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Published version:

Ekmekci, P., & Güner, M. (2019). Evaluation of Ethical Analyses in Seven Reports from the European Network for Health Technology Assessment. *International Journal of Technology Assessment in Health Care*, 35(4), 273-279. doi:10.1017/S0266462319000485

Health Technology Assessment (HTA) and Ethics: An Evaluation of Ethical Analyses in HTA Reports

Abstract

Ethics have been considered among the core domains of health technology assessment (HTA). However, there are still disputes regarding ethical analysis. Methodology has been an important issue for ethical analysis in HTA, since it is fundamental to determining the quality, transparency, objectivity, and transferability of HTA reports. There are still gaps in understanding how to frame and standardise methodology, and identify and avoid errors in the process. The European Network for Health Technology Assessment (EUnetHTA) has been developing methodology guidelines for HTA teams. The latest version is HTA Core Model version 3.0. The ethical analysis sections of HTA reports are reflections of the use of the model. Considering the lack of consensus on methodology for ethical analysis in HTA, the ethical dimension of HTA reports is a good example of how a methodological frame such as the EUnetHTA Model would work for ethical analysis. This study examines full final reports of EUnetHTA in terms of four criteria and evaluates their compliance with the ethical methodology and ethical perspective of the Model. The results show that although the Model was helpful for standardising the final reports of the assessment, there are still problems regarding the competency of the ethical analysis team, the perspectives on the purpose of ethical analysis, data sources and involvement of viewpoints of various stakeholders, use of ethical analysis methodology, and evaluation of ethical appropriateness of the entire HTA process.

Key Words: Health technology assessment, ethical analysis, ethical methodology, ethical expertise

Introduction

The concept of technology assessment (TA) was first introduced in 1960s as a consequence of an increasing role of technology in daily life. The extension of TA to health-related issues did not take long, since technology started to play a crucial role in the health sector. Major technological advances such as in vitro fertilization, intrauterine gender determination, anti-aging interventions, organ transplantations, genetic treatments, life sustaining interventions and stem cells have created the possibility to change medical practice dramatically. Hence, a branch of TA focusing directly on health emerged: health technology assessment (HTA). Today, an intervention to be used to promote health, prevent, diagnose, treat or rehabilitate disease, is considered a health technology. Health technologies include pharmaceuticals, medical devices, procedures, and organizational systems used in health care (1).

Several HTA institutions have been established worldwide (Table 1). Some of these institutions are national, while others are global or regional agencies. Global or regional agencies aim at providing a platform for developing and exchanging information and methodology for HTA (2).

Table 1: Global/regional institutions for HTA

European Agency for the Evaluation of Medicinal Products (EMA)
European Network for Health Technology Assessment (EUnetHTA)
European Observatory on Health Systems and Policies
EuroScan-International Information Network on New and Changing Health Technologies
International Network of Agencies for Health Technology Assessments (INAHTA)
WHO/Europe-Health Evidence Network (HEN)

Ethics has been considered as one of the essential elements of HTA. The ethical considerations of a technology emerge mainly from unpredicted, unknown or unwanted consequences of using that technology. The main issue is that the use of a technology, such as genetic testing, stem cell research, or allocation of scarce resources for life support systems in terminally ill, might challenge some ethical, religious, cultural or legal norms (3). Heitman argued (4) that ethical issues in HTA "...could be grouped into broad categories of normative concepts, diagnosis, prevention and therapy, research and the advancement of knowledge, and allocation of resources, ... evaluated in terms of the integrity of the project's goals, procedures, and effects, and evaluators' open and self-critical acknowledgment of their purposes".

Although ethics is considered among the core domains of HTA, there are still disputes regarding ethical analysis (EA) in HTA. Until recently, most HTA reports either did not involve EA, or include any mention of the ethical implications of the HT (5,6).

