Ethical analysis to improve decision-making on health technologies
Samuli I Saarni, a Bjørn Hofmann, b Kristian Lampe, a Dagmar Lühmann, c Marjukka Mäkelä, a Marcial Velasco-Garrido d & Ilona Autti-Rämö a

Abstract Health technology assessment (HTA) is the multidisciplinary study of the implications of the development, diffusion and use of health technologies. It supports health-policy decisions by providing a joint knowledge base for decision-makers. To increase its policy relevance, HTA tries to extend beyond effectiveness and costs to also considering the social, organizational and ethical implications of technologies. However, a commonly accepted method for analysing the ethical aspects of health technologies is lacking.

This paper describes a model for ethical analysis of health technology that is easy and flexible to use in different organizational settings and cultures. The model is part of the EUnetHTA project, which focuses on the transferability of HTAs between countries.

The EUnetHTA ethics model is based on the insight that the whole HTA process is value laden. It is not sufficient to only analyse the ethical consequences of a technology, but also the ethical issues of the whole HTA process must be considered. Selection of assessment topics, methods and outcomes is essentially a value-laden decision. Health technologies may challenge moral or cultural values and beliefs, and their implementation may also have significant impact on people other than the patient. These are essential considerations for health policy. The ethics model is structured around key ethical questions rather than philosophical theories, to be applicable to different cultures and usable by non-philosophers.

Integrating ethical considerations into HTA can improve the relevance of technology assessments for health care and health policy in both developed and developing countries.


Une traduction en français de ce résumé figure à la fin de l'article. Al final del artículo se facilita una traducción al español.

Introduction

Health technology assessment (HTA) is a multidisciplinary field of policy analysis. It studies the implications of the development, diffusion and use of health technology. Its power lies in providing a joint basis for policy discussions about health care, instead of each party bringing its own calculations and then disagreeing on who is right. However, it is also a fundamentally value-laden enterprise.

HTA started in the 1970s with the primary interest of ensuring the effectiveness and safety of new health technologies. The cost and comparative cost-effectiveness became increasingly important as methods of assessment developed parallel to methods in health economics. More recently, the effects of health technologies on organizations, as well as legal, societal and ethical aspects of technologies, have come under the scope of HTA. This reflects the aim to increase the relevance and applicability of the assessments and the realization that health technologies are always applied in a social context. However, a shortage of accepted and practical methods for incorporating these considerations within HTA has been recognized.

This paper describes a flexible, easy-to-use model for incorporating ethics into HTA. The aim is to make HTAs more internationally transferable and relevant to policy-makers in different health-care settings and cultures.

Ethics and HTA

The importance of considering technology’s impact on “social, ethical, legal and other systems” was recognized early and has subsequently been generally accepted. The importance of ethics in HTA is based on three insights. First, implementing health technologies may have moral consequences, which justifies adding an ethical analysis to a “traditional” assessment of cost and effectiveness. Second, technology also carries values and may challenge prevalent moral principles or rules of society that should be addressed by HTA.

Third, a more fundamental insight, is that the whole HTA enterprise is value laden. The goal of HTA is to improve health care, and as health care is value laden (in trying to improve the well-being of people), then HTA is value laden too. The conviction that health care and health policy should be evidence-based and decisions should...
be transparent is a generally accepted value-base within HTA. Important value-decisions are often made implicitly in HTA methodology: when choosing which technology to assess; interpreting research results; deciding on what counts as evidence; and whose view decides the rationality of implementing a technology.8,11–14 Considering a particular HTA, the formulation of the problem, the choice of outcome measures and comparative technologies also reflect values and determine the possible outcomes of the assessment. In summary, this approach to ethics aims to uncover and justify the underlying normative structure of HTA, to assure the usefulness of the assessment.13,15

Decisions to implement technologies imply resource allocation. Choosing a technology may imply devaluing or abandoning other technologies, but may also lead to reallocation of resources within health care, or between wider sectors of society.16,17 Ideally, political decision-makers are expected to balance individual and wider societal interests, taking into consideration all values at stake. Ethical analysis within HTA can provide insight into these issues, and assist decision-makers in interpreting information in a policy-relevant way.18

Despite the general agreement on the importance of integrating ethics in HTA,8,14,15 ethical issues are still rarely addressed in HTA reports.19–21

**EUnetHTA project**

The objective of the EUnetHTA project, launched in 2006, is to connect public HTA agencies, research institutions and health ministries and to enhance the exchange of information and support policy decisions. A total of 59 partner organizations participate from 31 countries.22 The ethics model belongs to a part of the project in which 25 HTA organizations are developing a generic “HTA core model” to guide future assessments.

The basic idea of the core model is to structure the contents of an HTA into pieces of information. These “assessment elements” are formulated as questions (e.g. the impact of technology on mortality). The first version contains 163 assessment elements divided into nine domains (Box 1), each with recommended methods of assessment.23

This enables a consistent structure of HTA, allowing users to find relevant and transferable information easily.

The EUnetHTA model on ethical analysis (available at: http://www.eunethta.net/Work_Packages/WP_4) aims to improve the international transferability, quality and usefulness of HTA to decision-makers by considering ethical issues relating both to the technology evaluated and to the HTA process itself. Thus, the model is not a separate exercise on ethical aspects of a technology, but integrates ethical reflection and value-awareness into the HTA process from start to finish.

A challenge in integrating ethics into HTA has been that although there is a multitude of philosophical approaches to ethics in HTA there is lack of consensus among philosophers, and a lack of methods applicable for non-philosophers.3,10,13,24–26 The model does not purport to solve the philosophical debate but to offer a tool usable by HTA organizations, irrespective of their resources (material, time and knowledge). Thus the model has three elements: a question-based approach26 that covers issues essential for ethical analysis within HTA; a brief explanation of methods that can be used to approach the issues; and a discussion on the integration of ethical analysis into the process of HTA. Key issues and examples of the model are presented below.

**Box 1. The domains of assessment in the HTA core model**

<table>
<thead>
<tr>
<th>Domain</th>
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<tbody>
<tr>
<td>Health problem and current use of technology</td>
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<tr>
<td>Description and technical characteristics of technology</td>
</tr>
<tr>
<td>Safety</td>
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<tr>
<td>Clinical effectiveness</td>
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<tr>
<td>Costs and economic evaluation</td>
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<tr>
<td>Ethical analysis</td>
</tr>
<tr>
<td>Organizational aspects</td>
</tr>
<tr>
<td>Social aspects</td>
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<tr>
<td>Legal aspects</td>
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</table>

**Planning the assessment**

The selection of comparison technologies and outcome measures are essentially value-decisions that determine the results of the assessment. Also the moral value of the comparator should be considered, even if it is already widely used. “Hard” outcomes such as mortality should not automatically override relevant patient-reported outcomes,27 and difficult-to-quantify societal and organizational effects should be included.

**The set of questions**

The set of questions aims to increase standardization, transparency and the international transferability of the assessment. They are especially useful for identifying and cataloguing the relevant ethical considerations, allowing for several methods to weigh and balance the issues.26 The questions highlight the interwoven nature of ethics and HTA, e.g. medical, safety or economic issues also yield important input for ethical analysis.

The model has 16 questions covering the core issues of ethical analysis. These were chosen from a comprehensive list of issues by a consensus procedure so that only issues that were considered both important and internationally transferable were included. These include, for example, principal questions, such as whether the technology can challenge moral, religious or...
Table 1. Sample of ethical issues included in the model

<table>
<thead>
<tr>
<th>Topic</th>
<th>Issue</th>
<th>Clarification</th>
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<tr>
<td>Principal questions about the ethical aspects of technology</td>
<td>Can technology challenge the religious, cultural or moral convictions or beliefs of some groups or change current social arrangements?</td>
<td>It is important to identify those groups within the society for whom the use of the technology may pose serious challenges due to their beliefs or convictions (e.g. blood transfusion, contraception). Identification of these conflicts and finding other acceptable possibilities to treat the condition in these groups is important. Identifying the conceptions behind these beliefs and values may help put them in perspective when considering the overall acceptability of the technology.</td>
</tr>
<tr>
<td>Autonomy</td>
<td>Does the implementation or use of the technology challenge patient autonomy?</td>
<td>Patients have, in most cases, a right to autonomy, i.e. the right to be self-governing agents. This requires the right to decide about things of importance to oneself but also requires relevant information and a capability to understand the information, consider it in relation to personal values and decide accordingly. Thus, technologies and health systems may interfere with a patient’s right to autonomy directly or indirectly by influencing the decisional capacity. For example, a technology that does not allow itself to be understandably explained to the patient (e.g. gene therapy for dementia) is potentially problematic, as are treatments that require patients to behave in a certain way (e.g. liver transplants given on condition of abstinence from drinking alcohol).</td>
</tr>
<tr>
<td>Beneficence/ nonmaleficence</td>
<td>Can the technology harm any other stakeholders? What are the potential benefits and harms for other stakeholders and what is the balance between them? Who will balance the risks and benefits in practice and how?</td>
<td>Some technologies have the potential to unfold unwanted or harmful effects, not only on the patients that the technology is directly applied to, but also indirectly on other stakeholders. These harmful effects may manifest in physical, social, financial or even other domains of life (e.g. results of genetic tests may negatively interfere not only with the family planning and social life of the individual being tested but also of his or her relatives).</td>
</tr>
<tr>
<td>Justice and equity</td>
<td>What are the consequences of implementing/not implementing the technology on justice in the health-care system? Are principles of fairness, justness and solidarity respected?</td>
<td>A new intervention may require a re-allocation of human resources, funding and training. A large re-allocation of resources may seriously jeopardize other patient groups (e.g. new technology that requires human resources in acute care). How this affects the existing health-care system has to be studied for all stakeholders. Can the technology be applied in a way that there is equal access to those in equal need? How can this be guaranteed? Could potential discrimination or other inequalities (e.g. geographic, gender, ethnic, religious, employment, insurance) prevent access? Are specific safeguards needed? Potential inequalities and discrimination should be justified.</td>
</tr>
</tbody>
</table>

The implementation or use of the technology, the resources available, and cultural values of a society. The risks of technology with respect to patient autonomy, human dignity or integrity must be addressed, especially considering vulnerable patient populations with special needs for information and support. Issues of basic human rights must be included – will the technology help in realizing these, or threaten them? A key issue is to include all stakeholders in considerations of benefits and harms. This leads to assessing the effects of the technology on the justness, equity or fairness of health care: Who will get access to the technology? What has happened to related technologies before? Is legal regulation needed? Sample questions with clarifications are presented in Table 1.

**Methods for ethics**

The best method for answering ethical questions varies depending on the technology, the resources available, and the national and organizational values and culture. Novel technologies may raise new ethical dilemmas (e.g. pre-implantation diagnostics) and old technologies can become controversial in new contexts (e.g. male circumcision), requiring specific emphasis on ethical analysis. Expansions of technologies considered ethically unproblematic (e.g. new antibiotics) often make thorough ethical analysis less useful. It is important to see the technology in context: societal and ethical effects of a certain technology are likely to vary depending on the cultural norms and the structure and functioning of the health-care system. Thus the model describes several methods that can be used to conduct the analysis, but leaves the selection of the most suitable method to the discretion of the user. Table 2 lists methods based on philosophical theories actually used and that have proven useful within HTA, as identified by the International Network of Agencies for Health Technology Assessment International ethics working group. Local applications are also presented.

**The process of ethical analysis**

The key to successful ethical analysis is integrating it into the HTA so that ethical issues are considered reflectively during the whole assessment process, starting from the planning stage; this contrasts with conducting a separate ethics exercise after all data have been gathered. The role of experts of the technology in providing the material and contextual input is emphasized. Expertise in methods of ethics can be of great benefit but is neither necessary nor sufficient. Literature searches may have to be conducted several times as new ethically relevant issues are being identified. All stakeholders must be identified, and a party responsible for the ethical aspects nominated. As
HTA institutions vary greatly in their resources, mandates and organizational structures, the optimal process must be locally tailored.

**Reporting**

The way to report the ethical issues, especially the need to make normative conclusions, depends on the mandate of the HTA agency: some agencies officially give guidance, while some just summarize evidence. Ideally, the legitimate decision-makers make the value-decisions, and thus values and assumptions underlying the assessment should be presented as openly and transparently as possible. The model includes a structure for considering and reporting outcomes of different implementation alternatives to all stakeholders separately. This increases transparency and has proven useful for presenting results to decision-makers.

Detailed presentation is essential for international transferability.

**Discussion**

We have described a model for incorporating ethics into HTA. The work is based on the insight that ethics seen as an “add on” to solve the moral issues of a technology is likely to have little effect on the implementation of the technology. Ethical analysis performed in isolation of the HTA process appears to be too narrow and comes too late. The model addresses and guides the whole HTA process, from planning, through to analysis and to preparations for decision-making, considering all stakeholders. The model is flexible to different HTA settings and easy to use, and can help make assessments more transferable between countries and increase the relevance of HTA to policy-makers.

