

## