ADDRESSING ETHICAL AND MORAL ISSUES IN HEALTH TECHNOLOGY ASSESSMENT: DEVELOPMENT OF A PRACTICAL FRAMEWORK

Report to the Canadian Centre for Ethics and Corporate Policy Graduate Award Committee

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Contents

Executive Summary

In response to the increasing demand for expansion of health technology assessment (HTA) methodology to include ethical issues more systematically, this document reports on a multi-stage study that aimed at construction of a new practical framework for integration of ethical issues in HTA.

The document is divided into three major parts. The first part provides the results of a systematic review of literature that was performed to identify and compare the scope and details of previously proposed frameworks for ethical considerations in HTA. Of the 1390 potential citations that were identified during the systematic search, 21 frameworks met the inclusion criteria and were included in the review. The identified frameworks varied in their philosophical approach, structure, and comprehensiveness. The review showed that ethical frameworks for HTA had been designed for different purposes throughout the HTA process. These purposes ranged from helping HTA producers in identification, appraisal and analysis of ethical data to supporting decision-makers in making better informed value-sensitive decisions. They frequently promoted combining normative reflection with descriptive approaches to the analysis of values and preferences of potential stakeholders and other societal or technical actors. The reviewed frameworks proposed a wide range of analytical methods including: principlism, casuistry, coherence analysis, wide reflective equilibrium, value analysis, eclectic approach, triangular model, complexity theory, actor-network theory, and social shaping of technology.

The second part of the report describes the results of an exploratory survey that was performed to learn about current practices, motivations and challenges in including ethical considerations in HTA. Directors or representatives of 26 HTA agencies around the world completed our online survey questionnaire. The results showed that close to 90% of the HTA agencies assigned some level of priority to inclusion of ethical considerations in HTA. However, a relatively small proportion of them incorporated relevant ethical analysis methods in their assessments. More than a quarter of the responding agencies were not aware of any guidance documents for addressing ethical issues or found the existing guidelines and frameworks not useful. The lack of practical guidelines and complexity of the existing frameworks were the most commonly stated barriers; and the availability of well-designed frameworks or guidelines was considered as a key motivator by the respondents.

The third part outlines a new stepwise framework that has been developed to help facilitate a consistent and efficient ethical evaluation process for the assessment of healthcare technologies. The proposed framework guides HTA practitioners through seven main steps: defining the objectives and scope of the assessment, recognizing potentially relevant ethical problems, designing the evaluation, defining key requirements, data collection, processing and analysis of data, and knowledge translation.

The report concludes that despite the growing recognition of the importance of ethical considerations in HTA, no guidance document is currently available that includes sufficient operational guidelines to help HTA practitioners in adopting appropriate ethical assessment approaches. The framework that has been presented here can be regarded as a starting point towards a set of comprehensive strategic guidelines and the supporting instrumentation for integrating ethics in HTA. Further improvements are expected with the ongoing refinement of the framework and adding flow charts, auxiliary tools or checklists to facilitate the ethical evaluation process. The practical application of the framework will be tested through application in various HTA projects.

Introduction

Health technology assessment (HTA) is defined as a multidisciplinary process of studying the medical, social, ethical and economic implications of development, diffusion and use of a particular health technology.[1] HTAs can be less useful for decision making if they fail to systematically and objectively consider the ethical issues that might lead to different decisions, or if they do not represent moral values that may have an impact on dissemination and implementation of new health technologies.[2]

 Although ethical assessment is listed as one of the purposes of HTA, priority setting and policy-making for new heath technologies in most jurisdictions, including Canada, relies mainly on the assessment of clinical- and cost-effectiveness, and ethical considerations around the technology are usually absent or poorly addressed in the majority of HTA reports. Different reasons have been stated in the literature for the limited consideration of ethical issues in HTA practice including: diversity of the available methodologies and lack of consensus on a practical method,[3,4] limited information on the appropriate scope and level of details of an ethical analysis in HTA,[4,5] attitudes of HTA professionals toward ethical assessment,[3] and uncertainties around the role of ethics expertise in HTA.[5,6]

This research work was motivated by the increasing demand for expansion of the HTA methodology to include ethics-related issues more systematically and aimed to develop a framework that provides a more practical format for HTA-producers, especially those who are not accustomed to perform ethical evaluations. This research was conducted in multiple phases, each one building on the findings of the previous phase. We started from a systematic review of the literature to identify existing guidance documents for ethics in HTA in order to provide an overview of their methodological features. We then evaluated theattitudes and practices of major HTA organizations throughout the world towards the use of such frameworks. This phase of the research also aimed at exploring potential enablers and barriers that might influence incorporation of ethical issues in the reports produced by the HTA agencies. Finally, a new framework was refined, using previously identified frameworks and the results of the survey, through discussions with experts in the HTA and ethics fields.

More detailed descriptions of the methods used in different phases of this study are described in the relevant sections to follow.

1. Systematic review of methodological guidance for evaluation of ethical considerations in health technology assessment

1.1 Objectives

The objective of this systematic review wasto identify the existing guidance documents for the ethical appraisal of health technologies and to provide an overview of their methodological characteristics.

1.2 Methods

A systematic search of the literature was performed, without limits of time and language, through the following bibliographic databases, to identify the guidance documents or practical frameworks published up to June 1st 2013: Ovid Medline, EMBASE, PsycINFO. PubMed, Wiley's Cochrane Library, and the Centre for Reviews and Dissemination's HTA database. Additionally, grey literature was identified by searching the websites of selected HTA agencies and hand searching of the bibliographies of selected articles.

Methodological articles providing formal conceptual or practical frameworks, models, or tools for dealing with ethical aspects of health technologies were selected for the review. Citations that primarily offered a theoretical discussion or comments on if and why ethics should be included in HTA, andthose that provided ethical frameworks for assessment of non-healthcare technologies (e.g. information technology) or for purposes other than HTA were excluded. Two independent reviewers screened titles and abstracts of all articles to exclude those that clearly did not match the inclusion criteria. The remaining articles were retrieved in full text form and assessed for eligibility by one reviewer and checked by a second. Disagreements were resolved by consensus.

A thematic analysis of data was performed to identify common themes or methodological considerations. The included frameworks were further evaluated for their stage of application in HTA, theoretical foundation, ethical issues requiring consideration, and methodological approaches for collection, appraisal, synthesis, or interpretation of ethical data. Data were also abstracted on practical tools provided to help addressing ethical issues, case studies presented to facilitate understanding of the suggested approach or model in practice, and resources required for ethical analysis.

1.3Results

A total of 1390 potential citations were identified through the systematic search, of which 1262 citations were excluded after title and abstract review leaving 128 citations for the full text assessment. A further 107 articles were eliminated during the full text review.This process resulted in a total of 21 frameworks being included in this review. Figure 1 shows the detailed study selection process.

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┌──────────────────┐     ┌──────────────────┐     ┌──────────────────┐     ┌──────────────────┐
│ 1847 citations   │────▶│ 1390 citations   │────▶│ 1390 titles and  │────▶│ 1262 citations   │
│ identified through│     │ after duplicates │     │ abstracts screened│     │ excluded         │
│ database search  │     │ removed          │     │                  │     │                  │
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107 full-text articles excluded:
HTA guidelines
Not a guidance document or a practical framework(39)
HTA-related frameworks or guidelines with no ethics component (24)
Ethical guidelines or frameworks not related to HTA (7)
Systematic or qualitative reviews (9)
Duplicate publications (4)
unable to translate (2)

31 additional citations identified through other sources

128 full-text articles assessed for eligibility
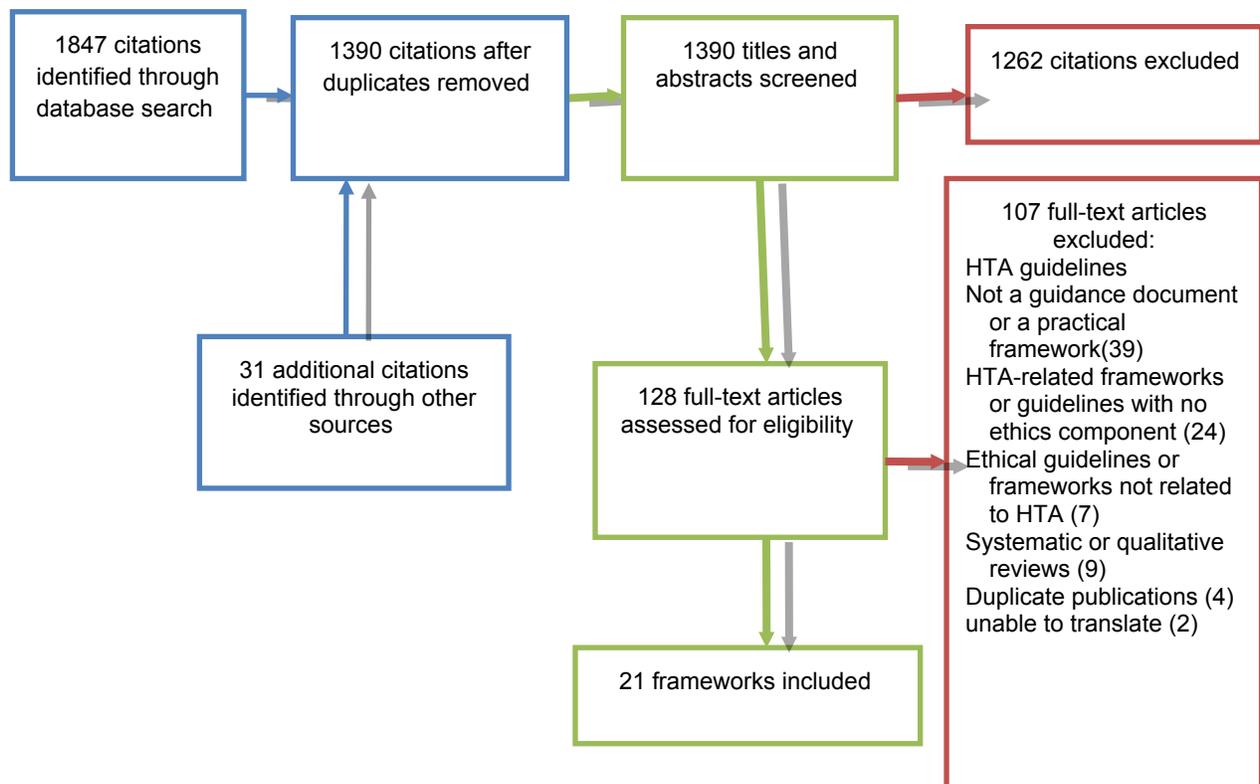
21 frameworks included

Figure1- Study selection flow diagram

All of the included articles were published in English, between 1999 and 2012, suggesting either a generic approach applicable to all health technologies,[2,6-21] or a methodological approach that could be used in the context of a specific group of technologies.[22-25]Through a thematic analysis, we found three general approaches to assessment of ethical issues: (I) reflection through ethical principles and theories (classical methods), (II) supplementing classical methods with participatory and interactive approaches, and (III) providing pragmatic tools for collection and synthesis of ethical evidence or for discussion of ethical data in decision-making.

In order to identify ethical theories that were used as foundations for development of the included frameworks or models, we looked for four types of ethical theories: consequentialist ethics (which

focuses on consequences of an choice or an action), deontological ethics (which focuses on duties, rules and obligations), virtue ethics (which emphasizes moral character and virtues of individuals), and feminism perspectives (that are concerned about the context, power balance in decision-making, and individual situations).[26] Notably, the majority of the authors either implicitly or explicitly pursued a pluralistic approach to explain their conceptual or procedural frameworks, instead of using a single moral theory.

A wide range of ethical areas were identified by the included frameworks to be relevant to HTA, including: benefit and harm (safety),[8,9,14,18,22-24] autonomy,[9,14,18,22-24] equity (fairness or distributive justice),[7-9,13,14,21] stakeholder values,[6,12-14,16-19,21,25] utility,[8,14] acceptability,[11,21,24] psychological impact,[11,14,21] impact on family and care-givers,[14,21,23] quality of life,[9,23] efficiency,[8] opportunity cost,[8,21] and ethical issues related to appropriateness of methods chosen for economic evaluations.[2,14]

Procedures proposed for ethical analysis

The details of the analytical procedures proposed for ethical reasoning are summarized inTable 1. As shown, some frameworks provided practical tools for HTA-producers to evaluate and report ethical and other aspects of healthcare technologies in a structured manner. These tools included eclectic checklists consisting of generic or context-sensitive ethical questions as road maps for ethical reflections,[7,14,23] ethical matrices to facilitate ethical analysis, and multi-criteria decision tools to assist HTA decisions.[8,20]Some frameworks stressed the integration of quantitative and qualitative data for the purpose of ethical analysis.[12,15,18]

Stakeholder engagement

Around 60% of the selected frameworks emphasized the need for assessment of ethical aspects through stakeholder involvement or a broader social discourse.[2,6,10-14,16-21,25] The proposed participatory models were categorized thematically, based on the level of stakeholder engagement, to the following types: (a) *consultative models*[2,10,12-14,20,21,25] in which a range of relevant stakeholders are contacted in order to learn about their personal and societal values and to obtain their concerns about the technology, alternatives and the impact of potential decisions; (b) *interactive models*[6,17-19] that involve experts, stakeholders and citizens in a deliberative process in order to identify, discuss and reflect on the ethical aspects of technology; and (c) *constructive models*[11,16] that emphasize a mutual influence of technology and society, and argue that in order to have an impact on the design of the technology, public engagement should take place early in the development process. Consultative methods seek information from stakeholders as

inputs for the ethical analysis or decision-making process, whereas interactive or constructive models are more participative and are based on argumentation, public reasoning and agreement.

The following participatory techniques were introduced forthe collection of primary data on stakeholders' values and behaviours. These included: awareness initiatives,[11] social controlled experiments,[11,16] circle of conversations,[6,18,19] focus group discussions,[18] dialogue workshops,[11] Delphi technique and consensus conferences.[6,11,16]

Table1- Summary of identified procedures for ethical analysis in HTA

Assessment Phase		
Principlism	An approach that promotes the use of four fundamentalprinciples of bioethics: beneficence (responsibility to maximize benefits), non-maleficence(not causing harm), respect for autonomy (respecting the decision-making capacity of individuals), and Justice (equitable distribution of benefits and costs).	18,22-24
Casuistry	A reasoning method based on paradigm and analogy which starts from the description of a particular case and compares ethical dilemmas around this case with examples of ethical dilemmas related to similar cases to identify the paradigm that best fits the case.	15,19
Coherence analysis	An approach that reflects on the consistency of ethical theories, principles, and value judgments, without being prescriptive.	6
Wide reflective equilibrium	A deliberative method for establishing a decisional balance through a broad social reflective process in which stakeholders and citizens discuss and justify their values and beliefs until a full "inter-subjective" reflective equilibrium is achieved.	17
Axiology-based value analysis	An approach for mapping values held by individuals or the society and studying their interactions or conflicts.	2,13
Eclectic approach	An evaluation method that includes a variety of questions reflecting different perspectives and normative theories. The information related to these questions should be synthetized in the process of ethical reasoning.	7,14,21
Triangular model	A human-centered model for evaluation of healthcare technologies that recommends combining factual, anthropological and ethical data and synthetizing through ethical reflection at a normative level.	10
Complexity theory	A framework that takes into account the complex and unpredictable inter-relations between the technology and the environment in the evaluation of healthcare technologies and seeks to involve stakeholders in the assessment.	12
Actor-network theory	An approach that recognizes the need for consideration of a complex network of scientific, technical, social and political actors in HTA, and describes potential changes and inter-relationships of actors, environment, and the technology.	25
Social shaping of technology	A framework that emphasizes co-shaping of technology and society and promotes deliberation on social and ethical issue around technology earlier on in the technology development process.	6,11,16
Decision making phase		
Ontario Health Technology Advisory Committee (OHTAC)'s Decision Determinants	A framework consisting of four determinant criteria that should be included in HTA decision making process: clinical benefit, consistency with ethical and social values, cost-effectiveness and feasibility of implementation.Systematic literature review and deliberative public engagement are suggested for the collection of data required for decision making on the new health technologies	20
Multi criteria decision analysis (MCDA)	A decision support tool based on multi criteria decision analysis (MCDA), using the information from the literature and stakeholder opinionsto rank the alternative healthcare technologies. The tool focuses on quality of evidence, disease severity, and efficacy of interventions, cost-effectiveness, as well as ethical principles of	8

2. Survey on enablers of and barriers to addressing ethical and moral issues in health technology assessment

2.1 Objectives

This cross-sectional survey aimed at exploring the degree to which and howthe HTA agencies included ethical considerations in their HTA products, and identifying key enablers and barriers to the incorporation of ethical issues in HTA.

2.2 Methods

A questionnaire consisting of 18 questions was designed through a comprehensive review of the literature and consultation with experts. The questionnaire was in English and included general information about the respondent and the HTA agency,questions related to the current situation of handling ethical issues in HTA reports produced by the agency, and questions asking about factors influencing incorporation of ethical issues in HTA. The questionnaire was pre-tested with 5 potential respondents to ensure face validity and technical functioning. The feedbacks from the pretest respondents were used to modify the final version of the survey.

A link to the survey was sent, through an e-mail invitation, to all of the HTA agencies affiliated to the International Network of Agencies for Health Technology Assessment (INAHTA). This network consists of 53 HTA producer agencies from 29 countries in North and Latin America, Europe, Africa, Asia, Australia, and New Zealand. Heads of the HTA agencies ortheir designated representatives were identified by accessing the websites of all INAHTA member agencies. The recipients were asked to complete the questionnaire by following the provided link to the survey (through the Survey Monkey internet web service), or to forward the email to the most appropriate person in the agency to respond. Two reminder emails were sent to maximize the response rate.

To protect security and confidentiality, the questionnaires were collected anonymously, with the Internet Protocol (IP) addresses of participants accessing the survey omitted. All raw data was stored in password-protected documents and maintained on a secure server, with access restricted to the main investigator. Ethics approval was acquired from McMaster University's Research Ethics Board for the survey(Project #13-103, March11 2013).

2.3 Results

Directors or representatives of 31 HTA agencies responded to the survey invitation; however, two of those refused participation due to their busy schedules and three failed to complete the online questionnaire, leaving a sample of participants from 26 HTA agencies. As shown in figure 2, of those HTA agencies that completed the survey, 21% were departments of government ministries (mainly ministries of health), 59% were governmental or quasi-governmental[1] agencies, and 14% were academic research institutions. A lower proportion of the survey participants were from hospital HTA units (3%) or independent HTA agencies (3%). The participants consisted of heads of HTA agencies or units (41.4%), program managers (10.3%), or HTA researchers (48.3%).
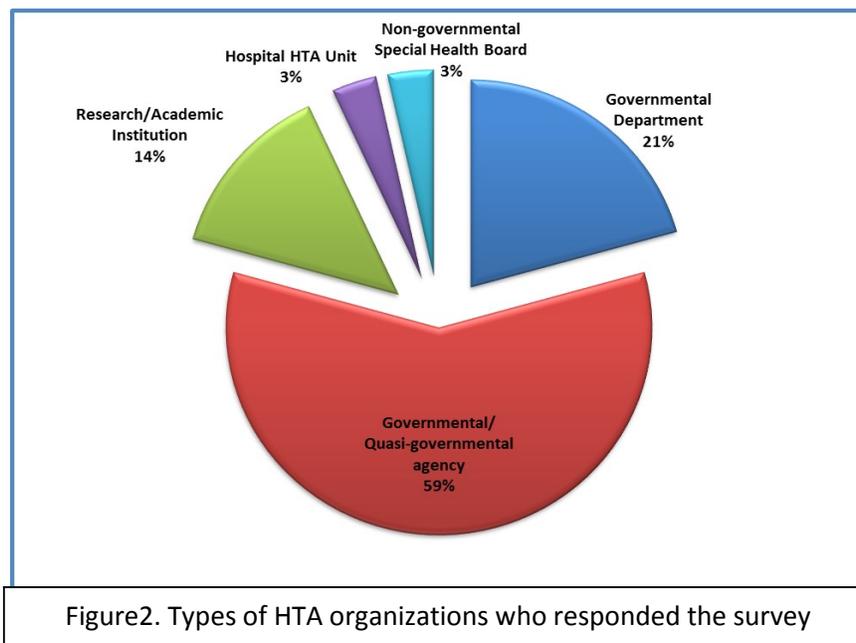

Figure2. Types of HTA organizations who responded the survey

Figure3 demonstrates the types of health technologies that were assessed by the responding HTA agencies. As shown, medical devices and procedures were the most common technologies covered by the HTA agencies (100% and 92%, respectively), followed by public health interventions (70%), pharmaceuticals (58%) and health system interventions (58%).

The variability in the types of assessment reports produced by the participating agencies is shown in Figure 4. More than 80% of the agencies produced full HTA reports and rapid assessments. The median[2]

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[1] Quasi-governmental agencies are privately-managed organizations that are supported by governmental funding.
[2] Median=50th percentile; a median of 5 HTA reports shows that half the agencies had less than 5 HTA reports published per year and had more than 5 reports in this category.

number of published assessments for each of these agencies in one year was reported to be 5 (inter-quartile range [IQR][3] 1 to 10) for HTA reports and 5 (IQR 1 to 20) for rapid assessments. About 50% of the agencies performed systematic reviews, with a median of 1 (IQR 0 to 4) per year.
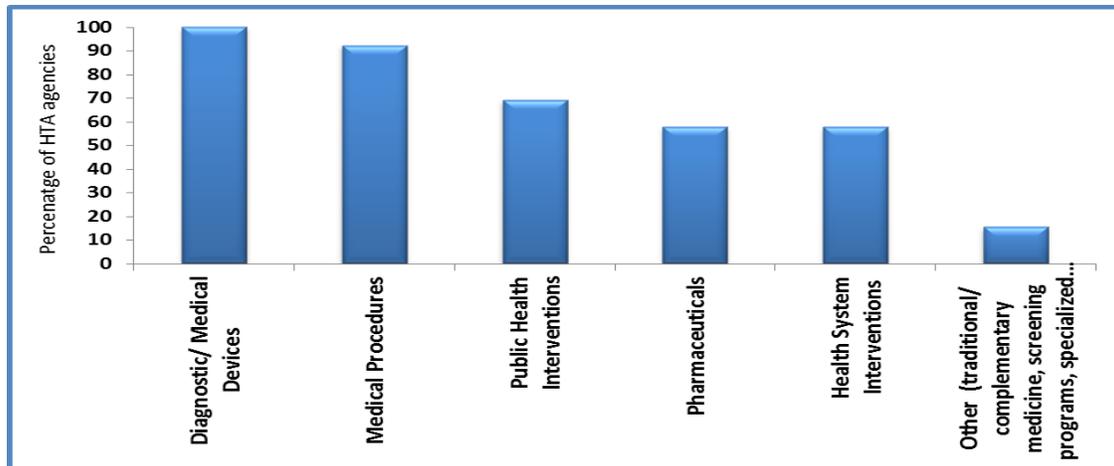
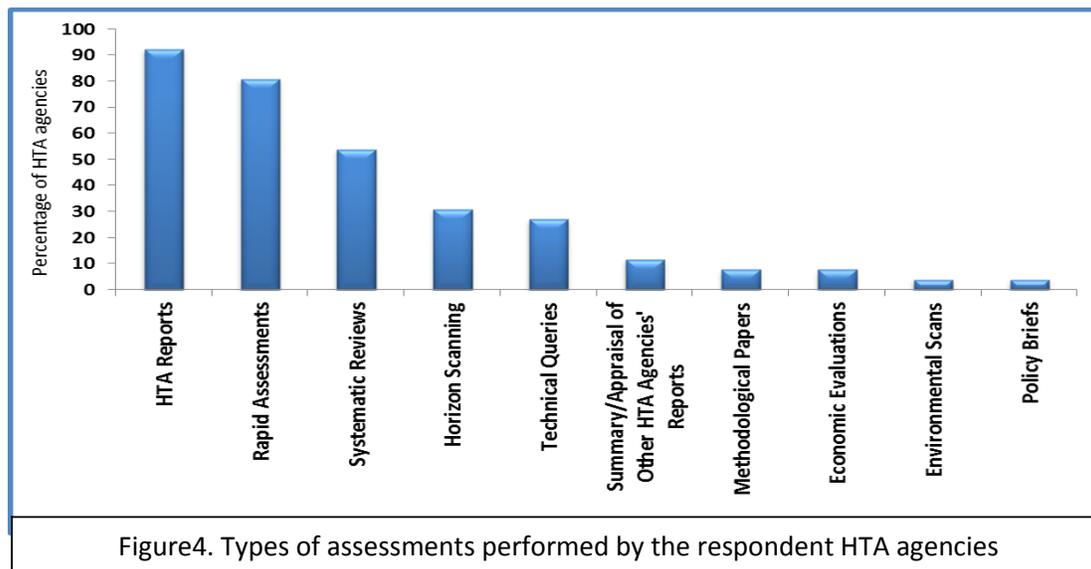Figure3. Types of health technologies being appraised by the respondent HTA agencies

Figure4. Types of assessments performed by the respondent HTA agencies

Assessment of ethical issues in HTA

Our findings showed that a median of 10% of the HTA products produced by the agencies included an assessment of ethical aspects (IQR 5% to 50%) and a median of 5% considering only equity aspects (IQR 0% to 40%). Approximately 40% of the respondents reported that their agencies gave a high or very high

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[3]IQR is the difference between the third (75%) and first (25%) quartiles of the distribution. This statistical measure is used to show the variation around the "median" value.

priority to the consideration of ethical issues, while half of the agencies assigned a low or medium level of priority to the ethical aspects of health technologies (Figure 5).

Figure5. Level of priority assigned for consideration of ethical issues
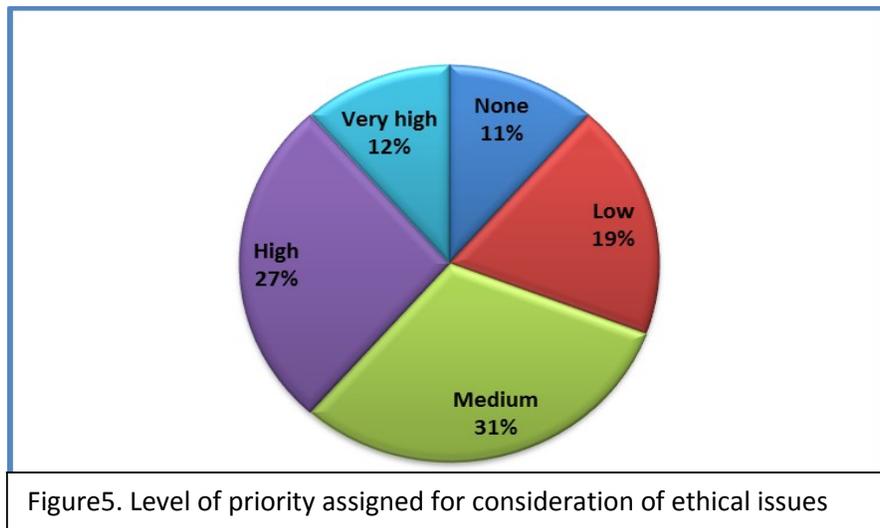
In response to the question that asked respondents to indicate who in their organization was responsible for incorporation of ethical issues,8% believed that this question was not applicable to the types of reports made by their agencies, 77% mentioned that a team of HTA professionals, not including an ethicist,was responsible to address ethical considerations, if needed. In 15% of the agencies ethical evaluations were typically performed by individual ethicists or multi-disciplinary teams including ethicists.

Seven of the 26 respondents (27%) indicated that written instructions on how to address ethical issues around health technologies existed in their organizations, and eight (30%) stated that their agency had a guidance document in preparation that would serve this purpose. The remaining agencies did not have any instructions for addressing ethical considerations.

Figure 6 shows how the respondents rated the usefulness of existing ethical frameworks or guidelines.Notable is that more than 20% of the survey participants were not aware of any guidance documents that could be useful for ethical assessment in HTA.

Figure6. Participants' perception of usefulness of existing guidance documents
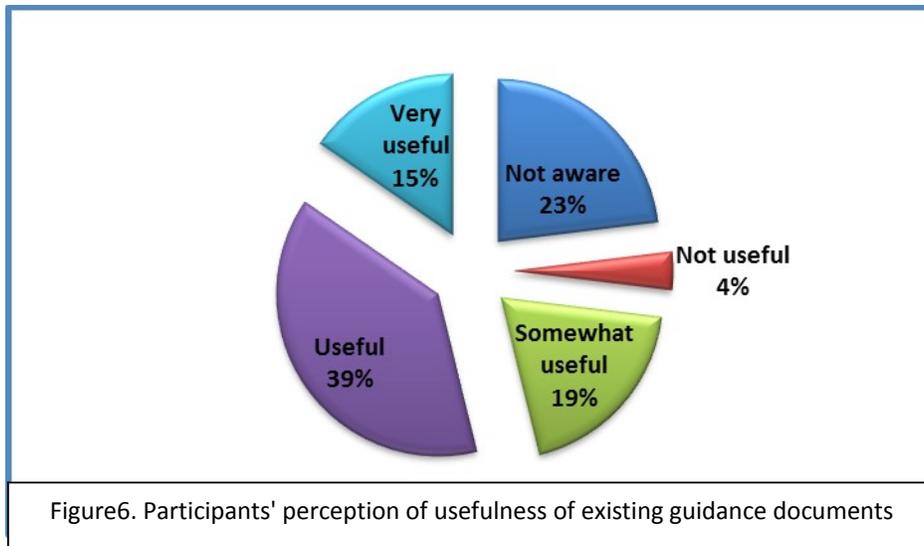
Factors influencing the incorporation of ethical issues in HTA

When asked what barriers might discourage HTA professionals from addressing ethical issues in their assessments, the most frequently reported barriers were: limited ethical knowledge and expertise of HTA producers, lack of sufficient time and resources, scantiness of useful evidence concerning ethical aspects of health technologies, problems in identifying and using the existing ethical guidelines, and conflicting policies and rules. The respondents also identified a number of other obstacles that were not listed in the questionnaire, such as lack of organizational requirements and negative attitudes of HTA professionals towards assessment of ethical aspects (Figure 7).

We also asked representatives of the HTA agencies about what would help or encourage them to apply ethical evaluation methods in their assessments. The respondents most frequently reported educational sessions, involvement of ethicists and stakeholders in the HTA process, and improvement of existing guidance documents as the key enablers. The respondents identified additional motivators in the free text section, such as practical examples to aid ethical assessment and availability of sufficient resources (Figure 8).
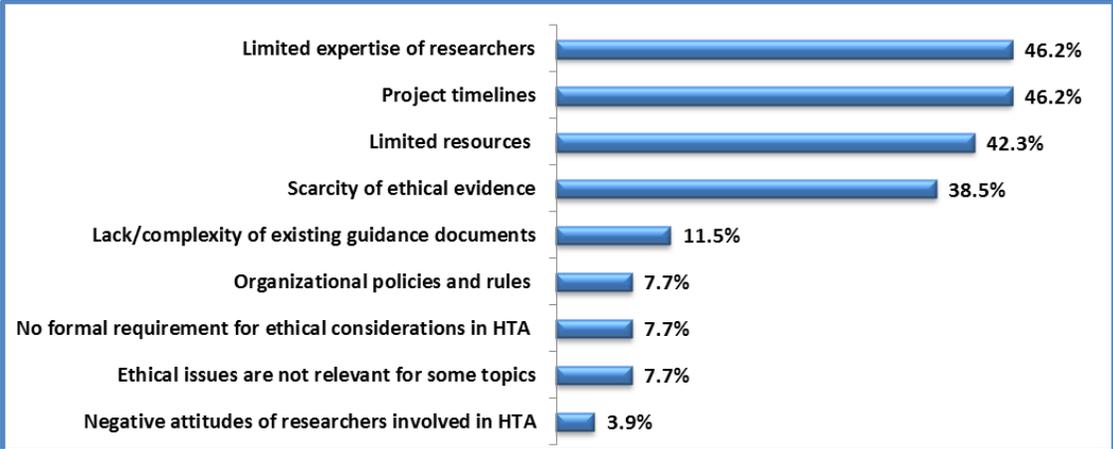
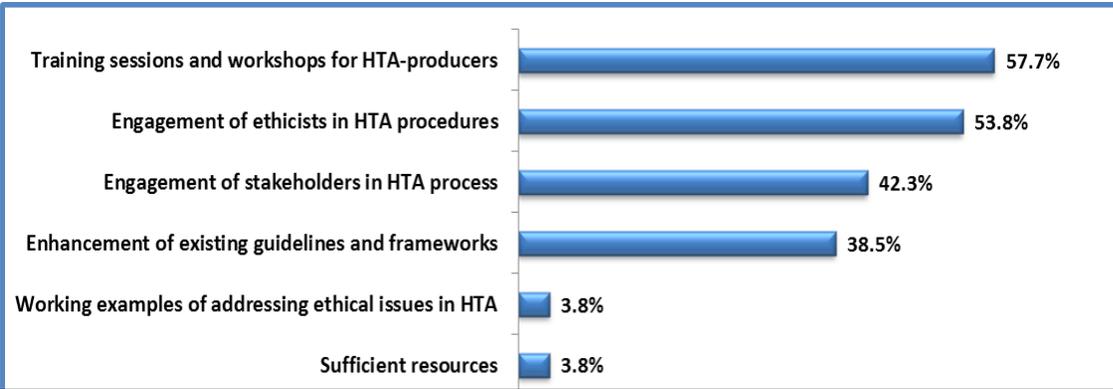Figure7. Perceived barriers to the incorporation of ethical considerations in HTA

Figure8. Perceived enablers of the incorporation of ethical considerations in HTA

3. A framework for incorporation of ethical consideration in health technology assessment

In what follows, we outline a framework that was developed through our multi-phaseresearch process:

3.1 Background:

In the first phase of the project, through a systematic literaturereview, we identified multiple frameworks, of varying complexity and scope, for incorporation of ethical considerations in HTA. These frameworks weregenerally designed for the purposes of identification, appraisal and analysis of ethical data as well as supporting decision-makers in making better informed decisions (see section 2.3). The majority of the identified frameworks promoted combining normative reflection with descriptive approaches to the analysis of values and preferences of potential stakeholders and other societal or technical actors. The following approaches were proposed for analysis of ethical data during the assessment process: principlism, casuistry, coherence analysis, wide reflective equilibrium, value analysis, eclectic approach, triangular model, complexity theory, actor-network theory, and social shaping of technology. These methodological guidance documents varied in nature from conceptual frameworks to detailed models supplemented by analytical tools or case studies. However, they provided little guidance on how to implement the methodology in practice.

In the second phase, we conducted a survey of the main HTA producing agencies throughout the world to learn about their experiences and methodological preferences regarding addressing ethics-related aspects, as well as their perceptions of the key barriers and enablers to incorporation of ethics in HTA. Our results showed that although close to 90% of the HTA agencies assigned some level of priority to inclusion of ethical considerations in HTA, a relatively small proportion of them incorporated relevant ethical analysis methods in their assessments. More than a quarter of the responding agencies were not aware of any guidance documents for addressing ethical issues or found the existing guidelines and frameworks not useful. When asked about the important barriers and enabling factors, some agencies believed that the lack of practical guidelines and complexity of the existing frameworks were important barriers. A considerable number of the respondents considered the availability of well-designed frameworks and guidelines as a key motivator (see section 3.3).

In the next phase of this research project,various elements of the previously identified frameworks and the results of the survey were discussed with experts in HTA and ethics fields to construct a simple framework thatfacilitatesthe steps required for consideration of ethical implications the technology throughout the HTA process.

3.2 A frameworkproposal

We offer the following iterative steps to guide HTA teams in evaluation of ethical aspects in HTA:

Step1. Defining the objectives and scope of the assessment

Before starting an ethical assessment, it should be ensured that the objectives of assessment are clear because the methods chosen for the collection and analysis of data will depend on the purpose of the assessment. Then, as with any other evaluation process,ethical assessment should begin with an exploratory phase to identifythe existing knowledge base surrounding the technology of interest (technological aspects, modes of application, range of possible clinical indications, etc.), potential beneficiaries and stakeholders, safety issues, and therapeutic, economic and organizational impacts of the technology.

Step2. Recognizing potentially relevant ethical problems

Recognition of existing ethical dilemmas orthe ones that are perceived likely to emerge after implementation of the technology(hypothetical dilemmas) is essentialfor theformulation ofethical questions that need to be answered.It might not always be necessary to makea comprehensive list of existing ethical conflicts or controversial issues through a systematic inquiry. However, it is important to discuss and specify which of the recognized ethical dilemmas and arguments are more relevant to the assessment and provide a justification for why these could be relevant. Thisstep might be affected by the researcher's philosophical orientation and background knowledge.

Step3. Designing the evaluation

We found no unique approach that could be used for ethical analysis in HTA. There has also been limited research conducted to specify healthcare technologies for which the existing analytical approaches are suitable.Therefore, in deciding which analytical method to use, it is important to consider the appropriateness of the method for the given context, the objective of ethical analysis, and the way in which the method addresses problems within its application domain. A description of analytical approaches identified by our systematic review can be found in Table 1. Beforedeciding to use an analytical approach, it is also critical to consider its potential weaknesses and limitations. In general, normative approaches are prone to subjective bias.[18] They also require a sufficient knowledge of ethical

theories, which may not be available within most of HTA organizations (see section 3.3). Other examples of method-specific limitations include the problem of conflict between two or more principles in the principlist approach,[27] or the subjectiveness of analogic arguments and intuitive judgments in case-based approaches such as casuistry.[15]Value-based descriptive approaches, whichmainly employ public involvement methods, can also be challenging to perform due to their complexity, costliness, and time consuming nature.[28]

Step4. Defining key requirements

The following resources are usually necessary in performing an ethical assessment:ethical expertise, sufficient financial resources and time for conducting the assessment, especially if participative approaches are used; and capacity for training, if needed.

It must be ensured that sufficient knowledge, experience, and skills exist in the organization to perform a comprehensive ethical analysis. Furthermore, the capacity in methodologies associated with ethical analysis through public discourse are often lacking in some HTA organizations.[29] Therefore, to get involved in public participatory processes, HTA professionals might need to acquire a range of new skills in different methods of public engagement before getting involved in such research activities.[6,30]

Step5. Data collection

In order to get a deep understanding of ethical dilemmas surrounding a particular healthcare technology, it is essential to collect extensive data on relevant facts, and issues such as values and preferences of stakeholders or the society, quality of life, access, acceptability, and other pertinent issues relating to a particular healthcare technology.Depending on the aims and methodology of the evaluation, a range of data collection methods can be employed, including: surveys, observations, analyses of texts and documents, stakeholder interviews, focus group discussions, Delphi panels, consensus conferences, etc. Due to the iterative nature of data collection to analysis process, additional stakeholders or informants who are able to provide additional facts, and verify or correct uncertain information might be selected, on the basis of the preliminary analysis, and new techniques might be employed to gather required information. Therefore, selection of data sourcesand data collection methods should remain flexible throughout the ethical evaluation.

Step6. Processing and analysis of data

Ethical reasoning is the process ofexamining ethical dilemmas through evaluation of various types of information and applying guidance from moral norms, principles, or theories.A combination of empirical, normative, and descriptive information may be useful in ethical reasoning. However,the collected data should be carefully assessed regarding its reliability and credibility before ethical reasoning takes place.

In addition, before integrating stakeholders' values into the analysis, it is important to identify conflicting values and investigate, if necessary,the reasons for the different value choices and to review existing arguments for and against each choice. Performing astakeholder analysis thatidentifies the interests of various stakeholders and their influences over potential decisions might be helpful in understanding the sources of values and preferences.[31,32]

Several ethical theories can be used to guide an ethical analysis process. Utilitarianism and deontology are the two most commonly referenced perspectives in moral philosophy.From the utilitarian perspective the ethical action or decision is the one that will produce the greatest benefit for the greatest number of people; whereas, deontological perspective focuses on duties, rules and obligations to respect the rights of individuals.[26] Examples of other ethical theories that have been commonly used are egalitarian perspective which focuses on fairness and justice, andvirtue ethics which views the moral character and virtues of individuals as the central point of rightness or wrongness of actions.[26]Examination of technology and its consequences from multiple ethical perspectives is suggested by several authors in order to arrive at a robust judgment, to address complexity of ethical dilemmas and uncertainties around healthcare technologies, and to better justify HTA decisions.[2,6-8,10-17,25]It is important to note that the results of theory-based analyses may be influenced bythe analysts' knowledge, theirexperiences, values, and attitudes, as well as the technological, organizational, social, and political contexts in which the analyses are performed.

It has been argued in the literature that the role of ethicists is important in performing ethical analysis in HTA,[4-6,33]The HTA Core Model and four European guidelines explicitly recommended that ethical analysis should be performed by someone with recognized expertise in ethics.[34-38]Ethicists may play various roles depending on the type of the assessment. If a traditional method (e.g. principlism, casuistry, or coherence analysis) is chosen for the ethical evaluation, the normative assessment should generally be performed with the help of ethicists or other experts with knowledge of ethics. In participatory or interactive assessments, where expert and lay opinions are considered equally valuable,ethicists can play an active role by providing rationale for potentially useful analytical approaches, scientific and theoretical inputs to stakeholder and public debates and assisting stakeholders in reaching into a consensus.[6]

Step7. Knowledge translation

The purpose of HTA is primarily to support healthcare policy-makers in making evidence-informed decisions, and secondarily to help advance knowledge about a particular health technology and stimulate further research.[39] Therefore, the dissemination of the HTA findings, including ethical aspects, must be timely and appropriately tailored to the needs of potential users.

In order for the results of an ethical assessment to be utilized as an input for policy-making, the knowledge transmission activities should take place in all stages of HTA through an effective interaction between HTA-producers and policy-makers.[40] The results need to be communicated in a manner that can be understood and easily utilized by policy-makers. The feedback from potential users should be received throughout the project and used to improve the quality of the research. HTA reports should address various dimensions of an existing or hypothetical ethical problem surrounding the technology of interest, using all relevant evidence from research and non-research sources, and applying suitable analytical approaches. It is also important to address how different various stakeholders and members of society might be affected by the implementation of the technology or otherwise.

HTA findings can also be disseminated among other relevant target groups, such as healthcare researchers, clinicians, healthcare service providers (e.g. hospitals), third party payers, biomedical manufacturers, patients, and the general public. However, it is essential to translate the findings (including the results of the ethical analysis) into formats that are understandable and useful to the above-mentioned groups of audience.[38]

4. Conclusions

Despite the increasing attention given to the incorporation of ethical considerations in assessment of healthcare technologies, there has not been a generally accepted framework for this purpose. The intention of this research project has been to construct a practical framework that allows HTA producers to adopt ethical assessment approaches that might fit best their purpose of assessment.

Our framework can serve as a starting point towards a set of comprehensive strategic guidelines and the supporting instrumentation for integrating ethics in HTA. It should be noted that the contents of the framework presented here are being revised and refined through consultation with experts and policy-makers. In addition, the practical application of the framework will be tested through application in various HTA projects. Based on the results from the case studies and feedbacks received from the experts and potential users, the next stages will be: (a) to modify the framework by adding or removing steps; and (b) to enhance its practicality by adding flow charts that illustrate details of various steps, and auxiliary tools or checklists to facilitate the ethical evaluation process. Then, the final validation of the framework will be carried out using further case studies.