Methodology has been a significantly important issue for the EA of HTA since it is fundamental to determining the quality, transparency, objectivity, and transferability of HTA reports. There

are still gaps in understanding of how to frame and standardise methodology and identify and avoid errors in the process (7). Although several attempts have been made to develop frameworks for EA in HTA, no agreement has been reached regarding aims, scope, philosophical approach, structure, and comprehensiveness. There are deep disputes over choice of data resources and the analysis of ethical data (8). Studies show that the diversity and complexity of methodology in EA is an important aspect of the problem (9). Lack of consensus on applicable and practical methodologies, and on the scope of EA and confusion regarding who should perform it, have been reasons to avoid inclusion of EA in several HTA reports (10,11,12).

EUnetHTA has been developing methodology guidelines for HTA teams. The latest version is HTA Core Model version 3.0, which was published in 2016 following a grant provided by the European Commission (3).

HTA Core Model 3.0 (the Model) contains a standard set of questions which aim to define the research questions in the HTA within a standard structure. The Model has various applications, each specifically dedicated to assessment of therapeutic, diagnostic or screening HTs, and allows full or rapid assessments, which would lead to either comprehensive evaluation of the HT or a relatively abstract one, respectively. A core HTA is a full analysis of a HT and it should include nine domains of the Model, of which ethics is one. The Model states that the involvement of ethics is not limited to the ethical analysis of the proposed HT, and emphasizes that the ethical aspect should be addressed in a broad sense to cover the values and interest behind the decision to perform the HTA on that particular technology instead of another one. Additionally, the timing of the HTA, the interests of the HTA team, the choice and implementation of methodology, and the interpretation of results, are value laden aspects to be considered in an ethical frame in the field of HTA. The Model lists the ethical issues to be considered before starting the assessment, while gathering the assessment team, during the assessment, and in writing up the final report (3).

The Model involves nine domains:

1. Health problem and current use of technology (CUR)
2. Description and technical characteristics of technology (TEC)
3. Safety (SAF)
4. Clinical effectiveness (EFF)
5. Costs and economic evaluation (ECO)
6. Ethical analysis (ETH)
7. Organizational aspects (ORG)
8. Patient and Social aspects (SOC)
9. Legal aspects (LEG)

The topics in the ethical analysis domain are: benefit-harm balance, autonomy, respect for persons, justice and equity, and ethical consequences of HTA. Each topic contains several issues focusing on specific questions (Table 2).

Table 2: Topics and issues for the ethical analyses domain of the HTA core Model

Topics	Issues
Benefit-harm balance	What are the symptoms and the burden of disease or the health condition for the patient?
	What are the known and estimated benefits and harms for patients when implementing or not implementing the technology?
	What are the benefits and harms of the technology for relatives, other patients, organisations, commercial entities, society, etc.?
	Are there any other hidden or unintended consequences of the technology and its applications for patients/users, relatives, other patients, organisations, commercial entities, society etc.?
	Are there any ethical obstacles to evidence generation regarding the benefits and harms of the intervention?
Autonomy	Is the technology used for individuals that are especially vulnerable?
	Does the implementation or use of the technology affect the patient's capability and possibility to exercise autonomy?
	Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used?
	Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles?
Respect for persons	Does the implementation or use of the technology affect human dignity?
	Does the implementation or use of the technology affect the patient's moral, religious or cultural integrity?
	Does the technology invade the sphere of privacy of the patient/user?
Justice and equity	How does implementation or withdrawal of the technology affect the distribution of health care resources?
	How are technologies with similar ethical issues treated in the health care system?
	Are there factors that could prevent a group or person from gaining access to the technology?

Legislation	Does the implementation or use of the technology affect the realisation of basic human rights?
	Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations?
Ethical consequences of the HTA	What are the ethical consequences of the choice of endpoints, cut-off values, and comparators/controls in the assessment?
	Are there any ethical problems related to the data or the assumptions in the economic evaluation?
	What are the ethical consequences of conducting the technology assessment at this point of time?

In the Model it is recommended that there should be a designated person to facilitate and report ethical analysis and it is *preferable* that this person is an ethics expert. However, it is stated that more importantly, scientific and clinical experts should be included in ethical analysis (3).

Casuistry, coherence analysis, interactive participatory HTA approach, principlism, social shaping of technology, wide reflective equilibrium, a triangular model based on the human-person centred approach, and an axiological approach are listed as the main methodologies for HTA ethical analysis. These are the methodological approaches which were identified by INAHTA and supplemented by EUnetHTA working groups (Table #).

EUnetHTA has been publishing HTA reports which use the proposed methodology. Hence the EA sections of these reports are reflections of the use of the Model. Considering the lack of consensus on methodology for EA in HTA, the ethical dimension of HTA reports is a good example of how a methodology frame would work for EA.

This study examines full final reports of EUnetHTA and evaluates their ethical analysis sections' compliance with the ethical methodology and ethical perspective of the Model. The aim of the study is to determine and discuss the pitfalls of the ethical analysis performed in the published reports.

Methodology

This study examines full HTA reports from EUnetHTA. Although there are several HTA reports published by various agencies worldwide, only reports from EUnetHTA are included in the study. There are three reasons for this: (1) EUnetHTA is an umbrella agency that pursues quality, transparency, transferability, and objectivity in HTA and hence, reports produced by EUnetHTA might be considered to be prepared with a high level of attainable standards; (2) EUnetHTA reports are published on-line systematically, which makes it possible to access the necessary data for the study; (3) EUnetHTA reports have EA sections written using the methodology proposed in the Model.

In the “assessment” section of official web site of EUnetHTA, there are assessment reports of EUnetHTA JA3 (2016-2020), EUnetHTA JA2 (2012-2015), EUnetHTA JA1 (2010 – 2012), and EUnetHTA Project (2006 – 2008). Among these, seven are full HTA reports with final reports (13). Two of the assessments were done in the EUnetHTA 2006-2008 period, two were done in the EUnetHTA JA1 2010-2012 period, and three were done in the EUnetHTA JA2 2012-2015 period (Table 3). All rapid assessments were excluded from the study regardless of the year they were produced.

Table 3: Full Health Technology Assessments included in the study

EUnetHTA Program Year	Name of the HTA	Publication year	Intended use of technology	Target population condition, sex, age and breadth
EUnetHTA 2006-2008	1. Core HTA on MSCT Angiography	2008	Diagnosis	Not specified
	2. Core HTA on Drug Eluting Stents	2008	Treatment	Not specified
EUnetHTA JA1 2010-2012	3. Abdominal Aorta Aneurysm Screening (AAA)	2013	Screening	Elderly Any sex
	4. Prognostic tests for breast cancer recurrence (PTBCR)	2013	Diagnosis and treatment	Any age Females
EUnetHTA JA2 Full/Comprehensive assessments 2012-2015	5. Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening. (Core HTA 1)	2014	Screening	Adults and elderly Any sex
	6. Use of Intravenous immunoglobulins for Alzheimer’s disease including Mild Cognitive Impairment. (Core HTA 2)	2015	Treatment	Elderly Any sex

	7. Structured telephone support (STS) for adult patients with chronic heart failure. (Core HTA 3)	2015	Prevention	Adults and elderly Any sex
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These seven reports were included in the study and were read and analysed in accordance with the following parameters:

1. Competency of the person/group who conducted EA: The competency of the person/group who conducted EA is evaluated based on their training and expertise in ethics. The term ethical expertise is used in terms of epistemic expertise which refers to those whose expertise is a function of what they know (14). Hence, to consider the EA team competent for doing EA, there should be evidence that these people had adequate training to be able to perform a logically consistent EA by using any of the methodologies listed in the Model. The curricula vitae of analysts were examined to see if they had particular training to enable them to do the EA task. Their work experience was also evaluated since considerable expertise can be gained by hands-on training. The analysts were considered competent if they had a masters or doctoral degree in ethics or if they had any evidence of training or job experience to demonstrate their familiarity with ethical analysis and the relevant methodology. The team was considered competent if there was one person in the team with the defined qualifications.
2. Focus or aim of EA: Although the Model does not require the analysts to specify the focus or the aim of the EA section, most reports contain this part. When the reports were examined it was noticed that the focus or aims of the EA sections were quite diverse. Hence, it was considered that assessing the reports for this criterion would reveal important results regarding the perspectives of the EA team regarding their task, which would definitely have an impact on the scope and content of the EA they perform.
3. Assessment elements: The assessment elements have changed with the implementation of the Model. Hence, while the HTA reports after 2016 contain standard assessment elements, the ones produced before the initiation of the Model have some significant variations, which might becloud the analysis. With regards to this, the assessment element questions for two HTA reports, which did not provide assessment elements tables compatible with the Model, were examined carefully. Each question was checked against the standard questions of the Model in terms of their context and implications, and were categorized under the appropriate assessment element.
4. Methodology of EA: the Model suggests using one of the 8 analysis methodologies to perform EA. Moreover, the Model defines the appropriate data resources for each issue in detail. The HTA reports were assessed for the methodologies they used and their data sources.

Results

1. Competency of the person/group who conducted EA: Competency in EA was present in three reports. Two of these reports were published in 2008 and one was published in 2013. The four reports which were published in 2013, 2014 and 2015 did not include any ethical experts in their EA team.

2. Focus or aim of EA: The goal of the ethical analysis section of the HTA was not specified in any of the HTA reports, since it is not a particular requirement of the Model. The reports which included statements about the aim or focus of ethical analysis displayed diverse implications. One report addressed the goal of the EA at the level of the core HTA and stated that the aim was to define the framework for the ethical analysis and provide criteria for the application of this framework (15). According to this report the ethical analysis at HTA core level should be considered as “a general framework to guide experts doing HTA at a local level.” There was a report with attribution of a relatively abstract aim for the ethical analysis section: “to highlight the ethical implications of using the HT for the prediction of risk of the target disease.”

In another report it was stated that the ethical analysis section was aimed at “providing a balance between norms and values through the consideration of social, political, cultural, legal, religious, and economic aspects arising from the opposition to the generally accepted environmental values, healthcare system goals, and the application of new technologies” (16), while a different report declared that the focus of the EA section was “to present ethical arguments related to the autonomy and benefits for the patient as well as possible complications and limitations pertaining to the implementation of the health technology discussed, without aiming to give a definite answer or ‘ethical prescription’” (17). Another aim which was specified in the reports was “to gather experiences from a novel way of preparing HTA work, rather than prepare a valid assessment on the particular HT” (18).

3. Assessment elements: Benefit-harm balance and autonomy are the only two topics which were included in all evaluated HTA reports. The justice and equity topic was evaluated in 6 reports where legislation, questions about effectiveness and accuracy, and principle questions about the ethical aspects of technology were addressed in 4 HTA reports. Respect for persons as a topic was addressed only in 2 reports. However, it should be considered that the respect for persons topic includes the similar issues to those within the human dignity and human integrity topics. Hence, a careful examination reveals that the HTA reports which lack the respect for persons topic have covered the same issues under the topics of human dignity and human integrity. The topic “ethical consequences of the HTA”, was covered in only three HTA reports. This is the lowest coverage among the topics which are labelled as core and critically important in the Model.

Regarding specific issues, the section below outlines each issue and provides the percentage of reports that addressed this issue. Issues are coded as F00##.

- F0006: “Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used?” was addressed in 100% (n=7) of reports under the autonomy topic.

