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Ethical evaluation in health technology assessment reports: An eclectic approach

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Objectives: Ethical evaluation has become an important part of health technology assessment (HTA), but so far no generally accepted method for doing this exists. This article explains the eclectic approach developed at the Finnish HTA office.
Methods: Each HTA report is produced in cooperation with the methodological and clinical experts from various levels of healthcare organizations. An open framework for ethical evaluation when assessing different types of interventions is used to identify all possible stakeholders for each particular intervention. The ethical consequences for each party are identified during the entire process of the HTA project.
Results: The results of an ethical evaluation in four different HTA projects (two on screening, one on surgical intervention, and one in rehabilitation) show that an open framework is useful for opening discussion and understanding the scope of each ethical evaluation. Both content and methodological experts have found the process to be useful in capturing the broad consequences of implementing a new method.
Conclusions: Ethical evaluation is a continuous process that considers the prevalent morals, values, and behavioral models of the society. An in-depth ethical evaluation helps the decision-makers to realize the consequences that implementing a new method has on individual citizens, the healthcare system, and society.

Keywords: Ethical evaluation, HTA

Health Technology Assessment (HTA) is a systematic study of the effect and consequences of the use of a particular technology in a defined context (6). The aim is to produce objective knowledge for decision makers on the benefits, costs, and harms of a technology so that the healthcare system can be based on relevant evidence. Appraising evidence and making decisions on the use of healthcare resources is, however, never a straightforward process. Social and ethical values and identification of the various consequences of implementing a new technology play an important role in the final decision. An in-depth ethical evaluation within an HTA report provides a more profound understanding of the various aspects that need to be taken into account during the decision-making process (10).

The fledgling methods of eliciting ethical issues relevant to a health technology assessment topic are not well described; neither does a generally accepted method exist. The International Network of Agencies for Health Technology Assessment (INAHTA) survey in 2003 revealed that, of the thirty-six member organizations that replied, 47 percent included ethical issues in their assessments (11). Moreover, the methods for evaluation and written conclusions differed markedly between the various organizations.

Structured questions as suggested by Hofmann (11) are helpful but not applicable to every situation. Neither do they reflect the actual assessment questions that surface directly in discussions between methodological and clinical experts. Ethical evaluation within HTA requires creative collaboration

between various professionals—experts in HTA methodology, content, and ethics. Within this continuously developing field of health technology assessment, ethical evaluation needs a variety of approaches tailored to each particular technology.

In this article, we use "ethics" as a generic term for the various ways of understanding and examining the moral life (4). Every society creates norms that reflect its values. These norms form the basis for laws and moral rules that protect the individuals from harming each other. Some rules are made explicit in the form of regulations; others remain implicit but are nonetheless followed. Normative ethics tells us how life ought to be. Non-normative ethics studies how people reason and act and tries to understand what the life factually is. Within a profession, the non-normative ethics may differ markedly between various specialties: such as for instance with the attitude toward follow-up and care of patients with nontreatable diseases within medicine. Healthcare decisions based on rules, norms, and evidence of effectiveness are also influenced by the personality and moral responses of the persons making the decisions.

In Finohta, we have developed a framework for ethical evaluation when assessing different types of interventions. Each HTA report is produced in cooperation with the methodological experts from Finohta and clinical experts from healthcare organizations. Professional ethicists are today consulted during the HTA process when it is considered necessary, but they are always included in the peer review process. In this study, we present four examples of ethical evaluations included in our projects, of which three have been completed (1;3;12).

GENERAL FRAMEWORK FOR AN ETHICAL EVALUATION AT FINOHTA

Decision points for ethical evaluation during the HTA process in Finohta are presented in Table 1. The focus within the topic, the specific questions to be answered, and the definition of the primary outcome are defined by the assessment team. These value-laden choices have a major impact on the content and conclusions of the HTA report.

General and technology-specific ethical issues and consequences for various stakeholders can be identified during the HTA process. For each stakeholder, we have listed possible consequences of proceeding with or refraining from the implementation of the technology (as compared with other options). Ethical evaluation has multiple perspectives and should ideally be produced by persons genuinely representing each stakeholder. An exchange of opinions, weighing different values and searching for the common good is the core of a successful ethical discussion.

