing of HTA evaluations, to the study of the ethical implications of a particular technology, to the consideration of values underlying the development of a technology and of those held by the stakeholders of the technology. In relation to the above mentioned roles for ethics in HTA, the following approaches, amongst others, are proposed:

1) Descriptive/reflective analysis in the undertaking of assessments to recognize values involved in the framing of HTA questions,

2) The application of biomedical ethical principles (principlism) for the study of the ethical implications of a particular technology,

3) Historical analysis to detect values underlying the development of a technology, and

4) Stakeholder analysis for the identification of stakeholder values.

In a greater part, methodological questions linked to the integration of ethics in HTA are considered separately from the need to consider the context of development of a technology. However, both the lack of consideration of ethics and of context in HTA evaluations is individually associated in the literature with the reduced relevance of assessments for policy making. Indeed, as Dobrow et al. argue, the transition from evidence-based medicine (EBM) to evidence-based policy making is only rendered possible by the inclusion of context (Dobrow et al. 2004). For complex technologies, which affect many interdependent actors and institutions, have diverse effects over time and space, have multi-level organization and multiple finalities, the need to include the context of development, and introduction of a technology increases further. An example where the inclusion of the context is necessary to increase the relevance of an assessment for policy making is pediatric cochlear implantation where the technology is valued differently, depending on whether deafness is perceived as a pathological disorder or as a feature of a specific cultural minority (Reuzel 2004; Ten Have 2004). This perception is culturally ingrained and has an impact on the acceptability of the technology. Indeed, the feasibility of implementing a technology and its social acceptability are co-dependent concepts which are context sensitive. The cochlear implants example also demonstrates importantly and eloquently how ethical considerations are intimately linked to contextual factors and, in certain cases, may only be perceived and addressed if the context is taken into account.

If, indeed, ethical implications of a technology are intimately linked to the context of development and uptake of this technology, methodological approaches seeking the integration of ethics in HTA need to be context sensitive and thus should not be viewed as a simple addition to conventional HTA analyses.

Ethical analysis seeks first to understand the situation in its morally relevant aspects, not the immediate resolution of an ethical dilemma. The application of biomedical principles, in particular those developed by Beauchamp and Childress (Beauchamp,

Childress 2001), is the most popular approach to resolve ethical dilemmas arising from the use of technologies in general bioethical practice and in the few HTA evaluations that adopt an ethical perspective (Leventhal et al. 2004). Some other approaches claim to identify limitations of "Principlism", as these approaches are coined, more recently also in the HTA literature (Ten Have 2004; Grunwald 2004). Other approaches regard principles as a kind of deductive ethical reasoning which they examine at length with respect to complex technologies in the development of the method for complexity in bioethics (Cleret de Langavant 2001). Indeed, moral dilemmas emerge from the context of development and implementation of a technology and from the social fabric where the stakeholders (with their own interests, values, motivations) interact and where cultural, historical, political, economic, and scientific factors have a role to play. The interaction between these various dimensions gives rise to moral dilemmas that would go unnoticed with the deductive approaches of applied ethics. These emergent dilemmas can only be perceived, let alone understood, if this complex context is documented by appropriate qualitative research. Many different disciplines such as sociology, history, management, political science, philosophy of science, and critical perspectives to research methodology (i.e. not only those normally considered in bioethics such as theology, philosophy, or law) can offer new perspectives and methodological tools to document this context. The contribution of qualitative research to HTA is not only increasingly recognized (Leys 2003), but the relevance of interdisciplinary research to HTA and the necessity to integrate ethical reflection to this endeavor has been recently defended (Decker 2004).

# QUESTION 4 – WHAT KIND OF ETHICAL ISSUES AND QUESTIONS ARE RELEVANT WITH RESPECT TO A GIVEN TECHNOLOGY?

– Consequences
– Duties
– Relevant law
– Human rights
– <u>Ethical principles (beneficence, non-maleficence, justice, autonomy)</u>

## Introduction

Although there may be no straightforward procedure for the consideration of moral issues in HTA, certain questions may prove helpful in guiding the reflexive activity properly to ethical reasoning. What is needed is an inductive approach that allows ethical implications to arise from within the context thanks to appropriate qualitative research. Lead questions, such as those proposed by Hofmann (see Appendix 1A) may help identify where documentation is needed (Hofmann 2005). These questions are not intended to be exhaustive nor exclusive with respect to moral issues but rather to elicit reflection on the possible implications of a technology and on ramifications with other dimensions, such as the social construction of the technology, interactions between various actors and institutions, conflicting interests of stakeholders, as well as historical, economic, social, and cultural considerations.

The uncovering of the moral dilemmas linked to the development and implementation of a particular technology needs to be integrated into (not just associated with) the evaluative process, broadening the conception of evidence, for it to be relevant to and usable by decision makers (that they be at the micro, meso, or macro levels of decision making).

## Question 4 in relation to the execution of the HTAs

The intent was to choose questions that related to the initiation and production of an HTA, identification and prioritization, and carrying out of the HTA (the pre-assessment; development of protocols; synthesis and generalization; and recommendations) (Busse et al. 2002).

As noted by Hofmann, these are only a collection of questions intended to be a practical starting point to integrating moral issues into HTAs.

**Pre assessment**

*Are there moral challenges related to components of a technology that are relevant to the technology as such?*
If a technology consists of other (partial) technologies, it is important to assess the controversial issues of these technologies as well as the final technology.

*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. Sometimes it is important to highlight these values, as they are of moral relevance. (The cochlear implant is a good example, as the endpoint – curing deafness – has itself moral and ethical implications). Correspondingly, there are responsibilities related to the possibilities established by the technology. As presymptomatic or prenatal tests have become available, the health care system

tends to become responsible when such tests are not performed or when they fail. This can be of relevance when assessing technologies.

*Is the symbolic value of the technology of any moral relevance?*
Technology tends to have status and this status can differ among patients, professionals, in industry, and with health policy makers. Certain hi-tech technologies tend to have high status among professionals. Cardiac lasers and hi-tech imaging systems appear to have a higher symbolic value than crutches. This symbolic value of technology can be of moral relevance and tends to be pertinent to the assessment of a technology.

*At what time in the development of the technology is it assessed?*
Technologies assessed "too early" may show a misleadingly negative (or positive) result, and technologies assessed "too late" may not be as useful to many patients as it could. Hence, the timing of the assessment can be of moral relevance.

*Are there related technologies that have or have not been assessed?*
Many existing technologies have not been properly assessed. Assessment of a new technology in the field where there is no tradition for assessment may seem unjust to the professionals and patients in the field. This may be of importance to the result of the HTA.

## Protocol development

*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. Is the aim of a technology reduced mortality, increased functional status, decreased morbidity, increased life expectancy, or increased quality of life? What if increased life expectancy results in reduced life quality? Moreover, should diagnostic technologies be evaluated on behalf of treatment outcomes or with respect to diagnostic accuracy or diagnostic impact? These are methodological questions that are of moral relevance. They are also central to the disputes about HTAs and their results. What are the moral implications of methodological norms, such as focusing on internal validity and including only RCTs?

*Are there morally relevant issues related to the selection of meta-analysis and 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 value that may be of moral relevance. 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? These are moral issues related to methodological values and choices.

*Are there moral issues in research ethics that are important to HTAs?*
This is of importance if the moral issues affect the validity of the study. Should ethics be included in the checklist of systematic reviews, and what issues should count? 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 included in HTAs? Furthermore, who should be included in the control group and what treatment should they get? There is a profound debate as to what group is suitable as a reference group in clinical studies. Correspondingly, other

moral issues are related to clinical equipoise. Many clinical trials do not report details of ethical issues, such as financial support, conflict of interest, justification of sample size, or publication biases. Therefore, it can be important to include moral aspects with respect to research in the procedure of the systematic reviews in addition to the ethical evaluation of the technology

**Synthesis and generalization**

*Are the users of the technology in the studies representative of the users that will apply it in clinical practice?*
As it is well known that studies performed by "enthusiasts" show different results from those performed by others and that the results of experts can be quite different from those performed of "novices", the assessment of the education and qualification of the group that actually will use the technology in question is morally relevant. If the technology is to be used in a context different from the one where it has been tested, we may end up by doing more harm than good. The enthusiasts who conduct and publicize such studies have a moral duty, one might argue, to ensure that these factors are taken into account, as do those who incorporate those studies into HTAs.

*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 which is addressed in the HTA? That is, is it representative for the patient group it will be used for in practice (external validity)? For example, to continue to ignore the lack of evidence about many drugs in children and in the elderly has a clear moral and ethical dimension that is not discussed in most HTA reports.

**Recommendations**

*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? Assuming the results of the evaluation are implemented, the decision remains in the hands of the decision makers. It is not so much "as a result of the recommendations" but rather that these considerations of access to the technology be taken into account in the formulation of the recommendations; i.e. that access questions be examined while doing the evaluation).

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, what value has been put forth in the construction and use of the economic model?)

## Question 4 with emphasis on two important ethical issues

*Ethically relevant features:* Who are the partners involved: in doing the HTA and in clinical application of the technology? What is/ might be the interests of the partners?

The main question must be: what are the ethically relevant features of introducing the technology in the clinic?

*Ethical Analysis:* In analyzing the ethical questions, it might be useful to be aware that such questions appear within different contexts. One should distinguish between personal, professional, and political ethics. The physician has professional responsibility and the organization of health care may embody a political ethic, e.g. in granting equal access to health care.

The most difficult question is: what is the normative basis for assessing the ethical problems? All levels should be considered with different relevance depending on the technology. Also, the different levels are not mutually exclusive but interact with each other. For example, at the professional level, the clinical applications of a technology depend in great part of the context of application, where political ethics may play a part. And, in turn, the political ethics may be dependent upon legislation and other official documents.

However, not all questions can be answered on the basis of legal and quasi-legal norms. It does not make sense to adopt one ethical theory in the context of health care. We cannot presuppose agreement on certain philosophical, ideological, or religious doctrines such as utilitarianism or Christianity. We need to find normative principles that are more or less common. A proposal for such principles is the one already mentioned (Beauchamp, Childress 2001):

- Respect for Autonomy

- Non-Maleficence

- Beneficence

- Justice

A very important and difficult question is how to relate an ethical analysis to the economical part of HTA. It could be claimed that a cost-utility analysis actually deals with an ethical issue transformed into a quantifiable matter. Put differently, one could ask whether the mere concept of cost-utility is utilitarianism in a disguise. In any case, it is not obvious that medical treatment has increased the quality of life or QALYs as its goal. Here we have a problem of ethics that has to do with the very concept of HTA.

## QUESTION 5 – HOW FAR SHOULD HTA GO IN:

A) Displaying values involved in the HTA-process itself?

B) Highlighting relationships between knowledge and norms?

C) In making recommendations with respect to ethical issues?

## A) Displaying values involved in the HTA-process itself?

The first question adds an interesting meta-perspective to the discussion about the place of ethics in HTA. Among the values implicit in using HTA in health policy are those of public accountability, quality of care, health promotion, and justice. Values involved in the practice of HTA itself include (scientific) objectivity, transparency, neutrality, etc.

Explicit reference to these values may be important as a reminder of the high quality standards that policy makers and society at large rightly expect of the processes in which HTA outcomes are produced. The observation (Weingarten et al. 2004) that many clinical trials do not report quality-sensitive issues such as financial support, conflict of interests, justification of sample size, or publication biases, points to only one area where improvement is still possible. It would not seem that one could go too far in this.

A very different reason for raising awareness about the values involved in HTA is that 'the strongly perceived need to establish the scientific legitimacy of the field' (Johri et al. 2003) makes the practice vulnerable to the risk of reductivism. This occurs where possibly relevant considerations that do not fit this ideal are either cut to size or else excluded from the analysis.

One example of the former is the failure to acknowledge the role of normatively laden assumptions underlying at least part of the construction of the data used in HTA. The choice of a particular instrument for eliciting 'quality of life' valuations, or the decision either to include or not to include certain cost factors in CEA, would be examples of this (De Neeling 2003). Where assumptions behind such crucial choices are left unaccounted for, HTA-outcomes may seem to be more robust or normatively 'neutral' than is in fact warranted. This also refers to the second part of the question.

A further instance of this reductivism is the tendency to limit the analysis to those aspects that, as it would seem, are most easily expressed in objective and neutral terms. In a recent German review as, indeed, in the INAHTA survey and in Leventhal et al. (Leventhal et al. 2004), it was found that only a small minority of short HTA reports have, until now, included an explicit discussion of the ethical aspects of the technology under consideration (Droste et al. 2003). This, the authors suggest, has everything to do with the fact that we still lack the conceptual and methodical foundations for the inclusion of these aspects in a way that would 'both account for and reduce their complexity'. As long as this is the situation, their inclusion would 'hardly be possible in a scientifically serious form'.

Others have argued the need to 'look beyond the scientific rigor of the evidentiary basis and to attend to procedural features' with an aim of 'encouraging greater public consultation and participation and increase the transparency of decision making' (Johri et al. 2003). This 'participatory' or 'interactive' approach (Reuzel 2001, 2004) would have the benefit of allowing HTA to cast as broad a net as necessary for

including all aspects relevant for policy decisions, including those which are now often ignored.

## B) Highlighting relationships between knowledge and norms?

How far, in specific cases, one should go in 'highlighting relationships between knowledge and norms' (question 5b), depends on how important that would be for providing policy makers with adequate guidance on the technology in question. Doing so is not an end in itself. The more important and relevant the ethical assumptions that have affected the nature of the assessment, and/or the more the impact of the technology is likely to be subject to ethical considerations, then the further the HTA should go in highlighting the relationship between knowledge and norms.

## C) In making recommendations with respect to ethical issues?

Since HTA itself is not a value free undertaking, this also holds for the orientation or guidance it offers to health policy making, for instance on the cost-effectiveness of a technology or intervention. In that sense, it is inevitable that the ethical dimension is included in its conclusions and recommendations.

How far to go? In a recent article, Grunwald makes a helpful distinction between situations which allow for assessment in terms of a pre-existing normative consensus (the article explores the criteria for this), and situations where such a consensus does not exist (Grunwald 2004). In the former type of situation ('business as usual') HTA is able to give orientation without any explicit ethical analysis; in the latter type, there is a normative problem surrounding the introduction of the relevant technology which requires explicit analysis and resolution. An instance of this was the debate on the moral acceptability of introducing cochlear implants for congenitally deaf children. Pre-implantation genetic diagnosis or the use of human embryonic stem cells would be other examples. As Grunwald points out, an important element of the role of ethics in HTA is to judge whether or not the situation under consideration belongs to either of those types ('business as usual' or 'moral conflict').

Making recommendations with regard to ethical aspects would seem less problematic where the situation falls into the 'business as usual' category than if the situation is one of moral conflict. In situations of moral conflict, ethically informed HTA can either limit itself to providing policy makers with a thorough analysis of the relevant dimensions of the problem, or try to contribute to forging a resolution accepted by all interested parties via interactive approaches, as was done in the case of the cochlear implants problem (Reuzel 2001, 2004).

# QUESTION 6 – WHAT IS THE RELEVANCE OF ADDRESSING ETHICAL ISSUES WITH RESPECT TO ACHIEVING SUCCESSFUL DISSEMINATION?

A) With respect to professionals?

B) With respect to health policy?

This question is based on the false assumption that the dissemination of an HTA is correlated with its relevance. Also, wide dissemination of HTA results does not equate with their implementation. The scientific literature on knowledge transfer and dissemination suggest that effective uptake of research depends on various factors including timing, the interactions researchers' development with decision-makers, the approaches chosen for knowledge transfer, and if the content of the research fits with decision-makers' views (Granados et al. 1997). Furthermore, should evaluators be responsible for the implementation of the results of an HTA or should their responsibility rest only in providing recommendations to assist decision making?