- F0005: “Is the technology used for individuals that are especially vulnerable?” and F0007: “Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles?” were addressed in 86% (n=6) of reports under the autonomy topic.
- F0009: “Does the implementation or use of the technology affect the patient’s moral, religious or cultural integrity?” was also addressed in 86% (n=6) of reports either under the respect for persons (n=3), human integrity (n=2), or human dignity (n=1) topics.
- F0012: “How does implementation or withdrawal of the technology affect the distribution of health care resources?” was addressed in 86% (n=6) of reports under two topics: justice and equity (n=5), and ethical consequences of HTA (n=1).

Two issues under the benefit and harm balance topic had not been considered in any of the HTA reports included in this study. These issues were A0005: “What are the symptoms and the burden of disease or health condition for the patient?”, and F0104: “Are there any ethical obstacles to evidence generation regarding the benefits and harms of the intervention?”

Some issues were addressed in more than one topic. For example, F0003: “Are there any other hidden or unintended consequences of the technology and its applications for patients, relatives, other patients, organizations, commercial entities, society etc.?”, and F0001: “Is the technology a new, innovative mode of care, an add-on to or modification of a standard mode of care, or replacement of a standard mode of care?” were addressed under benefit harm balance, and principle questions about the ethical aspects of technology topics. F0012: “How does implementation or withdrawal of the technology affect the distribution of health care resources?” was addressed under the ethical consequences of HTA, and justice and equity topics. The issues which were addressed under more than one topic and their frequency are shown in Table 4 below, with the overall frequency of topics across the reports shown in Table 5

Table 4: Issues addressed under more than one topic, with frequency counts

F0003: Are there any other hidden or unintended consequences of the technology and its applications for patients/users, relatives, other patients, organizations, commercial entities, society etc.?	Beneficence/non-maleficence Principle questions about the ethical aspects of technology	1 2
F0001: Is the technology a new, innovative mode of care, an add-on to, or modification of a standard mode of care, or a replacement of a standard mode of care?	Beneficence/non-maleficence Principle questions about the ethical aspects of technology	1 3
F0008: Does the implementation or use of the technology affect human dignity?	Human dignity Respect for persons	2 1
	Human dignity	1

F0009: Does the implementation or use of the technology affect the patient's moral, religious or cultural integrity?	Human integrity	2
	Respect for persons	3
F0014: Does the implementation or use of the technology affect the realization of basic human rights?	Justice and equity	1
	Legislation	1
	Rights	2
F0012: How does implementation or withdrawal of the technology affect the distribution of health care resources?	Ethical consequences of the HTA	1
	Justice and equity	5
F0017: What are the ethical consequences of the choice of endpoints, cut-off values and comparators/controls in the assessment?	Ethical consequences of the HTA	1
	Questions about effectiveness and accuracy	4

Table 5: Overall frequency of topics involved in HTA reports

Topic	The number of HTA reports the topic is addressed
Benefit harm balance (beneficence/ non-maleficence)	7
Autonomy	7
Respect for persons	2
Justice and equity	6
Ethical consequences of the HTA	3
Legislation	4
Questions about effectiveness and accuracy	4
Principal questions about the ethical aspects of technology	4
Human integrity	3
Rights	2
Human dignity	3

4. Methodology, data sources and quality assessment criteria of EA: 43% (n=3) of evaluated HTA reports used principlism methodology for ethical analysis. Coherence analysis methodology was used in one HTA report. In 3 reports the methodology for ethical analysis was not specified. In these reports data sources were explained in more detail.

One report, which did not specify its methodology, gave relatively detailed information on the implementation of literature review, and the search strategy. In this report the data source contained the results of the literature review and the results of other domains of the HTA. The adopted baseline quality criterion for the quality assessment criteria for this report was inclusion of the Medline Database in the literature review. The report stated that no further quality assessment criteria was applied (19).

In the description of the methodology section of one report, a long information section was included on the innovation to be assessed, how it works, if it is experimental, the object of treatment, and the course of the disease itself, instead of the methodology of the EA (17).