New ethical issues often emerge during the HTA process, when the assessment team learns more of the detail of the technology through literature and in discussions with professionals using the technology. Therefore, it is necessary to repeat the ethical appraisal process a few times during the assessment. Novel aspects may come up even at the final comment round. No matter how minor an ethical aspect may seem, it should be presented once it has emerged. This strategy may slow down the process unexpectedly.

The report is approved by the entire assessment team. Ethical evaluation is written as a separate chapter but its main aspects are interwoven in the discussion chapter so that evidence is balanced against ethical consequences.

Ethical aspects can be highlighted or downplayed when HTA results are publicized. The media can have a different view of their importance than professionals or the assessment group. Finally, when the effects of a report are evaluated, the ethical discussion prompted by it can be a major result in itself.

The following four examples of ethical evaluations of HTA projects at Finohta started during 2003–04. Two projects assessed screening (1;3), one an invasive procedure (12), and the one still ongoing looks at rehabilitation.

Table 1. Decision Points for Considering Ethical Aspects in HTA

Selection of HTA topic
Appointing clinical expert group and deciding if an ethical expert is needed
Focusing the questions
Setting timetable for the project
Identification of the ethical issues and stakeholders
Selecting method and process for ethical evaluation
Evaluation of the consequences of implementing/not implementing the technology
Presentation of the ethical evaluation and evidence in a balanced fashion
Peer review process: selection of ethical and clinical experts
Communication to politicians, professionals, and the public
Evaluating the effects of the HTA report

HTA, health technology assessment.

SCREENING FOR RARE METABOLIC DISORDERS

Many countries base their screening for rare metabolic disorders on finding phenylketonuria (PKU). Because PKU is a rarity (15) in the Finnish population, the only metabolic disorder screened for during the neonatal period in Finland is congenital hypothyreosis from umbilical cord blood. A suggestion to start a local pilot study screening for a wide range of metabolic disorders was planned. Before this screening, an HTA project was started to evaluate the cost-effectiveness of expanding the screening and implementing tandem mass spectrometry. The assessment pointed out that this new technology would require building a totally new screening organization for the sake of finding five to ten babies with a rare disorder annually (1;2).

The various ethical concerns were elicited using a cross-tabulation of stakeholders and situations with and without screening (Table 2). The content changed during the evaluation process as some of the possible risks were eliminated but new ones emerged. In this project, a lack of research and consequently of evidence led to problems, as it became clear that high quality research evidence may never be gathered for rare disorders. This matter was further discussed by the national screening committee, which decided not to recommend screening for rare disorders, mainly due to the lack of direct evidence on effectiveness.

PRENATAL SCREENING FOR STRUCTURAL AND CHROMOSOMAL ABNORMALITIES

Methods for fetal screening have developed rapidly, and many countries commonly offer screening to all pregnant women. Women may even consider screening as a routine check-up during pregnancy (13;14); thus a suspicion of fetal abnormalities or facing difficult decisions based on the screening results may come as a surprise. The implementation of screening has been partly driven by technological development and may thus fail to reflect the current values and goals of society.

In Finland, each community can choose which screening methods they offer to their inhabitants. This has led to wide differences in practice. Finohta was asked to identify optimal methods for screening for structural and chromosomal abnormalities. The working group repeatedly considered the ethical consequences of screening for chromosomal and structural abnormalities during the project. This group also used an open tabulation of stakeholders and consequences of various screening methods. The ethical issues were discussed in detail within the report and a summary of the overall analysis is presented in Table 3.

The iterative and thorough ethical evaluation resulted in a questioning of the values and moral justice behind screening for fetal abnormalities. The main areas of ethical disagreement were classified into four sets of questions, and an open discussion among stakeholders was requested before formulating a national policy. The questions were focused on (i) the aims of screening for chromosomal abnormalities, (ii) the aims of screening for structural malformations, (iii) decision on screening methods, and (iv) quality control. A set of questions is presented in Table 4. An open seminar to discuss the report after its publication was organized, recruiting over 300 participants from laypersons to health decision makers.