To achieve successful dissemination/implementation of HTA, results have been a constant problem since the early stages. The results of HTA have often been ignored by the health care professionals and not used enough by administrators and politicians in planning health care. The reasons for this have been debated, but one reason could be the failure to include societal and ethical issues that decision makers think are relevant for the implementation of the results. Hofmann has indicated some important ethical questions for both categories of users that if included in the HTA could lead to better dissemination (Hofmann 2005, Appendix 1A).

Relevant questions for *the professionals* could be:

- What are the morally relevant consequences of the implementation of the technology?

- Does the technology in any way challenge or change the relationship between physician and patient?

- How does the technology contribute to or challenge professional autonomy?

Relevant questions for those responsible for *health policy* could be:

- What are the morally relevant consequences of the implementation of the technology?

- Will there be a moral obligation related to the implementation and use of a technology?

- Can the use of the technology in any way challenge relevant laws?

- How does the implementation of the technology affect the distribution of health care?

## QUESTION 7A – WHAT KINDS OF METHODS MIGHT BE USED TO TACKLE THESE KINDS OF ISSUES IN AN HTA?

HTA, at present, lacks a systematic analysis of ethical considerations. For each topic, inclusion or exclusion of ethical issues should be discussed with the relevant decision-makers at the topic refinement phase. In this regard, morally relevant questions developed a priori with respect to assessing health technology could be used as a checklist to determine relevant ethical issues for consideration in an HTA (Hofmann 2005, see Appendix 1A). Other examples of methods used can be found in Appendices B to D.

Following the topic refinement phase, the project team might include selection of a primary author responsible for writing the ethical analysis. Content experts within the project team can help to identify ethical dilemmas that emerge from the development and use of specific technologies under assessment. A literature search strategy of relevant sources will identify primary studies and reviews on ethical aspects for the specific technology under assessment and related technologies. The study findings, derived from a qualitative analysis of the relevant ethical issues and resultant policy implications, would need to be phrased within the context of the health care system for which the assessment is being undertaken.

The methods that most likely would be used depend on the agency's view of HTA and on the way the agency wish to deal with ethics (as an adjunct analysis, through start-up meetings, as an integrated part of the assessment process via multidisciplinary team assessments, or by setting up a participatory approach to TA (like public involvement). There are various methods (described above) that may be used and a combination of methods may be appropriate depending on the HTA project under consideration.

## QUESTION 7B – HOW MIGHT INAHTA HELP TO AGREE APPROPRIATE METHODOLOGIES AND QUALITY CHECKS?

This Working Group could develop a document (as a benchmark) of preferred methodologies for integrating ethical considerations in an HTA available to INAHTA members. At annual meetings held by INAHTA, member agencies could provide updates on their current initiatives/HTA projects that integrate ethical considerations.

## QUESTION 8 – WHAT CAN BE DONE TO FIND OR DEVELOP SKILLS THAT WOULD BE REQUIRED BY HTA AGENCIES UNDERTAKING ETHICAL ANALYSES?

Some of the proposed approaches to develop skills within HTA agencies include:

1. Develop contact lists of individuals with expertise in ethics related to health technologies (co-authors and external reviewers).

2. Include individuals with ethics expertise on the project team.

3. Provide guidance to authors to enable consistent approaches – this might assist with practical implementation of the technology and impact on the health policy process.

4. Increase awareness of decision makers about the importance of integrating ethical considerations in HTAs.

5. Build on internal capacity by recruitment of researchers with knowledge/expertise in the social sciences.

6. Encourage participation and presentations by HTA researchers at national/international health-care ethics meetings.

7. Ensure subscriptions to journals and textbooks within library services have a broad focus (ethics, legal, psychosocial).