Other reports which did not specify methodologies used for ethical analysis provided *some* information about their data sources. The primary source was literature review and information from “ongoing assessment”. The authors of these reports declared that they left out data from patient’s perspectives on outcomes used in clinical trials due to time and resource limitations, and no assessment of methodological study quality was undertaken (20).

Ironically, in the reports in which ethical analysis methodologies were specified there was none or very limited information regarding the data sources. In one report the data sources were specified as the results of the other domains and literature review. No details about search strategy for the literature review were provided. The other reports with specified methodologies (principlism) provided very limited information about the literature review or gave no information about the data source. Among the HTA reports with specified methodology for ethical analysis, only one mentioned quality assessment, and stated that “quality assessment is not needed, since the goal at the level of the core HTA is only to define the framework for ethical analysis”.

None of the reports used data coming from expert opinions, patient/service user opinions, or the views of organizational stakeholders, while one report extracted core data from Wikipedia (17).

Discussion

The Model states that apart from the EA domain, ethics has a broader application within the HTA process such as being a driving force to do the HTA, morally relevant reasons for performing or not performing HTA on the particular topic, the interests of the producers of the technology, the existence of related technologies that are morally contentious, the interests of the content expert groups, the morally relevant issues related to the selection of meta-analysis, studies to be included or excluded in the HTA, the scope of the HTA and choice of research methods (HTA Core Model 3.0) to identify and evaluate the moral and ethical issues inherent in the entire HTA process. This broad sense of ethics in HTA has also been emphasized by

various groups (10,21,22,23). According to this perspective, evaluating the ethical implications of HT in the EA section of HTA reports is not enough to ensure that the HT and HTA procedure itself is subjected to systematic ethical analysis. Annex 3 of the Model provides a comprehensive list of ethical concerns to ensure the ethical appropriateness of the HTA process in the broad sense. However, since these concerns are not transferred into issues to be answered in the ethics domain, they remain as good intentions and do not have any impact on the EA section or the HTA as a whole. Accordingly, the reports which were included in this study lacked this broad sense of ethics and did not address any of the ethical concerns listed above. Instead, ethics was limited to the EA section, and to finding answers to issues listed in the topics. Hence it is plausible to say the existing HTA reports fail to address the ethical compliance of the HTA procedure as well as the inherent values for the HT itself.

The inclusion of benefit and harm balance and autonomy topics to all evaluated reports shows that the assessors thought that these two are the most important ethical issues for which HTs might encounter risk. It is obvious that applying the Model has a positive effect on standardisation of reports and avoiding exclusion of core topics to be considered in the ethical domain. The flexibility of the Model helps the assessors to adapt the methodology to the requirements of the HT in question. However, the phrasing of issues and analysis of them propose a consequentialist approach which prioritises the possible impacts of the HT rather than the ethical implications of the HT itself. Moreover, the analysis of most ethical issues generally lacks a theoretical frame, and reveal an eclectic approach, which makes it harder for the reader to follow the ethical reasoning and justification of the report.

The question of what kind of expertise is required to perform EA has been discussed widely. Some authors oppose the possibility of ethical expertise based on several arguments. These arguments put forth that expertise in ethics is a fallacy because: a) there are no criteria to distinguish ethical experts from non-experts; b) no-one has special access to knowledge about what is wrong or right; c) ethicists disagree with each other so frequently and so radically that it creates suspicion about their competency; d) ethical statements are essentially metaphysical and objective ethical justifiability is doubtful since no final proof or disproof exists (14,24,25,26). These objections to the possibility of ethical expertise are enriched by additional arguments to exclude ethics from HTA by proving the dissonance between ethics and other domains of HTA. This involves the following arguments: a) the aim, methodology and models of rationality of HTA and ethics are categorically different; b) there is no agreement on the methodology of EA; c) other domains such as law, economics and sociology cover ethical issues; d) ethics is not as involved as much in HT as it is thought to be (27).

Lack of familiarity with the complex philosophical theories and ethical reasoning, and lack of expertise in understanding ethical justification methods have been cited as amongst the most important barriers to include comprehensive EA in HTA (9). On the other hand, an international survey revealed that 68% of HTA professionals thought positively of the importance of EA and 60.8% thought that at least one of the HTA experts should have formal training in ethics, and in cases where no ethics expert with formal training was available, then 78.4% of respondents thought that a professional ethicist should do the EA as an external consultant (12). The Model seems to agree with the redundancy of ethics experts in HTA by stating that the role of an ethics

expert is to facilitate and report the EA, not to perform the EA, and that involvement of scientific and clinical experts in the EA are more important (3).

The reluctance to involving ethical experts in the HTA report teams of the reports which were evaluated in this study is in agreement with the Model's perspective. The results of the study show that ethical expertise is disregarded since only three of the evaluated reports had ethics experts in their team for the EA domain. It was also interesting to see that in two HTA reports only one person did the EA and that person lacked ethical expertise. The lack of expertise had some explicit indicators. In some reports the answers to questions were not relevant to ethical concerns relating to the issue, or very abstract and too simple to provide a comprehensive perspective. The eclectic style of answers suggests that no systematic ethical reasoning was applied. Instead, the data from sketchy literature reviews are browsed by EA teams to support their ideas, or the results of other domains are cited. In some reports very fundamental issues such as the risks to fundamental human rights and human integrity are suggested to be assessed in the legal domain. A frequent attitude of the EA sections of HTA reports was to address ethical questions with regard to the consequences of implementing or not implementing a HT, not with regard to the technology itself.

The purpose or focus of EA in a HTA is: a) to make the HTA more efficient by addressing moral and normative issues crucial for dissemination of the HT; b) to discuss and reveal the morally relevant consequences of the HT by integrating perspectives of various stakeholders - patients' most importantly (6,28); c) to highlight the challenges to basic moral principles which are not specific to the HT in question, but are made topical by the development of the technology in general. For example, while doing EA for a HT developed for colon cancer screening, the EA should provide ethical justification for public screening techniques in general (5); d) to discuss those values which constitute the frame of the issues that the HT aims to solve, and solutions it suggests with particular attention to socially interfering implications (5). However, as stated in the results section, the purposes stated in the HTA reports which were evaluated in this study mentioned were different to these. The incongruities in the focus or aims of the reports might be a result of lack of knowledge about what ethical analysis is and how it is done. As is seen in the reports, the EA teams were not sure what their task was aiming towards. Hence very divergent targets were set: some wanted to provide a balance between norms and values through discussion of social, political, cultural, legal, religious, and economic issues arising from the opposition to the generally accepted societal values, healthcare system goals, and the application of new technologies, while others aimed to inform only which questions are to be answered and to propose how this might be done in the local context. The latter approach is in fact the purpose of specified in the Model and the task of the EA team is to perform the EA, not to provide additional frames.

Similar problems were explicit in the data resources. The EA sections of the reports deliver general ideas about the HT in question and the data for these general ideas are either obtained from other domains of the assessment, or by literature review which is mostly limited to PubMed. The search strategies are usually unspecified which implies that the data used for any justification is not based on a comprehensive and valid systematic review. It is suggested in the model that when doing a literature review for EA, the ethical implications of similar

technologies should be considered. Moreover, the various viewpoints of stakeholders should be acknowledged and weighed appropriately and transparently in the whole EA, and “a philosophical technique like deductive reasoning should be used to test the logic and coherence of arguments from the different viewpoints of stakeholders” (3). These features were lacking in most HTA reports which may confound the data inputted for EA. For a strong ethical justification, the premises should be based on valid data. It was very surprising that one of the HTA reports extracted target population breadth data from Wikipedia, which raises serious concerns about the responsible and scientific conduct of data gathering (17). Moreover, the accuracy in choosing key words, databases and of the overall search strategy plays a crucial role in the validity and sufficiency of the EA. The Model attaches importance to data resources and defines a variety of data sources which would bring all relevant data into the discussion. However, the results of this study show that the various sources suggested by the Model are not appreciated by the EA teams in the assessed reports.