Based on the report (3) and also the consultation round and seminar discussions, the national screening committee has proposed to the Ministry of Health a uniform national screening system to improve quality and equity of care, offering parents full freedom to select between four options: (i) not to attend any fetal screening tests; (ii) to attend screening only for features that support good care of pregnancy (due date, number of fetuses, and so on), (iii) to attend screening for fetal abnormalities (chromosomal and/or structural) with the option for termination of pregnancy if severe abnormalities are detected, or (iv) to attend ultrasound screening for structural abnormalities in late pregnancy (when termination is no longer an option) to arrange optimal conditions for delivery and care of the newborn.

INVASIVE TREATMENTS IN CORONARY HEART DISEASE

This assessment looked at the effectiveness of invasive interventions in treating coronary heart disease, prompted by the observation that practice increasingly favored the use of drug eluting stents and an increase in patients in need of acute care in Finland. This expert group included cardiologists, a cardiac surgeon, and methodological experts. The primary outcomes were avoidance of reoperations and death; these were analyzed from systematic reviews. Clinically important differences in effectiveness between the studied interventions—open heart surgery, angioplasty with or without stent, drug eluting stent, or fibrin-specific thrombolytic agents, depending on the condition—could not be observed (12). This result was not readily accepted by the external experts.

In this group, ethical evaluation was introduced to the clinical expert group when the effectiveness of the chosen interventions had already been partly assessed. This timing proved to be too late. The clinical experts did not consider opening a discussion on ethical values as important. A decision to promote one of the evaluated interventions could, however, have major consequences on the organization of health care and might lead to inequalities in care. Finohta thus decided to invite another group of health policy makers and professional ethicists to discuss the ethical aspects. This group considered the ethical evaluation relevant and important. Due to time constraints, the ethical evaluation was restricted to identifying questions that need to be resolved together with all stakeholders before changing current practice. Discussion focused especially on the equity of care, both nationally and regionally, between patients with the same and different health problems. A summary of this discussion is presented in Table 5.

REHABILITATION OF CHILDREN WITH CEREBRAL PALSY

This ongoing HTA project on the effectiveness of physical therapy for children with cerebral palsy (CP) turned out to be especially difficult for several reasons. High quality research is sparse, and the new method suggested for evaluating the level of evidence in CP research (5) does not follow the rules generally accepted in evidence-based medicine (7). Clinical practice within rehabilitation is strongly influenced by

Table 2. Ethical Evaluation when Screening for Rare Metabolic Disorders in Newborns

	Ethical aspects when no screening	Benefits of screening	Ethical aspects and possible harms when screening
A newborn, affected with the disease	Risk of death or severe handicap. The risk remains over lifetime.	Early diagnosis and treatment gives possibility to remain symptom free or with minimal harm.	Commitment to lifelong treatment may cause psychological stress. Identification of a disease form that may not cause symptoms during lifetime.
Newborn with one gene mutation, a carrier	Carrier status unknown, which may have either positive or negative consequences for the individual or his/her future descendants and relatives.	Knowledge of being a carrier and possibility for genetic counseling and other necessary healthcare services in the future.	Carrier status identified before being able to give consent for testing, which may cause unnecessary stress.
Healthy newborn	No unnecessary examinations.	Exclusion of disease.	Pain caused by taking the blood sample. Unnecessary examinations when testing falsely positive.
Parents of an affected child	Bitterness of parents when the child dies or is severely handicapped from a disease that could have been treated if screened for. Feeling of unfairness when comparing the cost-effectiveness of screening to other implemented treatments.	Possibility to keep the child symptom free with proper treatment. Possibility for genetic counseling in future pregnancies/family planning.	Identification of a severe disease in a symptom-free newborn. Commitment to lifelong treatment. Stress and fear for life-threatening situations (infections).
Parents of a healthy child	No information on the existence of rare disorders.	Exclusion of the disease.	Parents of healthy children unnecessarily disturbed by the offer of screening or worried about false-positive screening results.
Siblings of an affected child	Hidden or mild forms not identified. Knowledge of possibility of being a carrier or carrying the same disorder comes through death or handicap of sibling, which may be frightening.	Identification of diseases with no to mild symptoms. A possibility to test for being a carrier and get genetic counseling when needed.	Fear for being a carrier. Identification of disease that may not cause any symptoms during lifetime.
Other relatives of an affected child	Knowledge of possibility of being a carrier comes through death or handicap of relative, which may be more frightening. Hidden and mild forms not identified and thus the risk of being a carrier is not known.	Identification of genetic risk and possibility for genetic counseling.	Fear for being a carrier.
Healthcare system	Need to evaluate whether diagnostic and treatment possibilities are properly organized. Acceptance of the possibility that some infants may die or be severely handicapped due to delayed diagnosis.	The possibility to prevent permanent damage. Clarification of treatment and follow-up responsibilities from newborn through adulthood.	The personnel at outpatient maternity units need to inform parents about disorders they have never encountered. Acceptance of false-positive and false-negative results.
Society	Need to evaluate equity in relation to other rare conditions, expensive treatments in use and active screening programs.	Lower treatment cost for cases. General knowledge about rare conditions increases.	High yearly running costs. Avoidance of death or handicap of a few individuals at the cost of causing slight burden in many. The high costs of treating a person with disability are unintentionally emphasized, which increases the risks of discrimination.

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Table 3. Ethical Evaluation in Prenatal Screening for Structural or Chromosomal Abnormalities

Benefits when screening is offered	Benefits when screening is not offered
Improved autonomy if fear of fetal abnormality would lead to the choice of not having children. Diagnostic procedures may identify the specific etiology for the fetal abnormality, which improves the possibilities for genetic counseling. Parents have the option to choose abortion or continue the pregnancy. Follow-up during pregnancy, place of birth and treatment of the newborn can be planned. Decrease in prenatal and perinatal morbidity and mortality.	Less concern (no false-positive or -negative results). The birth of a child with an abnormality is not due to a poor screening method, which may make it easier to accept the situation. A number or fetal trisomies result in spontaneous miscarriage, and these parents do not have to choose between abortion and continuation of the pregnancy. No miscarriages due to diagnostic procedures. The public attitude toward abnormalities may be less discriminative.
Harms when screening is offered	**Harms when screening is not offered**
False belief that participating in screening for fetal abnormalities secures the birth of a healthy child. Diagnostic procedures carry a small but real risk of miscarriage. False-positive results raise unnecessary concern. Parents worry even when the identified fetal abnormality is mild and is considered by professionals to have no prognostic meaning. Parents worry if the effect of the finding on the quality of life of the child cannot be anticipated. The definition of a severe malformation is not precise; this can lead to situations in which decision-making is very difficult. The parents must consider their attitude and values toward an abnormal fetus and child and also in relation to having an abortion. Bitterness toward the healthcare system caused by false-negative screening results.	The etiology of a fetal abnormality may remain unclear when diagnostic procedures could not be made due to early spontaneous miscarriage. Fetal abnormalities may have an effect on the prognosis of the child (birth and early treatment cannot be planned optimally). The birth of an abnormal child is always a surprise to the parents. Increase in perinatal morbidity and mortality. Privately performed screening and diagnostic procedures may increase, weakening the quality of offered screening and diagnostic methods and causing inequity.

Table 4. Objectives of Screening Programs for Structural Abnormalities That Need To Be Evaluated Prior to National Health Policy Decision

Is it justified to screen for abnormalities that cannot be treated and that mostly result in miscarriage or perinatal death (e.g., anencephaly)?
Is it justified to screen for abnormalities that cannot be treated and may lead to disabilities of a widely varying degree of severity, ranging from regular need for assistance to independent functioning (e.g., spina bifida)?
Is it justified to screen for abnormalities that can be treated, i.e., the prognosis for the infant can be improved considerably either by treating the fetus or by choosing the best possible delivery place and method (e.g., transposition of the great arteries)?
If the objective of screening tests is both to give an opportunity to terminate the pregnancy and to allow the choice of the best possible place of treatment and delivery, what is the optimal timing for ultrasound scanning?
If the objective is to screen only for structural abnormalities that can be treated, what is the optimal timing for ultrasound scanning?
If screening is not considered necessary or is provided free of charge only to some, what attitude should be taken to screening for fetal structural abnormalities in the private sector?