8. Mentoring of researchers to foster development of skills in ethics and build capacity.

9. Invite speakers on health-care ethics to present at "Research Rounds".

# CONCLUSION

In summary, we do not believe that there can be only one method for handling ethical issues in HTA. To insist on one single method (be that principlism, virtue based ethics, etc.) could mean perpetuating the conception that ethics can be dealt with separately from the evaluative process. In our view, ethics is a process that shouldn't be reduced to the consideration of a set of values or principles in the abstract. Questions which are informed by principles may, however, elicit ethical reflection, but this endeavor must remain a reflexive exercise of unearthing emergent ethical implications of technologies by an integrated context sensitive analysis.

In this respect, various questions related to the different phases of the evaluative process itself and to the stakeholders of the assessment have been identified in order to allow for the emergence of ethical issues related to the technology evaluated.

It has been recognized that awareness should be raised about the values involved in HTA production and use such that it may fulfill its social and scientific role. Not only would transparency and accountability of the process be increased, but the relevance and validity of assessments would be as well. Indeed, since HTA is a value laden enterprise, it is misguided to attempt to treat knowledge and norms as distinct entities. Furthermore, with respect to the nature of recommendations (whether they concern ethical issues or not), the close relationship between knowledge and norms implies that ethical dimensions inevitably are included within the guidance provided by HTA. There remains the question as to how far one must go with respect to ethical analysis within an evaluation, the assumption being that all technologies do not raise the same amount of ethical awareness, or at least do not require absolutely novel ethical reflection. For complex technologies which have an impact on many institutions and stakeholders, novel ethical reflection may be necessary.

Inclusion of ethical dimensions in evaluations is thought to increase the relevance of HTA results and, in fact this, position is defended in this report. However, it is to note that although the relevance and dissemination of results of evaluations are linked concepts, the relevance of results does not ensure their dissemination, let alone their implementation. The dissemination and implementation of HTA results represent a field of enquiry on their own and should not be reduced to the question of the relevance of HTA results, be it related or not to the inclusion of ethical dimensions.

The report ends with a number of steps HTA agencies could undertake in order to develop and share skills related to ethical analyses in evaluations.

# ACKNOWLEDGEMENT

# REFERENCES

1. Bal R, Bijker WE, Hendriks R. Democratisation of scientific advice. *BMJ* 2004;329:1339-41.

2. Caron L. *Le démarrage des projets d'évaluation.* Document de travail AETMIS, 12 mai 2003.

3. Cleret de Langavant G. *Bioéthique:méthode et complexité.* Québec: Les Presses de l'Université du Québec, 2001; 309 p.

4. Blancquaert I, Cleret de Langavant G, Bouchard L. L'évaluation des technologies de la santé à l'ère de la génomique. Le défi de la complexité. *Ruptures, revue transdisciplinaire en santé* 2002;9(1):22–38.

5. Busse R, Orvain J, Velasco M, Perleth M, Drummond M, Gartner F, et al. Best practice in undertaking and reporting health technology assessments. *International Journal of Technology Assessment in Health Care* 2002;18(2):361–422.

6. De Neeling JND. *Cost-utility analysis.* The Hague: Health Council of the Netherlands, 2003; publication no. A03/01E.

7. Decker M. The role of ethics in interdisciplinary technology assessment. *Poiesis Prax* 2004;2:139–56.

8. Dobrow MJ, Goel V, Upshur REG. Evidence based health policy: context and utilisation. Social Science and Medicine, 2004;58:207–17.

9. Droste S, Gerhardus A, Kollek R. *Methoden zur Erfassung ethischer Aspekte und gesellschaftlicher Wertvorstellungen in Kurz-HTA-Berichten – eine internationale Bestandsaufnahme.* Köln: DIMDI, 2003.

10. Granados A, Jonsson E, Banta HD, Bero L, Bonair A, Cochet C, et al. EUR-ASSESS project subgroup report on dissemination and impact. *International Journal of Technology Assessment in Health Care* 1997;13(2): 220–86.

11. Grunwald A. The normative basis of (health) technology assessment and the role of ethical expertise. *Poiesis Prax* 2004;2:175–93.

12. Hofmann Bjørn. Towards a procedure for integrating moral issues in HTA. To be published in *International Journal of Technology Assessment in Health Care* 2005;21(3).

13. Johri M, Lehoux P. The great escape? Prospects for regulating access to technology through health technology assessment. *International Journal of Technology Assessment in Health Care* 2003;19(1):179–93.

14. Leventhal E, Brodin H, Gabbay J. *The incorporation of ethics in health technology assessments – a new conceptual framework.* A report for the NHS NCCHTA based on a Masters dissertation for an MSc in International Health Policy, University of Southampton, 2004.

15. Leys M. Health technology assessment: the contribution of qualitative research. *International Journal of Technology Assessment in Health Care* 2003;19(2):317–29.

16. Oortwijn Wija: *First things first.* Academic thesis. University of Amsterdam, 2000.

17. Reuzel RPB. *Health Technology assessment and interactive evaluation. Different perspectives.* Thesis Nijmegen University, 2001.

18. Reuzel RPB. Interactive technology assessment of paediatric cochlear implantation. *Poiesis Prax* 2004;2:119–37.

19. Ten Have H. Ethical perspectives on health technology assessment. *International Journal of Technology Assessment in Health Care* 2004;20(1):71–6.

20. Ten Have HA. Centenary of the Health Council of the Netherlands. V. Ethical-social issues. *Ned Tijdschr Geneeskd* 2002;146:1947–51.

21. Weingarten MA, Paul M, Leibovici L. Assessing ethics of trials in systematic reviews. *BMJ* Apr 2004;328:1013–14.

22. Beauchamp T, Childress J. *The Principles of Biomedical Ethics*, 5th Edition, 2001, Oxford.

# APPENDIX 1A: A SAMPLE OF THE QUESTIONS PROPOSED BY HOFMANN (2005)

| 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? |

# APPENDIX 1B: INTEGRATING ETHICS INTO HTA: START-UP MEETINGS AT AETMIS BY CARON 2005

"Start-up meetings" conducted at AETMIS is an institutional process intended to: 1) promote strategic planning; 2) discuss the design of the assessment; and 3) plan its execution. It is within those broad objectives that start-up meetings also become a process to support assessors in considering contextual aspects and ethical issues right from the onset of their HTA project.

Projects that will undergo a start-up meeting are selected by the scientific director. Once the project is selected, the ethics consultant and assistant to the scientific director meet with the assessor and give him/her a *Guide* (Caron, 2003) to help prepare the project presentation and questions the assessor might have for the audience. The Guide includes a series of questions covering the main steps of the assessment process (a process that, in practice, is dynamic and iterative):

1. Defining the technology and its context of utilization.
2. Gathering existing evidence and issues to consider.
3. Projecting intended impact and devising strategies for knowledge transfer.
4. Identifying stakeholders and mapping their claims and concerns.
5. Selecting assessment framework and methods.

Once the preparatory phase is completed, the start-up meeting can take place. The meeting is divided in two parts: a presentation of the assessment project by the assessor and then an open discussion among the participants to identify major issues, stakeholders, and assessment needs. The meeting is led by the ethics consultant who may rely, if needed, on a list of questions (Caron 2003) aimed at promoting a context-based ethically-informed HTA design.

The experience so far shows that start-up meetings encourage interdisciplinary brainstorming and input from the AETMIS community, which includes two bioethics consultants, as well as sharing of relevant methodological approaches. Start-up meetings promote the integration of ethical and social dimensions by examining the social context and likely impact of health technology implementation, by fostering the inclusion of all relevant stakeholders' perspective, and by promoting awareness of the normative dimensions embedded in every part of the HTA process. Such meetings are, for now, only applied to a subset of projects deemed to depart from "business as usual". Cases with major concerns and value conflicts (e.g. genetic screening) will additionally undergo thorough analysis by the consultants in bioethics at AETMIS.

# APPENDIX 1C: ETHICAL CONSIDERATIONS IN HTA REPORTS: THE CCOHTA INITIATIVE BY NOORANI 2005

Topic Identification

– Topic Proposal Form includes ethical issues as one consideration of a need to assess the proposed technology

Topic prioritization

– Criteria includes ethical, legal, and psychosocial implications associated with technology

Topic refinement

– Inclusion/exclusion of ethical issues discussed with advisory-panel members
– Content experts assist in identifying emerging ethical dilemmas

Assessment

– Selection of primary author (within project team) responsible for writing the ethical analysis
– Provide guidance to primary author on general approach (as per "Guidelines for Authors of CCOHTA Health Technology Assessment Reports")
– Literature search strategy of relevant sources to identify primary studies/reviews on ethical aspects
– Qualitative analysis of relevant ethical issues and resultant policy implications
– Findings and conclusions phrased within the context of the Canadian health care system
– External review by individual(s) with ethics expertise

# APPENDIX 1D: ETHICS ADVISING AT THE HEALTH COUNCIL OF THE NETHERLANDS BY DONDORP 2005

The Health Council of the Netherlands (GR) is the statutory scientific advisory body to the Dutch government in the field of public health and health care. In terms of the four phases of HTA often distinguished in overviews (identification, primary data collection, synthesis, and implementation), the focus of the GR is on the third (synthesis) and, also, increasingly on the first (early identification). The GR (est. 1902) has a long history of including an assessment of normative (ethical, legal, and social) aspects in its advisory reports. In doing so, it has more relied on the input of the relevant expertise (both in its multidisciplinary ad hoc committees and its internal peer review system) than on some formal method for assessing ethical aspects.

## Starting up the process

Most GR reports are drawn up in response to government requests. However, the council is already closely involved in the framing of these assignments. This is seen as a crucial moment for determining whether a report can be limited to the scientific or technical aspects of the relevant technology or intervention or should include an analysis of the wider normative context as well.

## Drawing up the report

If the latter is the case, this will be reflected in the work plan and the composition of the ad hoc committee charged with the task of drawing up the report. Depending on the subject and the assignment, GR committees often include one or two professional ethicists, along with legal and social science experts. It is their task to see to it that the report not only provides state of the art with regard to the scientific and technical aspects of the technology under consideration, but also gives a thorough and adequate analysis of the normative issues related to its introduction or use. This requires an assessment of the relevant ethical, legal, and social science literature, but also involves the charting of stakeholders and hearing their views.

## Review of the draft report

In order to enhance the quality of this dimension of the work of the GR, the Standing Committee on Medical Ethics and Health Law was established in 1977. Its main tasks are to provide input for the GR's work programme (also seeing to it that, wherever necessary, normative aspects are included as from the start) and to peer review draft reports drawn up by ad hoc committees. A question of recurring debate has been how far GR reports should go in making normatively laden recommendations, rather than presenting several possible positions.

## Ethical alerts

Apart from including an assessment of normative aspects in many of its synthesizing reports, the GR is also involved in drawing up ethical alerts. Its yearly 'Ethics and Health Monitoring report' contains short documents on new developments with possible normative implications that deserve the attention of health policy makers. For these reports (drawn up by the Standing Committee on Medical Ethics and Health Law) input is used from the extensive scientific network of the Council.

# APPENDIX 2 – WORKING GROUP MEMBERS (JUNE 2004)

Svend Andersen, Centre for Bioethics (representing DACEHTA), Denmark

Luc Bonneux, KCE, Belgium

Amanda Burls, NHSC, UK

Carlos Cano, CMS, USA

Lorraine Caron, AÉTMIS, Canada

Ghislaine Cleret de Langavant, AÉTMIS, Canada

Wybo Dondorp, GR, The Netherlands

John Gabbay, NCCHTA, UK

Colin Green, NCCHTA, UK

Kerstin Hagenfeldt (chair), SBU, Sweden

Christa Harstall, AHFMR, Canada

Bjørn Hofmann, NOKC, Norway

Florence Lalardrie, CEDIT, France

Marta Lopez-Argumedo, OSTEBA, Spain

Hussein Noorani, CCOHTA, Canada

Ela Pathak-Sen, NICE, UK

Emmanuelle Simon CEDIT, France