The methodologies suggested by the Model require competency in ethics. Epistemic expertise in ethics is defined as “the capacity to provide strong justifications for claims in an ethics domain” (14). Developing strong ethical justifications require knowledge about systematic ethical reasoning. In ethical discourse, justification means “to establish one’s case by presenting sufficient grounds”, without making logical mistakes such as asserting reasons which don’t support the conclusion, reasons developed by relying on data that is not valid, or insufficient reasons to reach the suggested conclusion. Moreover, the ethical analyst should have the knowledge and application skills in several models of justification. These models are: 1) a top-down perspective, meaning to be able to operate justification deductively, developing a claim from a set of premises; 2) bottom-up models which depend on inductively proceeding justification starting from paradigm cases known as casuistry; 3) integrated models such as coherence analysis or reflective equilibrium; or 4) common-morality theory or principlism (29).

It is difficult to believe that a team of experts without epistemic and performative expertise in ethical justification methodologies can perform sufficient and meaningful EA for a HT, and be able to identify and evaluate the ethical issues inherent to the whole HTA process, whilst addressing competing ethical considerations systematically. The results of the study support this statement. When we look at the methodology section of the EAs, we see that either methodology is not specified, or the term methodology is itself misused, being synonymous to data resources. The methodology of EA—if specified—is frequently principlism. Lack of details about the implementation of the methodologies creates suspicions regarding how appropriately they are operated.

Some of the methodologies suggested in the Model such as social shaping of technology (SST) or, a triangular model based on the human-person centred approach, require deeper philosophical knowledge regarding the intellectual dilemmas in the field. SST concentrates on the content of the technology to bring a broader perspective by integrating natural and social science concerns. The essence of SST depends on the discussion of the invalidity of technological determinism (30,31,32,33). The triangular model based on the human-person centred approach evaluates HT through a cycle of interviews with all relevant stakeholders to reveal their concerns about the HT, and to aim to identify the issues on which agreement and

disagreement is explicit to ease the decision-making process for the authorities (34). It is beyond doubt that these methodologies require more expertise and resources than analytical methods like principlism and might bring broader and divergent perspective to HTA. However, none of these methodologies are used in the reports included in this study.

Conclusion

The problems regarding ethics in HTA remain. Developing a core methodology frame would help to standardise the HTA process and enhance quality, transferability, and comprehensiveness of the entire HTA. The HTA Core Model is a generic methodology model that has appropriate flexibility for assessment of various HTs, with divergent ethical and scientific implications. However, the reports which were produced using the Model show that problems in the ethical aspects remain. Although the Model was helpful in standardising the final reports on the HTA, there are issues in the content and outcomes. Despite the fact that the ethical sense of the Model is well enough defined to embrace ethical concerns regarding the entire HTA as well as the specific EA section, some of the existing problems might result from insufficiency. For example, incorporating the ethical concerns of Annex 3 into a concrete list that should be checked before, during and at the end of HTA process, might avoid exclusion of ethical issues inherent to the HTA process. Further research is required to determine the pitfalls and to further advance the Model. On the other hand, the construction and content of the Model might not be the sole and primary reason for the problems discussed above. The issues of lack of expertise in ethics, and insufficiency of the teams for EA, have been referred to as major problems for ethics in HTA by a significant number of researchers. It is possible that this is the reason for the problems which were determined from the assessment of the HTA reports in this study. It is plausible to suggest that we need more professionals with adequate knowledge and experience to operate effective EA. Moreover, it is once more explicit from this study that stakeholder viewpoints in general, and patient perspectives in particular, have been overlooked in the HTA process. This is an important omission, since it represents a flaw in the data input for EA and the entire HTA process.

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