opinion leaders. Major differences in the type and amount of the recommended individual therapies exist both within one country and between nations

To facilitate discussion during expert group meetings, we used an open grid, where the rows and columns were collectively named to represent various stakeholders and types of problems. Table 6 shows the current discussion regarding three stakeholders. The expert group also identified risks inherent in the HTA assessment using the method presented by Hailey and Juzwishin (8). Risk evaluation turned out to be very useful, and during this process entirely new ethical aspects were identified.

DISAGREEMENT DURING ETHICAL EVALUATION

The values and moral views of the persons assessing the technology influence also the ethical evaluation. Although no single solution to every moral problem exists, dialogue promotes understanding. During ethical evaluations, we have faced several situations of disagreement (Table 7), two of which are presented here in more detail.

In Finland, the blood sample for screening hypothyreosis is taken from the umbilical cord not from the heel of the newborn. The heel sample is painful for the baby; the umbilical cord sample is not. This issue was discussed in detail during the project. Of interest, a recent Dutch report (9) on the ethical consequences of expanding screening for newborn disorders had not identified this issue as ethically

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Table 5. Examples of Aspects That Need To Be Appraised when Selecting Interventions for Cardiac Disorders

Access to care	Distance to invasive care facilities needs to be considered in policy decisions. The needs of other patients groups requiring acute care services at primary, secondary, and tertiary level have to be appreciated and balanced with those requiring acute cardiac care.
Allocation of resources	Implementing a new intervention method may have major effects on the need of various specialties (cardiologists vs. surgeons).
Cost-effectiveness and safety issues	Implementation of a new intervention method may require major investments. Long-term cost-effectiveness may be difficult to estimate. The impact of centralized vs. decentralized treatment on safety and cost-effectiveness has to be appreciated.
Equity aspect	Is it right to offer optimal treatment in one disease if this means decreasing resources in other disorders? How can vertical and horizontal equity be ascertained throughout the country?
Autonomy	How can informed consent be achieved when the patient is critically ill at the point of decision?
Other aspects	Commercial interest may have an effect on research protocols, conclusions, and clinical guidelines.

Table 6. Social and Ethical Aspects To Be Considered in the Rehabilitation of Children with CP: Summary of the Discussion from the Patient's, Siblings', and Parents' Point of View

	Threats associated with rehabilitation process	Possibilities associated with a successful rehabilitation process	Special challenges
Child with CP syndrome	The child doesn't understand the goals of rehabilitation. Goals are unrealistic, which may disappoint the child when not reached. Possibilities for a normal childhood and natural development are endangered. The child is not accepted as her/himself. The goals of the child are not being heard and appreciated. The search for weakness and faults is emphasized. Interventions are associated with pain or fear. Rehabilitation is diagnosis specific (e.g., a certain amount of individual therapies at a certain age for a specific diagnosis) instead of being planned according to individual needs, current resources, and realistic goals.	The strengths of the child are supported. The child has a realistic view of her/himself and accepts her/himself. The child is active in the rehabilitation process, makes own choices as to learning goals. The child participates at age-level activities outside the home. Pain can be controlled.	To enable appreciation of child's opinion. Rehabilitation is implemented in all daily living activities while simultaneously appreciating the resources of the child. How to prioritize the goals of rehabilitation when the child has additional/several difficulties. Specific challenges at various age levels: - infancy: timing with infant level of arousal; - toddler: support for adapting to school routines; - school age: support learning activities; - puberty: support motivation and self-confidence.
Siblings	Parental resources are focused on the CP child, healthy siblings become invisible. Siblings are ashamed of their handicapped sister/brother. Siblings may behave abnormally so as to receive attention.	Siblings can live a normal childhood. Siblings learn to approve of handicapped persons. Siblings see their role as important in the family.	Seeing and responding to needs of siblings. The periods of birth and diagnostic process of their CP sister/brother. Puberty and other time periods when siblings need special attention. Intensive rehabilitation period after surgery of their CP sibling.
Parents	The child is only followed without supporting the family or starting rehabilitation until a diagnosis is being made. Parents have unrealistic expectations. Parental resources are worn out while fulfilling the demands of the rehabilitation process. Parents don't dare refuse the suggested interventions (botulinum toxin injections, surgery). Parents and the family are left out of normal social contacts.	The abnormal features of the child will lead to appropriate follow-up and rehabilitation. Parents receive individual and sufficient support. Parents can trust that their child receives rehabilitation that is both beneficial and sufficient to their child.	Period when the child is followed without a specific diagnosis. Listening and responding to each parent's individual worries. Parents are afraid of suggested interventions and refuse them, which may later lead to the need to perform wider interventions (e.g., surgery). Birth of younger siblings. Parents demand all possible interventions they have heard of.