**Practical relevance of the model**

The first version of the model was published in 2007, and a pilot HTA was carried out in relation to drug-eluting versus bare-metal stents in coronary artery disease. Although more HTAs using the model on different settings are needed, the ethical analysis faced several problems which supported the feasibility and confirmed the key principles of the model. The pilot emphasized the importance of interactive, close and reflective cooperation between ethics and other domains of assessment, which was difficult within an international collaboration. Ethical considerations could not influence the selection of topic (which showed little concern for public-health impact or global perspective in HTA), the formulation of the research questions, or the organization of the whole assessment process.

The “patient-intervention-control-outcome” structure, commonly used to formulate research questions in HTA, applies poorly to ethics. This structure asks for facts that can be analysed in an experimental setting, whereas research questions for ethical analysis are wider and require different types of information, typically the valuation of different qualitative and quantitative issues from different stakeholders’ point-of-view.

Systematic searches of the scientific literature for publications reflecting the ethical or moral implications of the technology are difficult. Few articles discuss the ethics of specific health technologies. This emphasizes the inclusion of sources of information other than scientific papers and the need for an international system of transferable ethical analysis, such as the presented model.

Ethical analysis also challenges traditional HTA methods to assess the validity of collected information. As the data range from randomized controlled trials and qualitative studies to direct focus-group hearings, balancing reliability and validity becomes a challenge. Further, balancing the values and views of different stakeholders always requires normative assessments. Thus, the requirement to be as transparent about the methods of summarizing and reporting the evidence is fundamentally important. A peer review of the ethical analysis not only helps to keep the analysis as neutral as possible, but also increases the commitment of stakeholders to act on the results of the HTA.

As expected, not all of the 16 core questions were relevant, but going through them all helped to identify the relevant ethically problematic areas (in the stent case, especially the widespread off-label-use challenging the autonomy of particularly vulnerable patients.) The model was easy to use and did not require a professional ethicist.

**Is the model internationally transferable?**

A special challenge for HTA is – in accordance with the goals set out in the Ethics of Science and Technology Programme of the United Nations Educational, Scientific and Cultural Organization (UNESCO) – to take the global perspective and needs of the developing world into account.

The model facilitates each of the two theoretical methods for doing this: to make HTAs conducted in developed countries more relevant to other countries, and to encourage local HTA creation by providing a flexible HTA model.

**Table 2. Methods used for ethical analysis in HTA**

<table>
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<tr>
<th>Method</th>
<th>Description</th>
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<tbody>
<tr>
<td>Casuistry</td>
<td>Solves morally challenging situations by comparing them with relevant and similar cases where an undisputed solution exists</td>
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<tr>
<td>Coherence analysis</td>
<td>Tests the consistency of ethical argumentation, values or theories on different levels, with an ideal goal of a logically coherent set of arguments</td>
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<tr>
<td>Principism</td>
<td>Approaches ethical problems by addressing basic ethical principles, rooted in society’s common morality</td>
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<tr>
<td>Interactive, participatory HTA approaches</td>
<td>Involves different stakeholders in a real discourse, to reduce bias and improve the validity and applicability of the HTA</td>
</tr>
<tr>
<td>Social shaping of technology</td>
<td>Addresses the interaction between society and technology and emphasizes how to shape technology in the best ways to benefit people</td>
</tr>
<tr>
<td>Wide reflective equilibrium</td>
<td>Aims at a coherent conclusion by a process of reflective mutual adjustment among general principles and particular judgements</td>
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HTA, health technology assessment.
Analyse éthique pour l’aide à la décision à propos des technologies de santé

L’évaluation des technologies de santé (ETS) est l’étude multidisciplinaire des implications du développement, de la diffusion et de la mise en œuvre de ces technologies. Elle étaye les décisions de politique sanitaire en fournissant aux décideurs une base de connaissances associée. Pour être plus utile encore aux décideurs politiques, l’ETS s’efforce de prendre en compte, outre l’efficacité et les coûts des technologies de santé, leurs implications sociales, organisationnelles et éthiques. Il manque néanmoins une méthode communément acceptée pour analyser les aspects éthiques de ces technologies.

Cet article présente un modèle d’analyse éthique pour les technologies de santé, d’un emploi à la fois facile et flexible dans des contextes organisationnels et culturels divers. Ce modèle fait partie du projet EUneHHTA, axé sur les possibilités de transfert de l’ETS entre pays.

Le principe à la base du modèle éthique EUneHHTA est que l’ensemble du processus ETS est chargé de valeur. Il ne suffit pas d’analyser les conséquences éthiques d’une technologie, il faut aussi envisager les aspects éthiques de la totalité du processus ETS la concernant. Le choix des thèmes, des méthodes et des

Résumé

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L’évaluation des technologies de santé (ETS) est l’étude multidisciplinaire des implications du développement, de la diffusion et de la mise en œuvre de ces technologies. Elle étaye les décisions de politique sanitaire en fournissant aux décideurs une base de connaissances associée. Pour être plus utile encore aux décideurs politiques, l’ETS s’efforce de prendre en compte, outre l’efficacité et les coûts des technologies de santé, leurs implications sociales, organisationnelles et éthiques. Il manque néanmoins une méthode communément acceptée pour analyser les aspects éthiques de ces technologies.
La evaluación de tecnologías sanitarias (ETS) es el estudio multidisciplinario de las implicaciones del desarrollo, difusión y uso de las tecnologías de la salud. Proporcionando un acervo común de conocimientos a las instancias decisorias, la ETS permite fundamentar las decisiones de política sanitaria. Para revelar una mayor pertinencia normativa, la ETS extiende su ámbito de acción más allá de la eficacia y los costos para considerar también las implicaciones sociales, organizacionales y éticas de las tecnologías. Sin embargo, falta un método corrientemente aceptado de análisis de los aspectos éticos de las tecnologías sanitarias.

En este artículo se describe un modelo de análisis ético de esas tecnologías que posee la usabilidad y flexibilidad necesarias para poder ser aplicado en distintos entornos institucionales y culturales. El modelo forma parte del proyecto EU netHTA, centrado en la transferibilidad de las ETS entre países.

El modelo ético de EU netHTA se basa en la idea de que el proceso de ETS está orientado por valores. No basta con analizar las consecuencias éticas de una tecnología, pues hay que considerar también las cuestiones éticas asociadas a todo el proceso de ETS. La selección de los temas, los métodos y los resultados de la evaluación es fundamentalmente una decisión orientada por valores. Las tecnologías sanitarias pueden poner a prueba los valores y creencias morales o culturales, y su aplicación puede tener también importantes repercusiones en otras personas aparte del paciente, y esas consideraciones son esenciales para las políticas sanitarias. El modelo ético se ha articulado a partir de cuestiones éticas clave más que de teorías filosóficas, para que pueda aplicarse a culturas diferentes y ser utilizado por no filósofos.

La integración de las consideraciones éticas en la ETS puede mejorar la pertinencia de las evaluaciones de la tecnología para la atención de salud y las políticas sanitarias tanto en los países desarrollados como en los países en desarrollo.

References

Malخص

التحليل الأخلاقي لتحسين اتخاذ القرار بشأن التكنولوجيات الصحية

مثلاً تقييم التكنولوجيا الصحية، دراسة معتقدات الاختصاصات لأثر تطور التكنولوجيا الصحية، ونتيجة، واستخدامها. وهو يدعم القرارات الخاصة بالسياسات الصحية من خلال توفير معرفة مشتركة للاختيار، ووازادة ارتباط تقييم التكنولوجيا الصحية بالممارس، وتسوية الخلافات الاستثنائية، وثمة تحتاج إلى طرق عامة مقبولة لتحليل الأخلاقية الفنية، يجب أن تكون معقدة، كما أن تنفيذها قد يكون له أكبر تأثير على السياسات الأخلاقية أخرى.

لا يكفي الاقتصار على تحليل العواقب الأخلاقية للتكنولوجيا، وإنما ينبغي التفكير في مدى التأثير الاجتماعي، والتنظيمي، والتكنولوجي، يجب أن تكون معقدة، كما أن تنفيذها قد يكون له أكبر تأثير على السياسات الأخلاقية أخرى.

هذة الورقة البحثية تكشف عن نموذج تقييم التكنولوجيا الصحية يُمكنه تحسين ملاءمة تقييم التكنولوجيا الصحية والسياسات الصحية في البلدان المتقدمة والمتأخرة على حد سواء.
Special theme – Ethics and public health

Integrating ethical analysis in health technology assessment


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Samuli I Saarni et al.