CP, cerebral palsy.

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Table 7. Examples of Ethical Disagreement

Factual disagreement: What is the level of suffering when taking blood samples from the heel of a newborn?
Who should be protected and whose values prioritized in prenatal screening: fetuses or parents or persons with structural/chromosomal abnormalities
Disagreement about appropriate specifications: What can be concluded on the effectiveness of physiotherapy for the excluded population (mentally retarded children with CP)
Disagreement about balancing benefit, costs, and harms: Which consequences to include when implementing open heart surgery or stent in cardiac disorders?
The presence of a genuine moral dilemma: Can the possibility to abort a malformed fetus be accepted as one aim of screening?

CP, cerebral palsy.

relevant as the heel prick test has been a practice for decades in the Netherlands.

A genuine moral dilemma was identified during the ethical evaluation of screening for fetal abnormalities. In Finland, it is legally possible to have an abortion up to the end of week 24 if a severe malformation is verified. The definition of a severe malformation is, however, not precise. One child with Down syndrome may have several structural malformations, visual and hearing impairment. Another child with Down syndrome may, however, be only mildly mentally retarded without any additional disabilities. The expert group and the open seminar discussed extensively whether and when Down syndrome diagnosed during pregnancy can be defined as being a severe malformation.

DISCUSSION

In a doctor–patient relationship, evidence cannot override the need for acknowledging individual patient values. Vice versa, values never replace missing knowledge. The same holds for health technology assessment. Conclusions of the effectiveness of an intervention may be misleading if used alone. If ethical evaluation is not included in the process, we may miss essential aspects of the technology. Even when the effects, costs, and harms of a technology are reported and appraised objectively, a thorough ethical evaluation may additionally enhance the dissemination of the HTA report and affect its implementation (3;11).

We found our eclectic approach, using a structured framework, to be a very helpful tool in opening ethical discussion in each HTA project. The groups tackled different types of interventions (screening, surgical intervention, rehabilitation), while their ways of reporting the ethical evaluation differed. The original framework designed for a screening assessment could be applied as a basis. It was repeatedly modified according to the specific features of each assessment.

Our expert groups were able to open vivid discussions on ethical values within society and the intervention in question. The clinical experts found the processes of ethical evaluation both important and rewarding. Their bias typically stems from seeking a benefit for their own patients; they may overlook the effects of implementing an intervention on other parties. The methodological experts may overlook the equity consequences or fail to recognize the restrictions of the included studies in relation to all patients with a similar condition. Neither might be aware of the historical background of current practice and the needs of patients.

Ethical evaluation is a continuous process that tries to understand the prevalent moral, values, and behavioral models of society. Each profession creates its own ethical rules and regulations that are the basis for their profession; these combine knowledge, experience, and commitment to ethically acceptable goals. It is important that the differences in non-normative ethics between various specialties within health care are also identified to improve equity in care. With the help of an in-depth ethical evaluation framework, it is possible to help the decision makers capture the wide consequences that implementing a new health technology has on individual citizens, the healthcare system, and society.

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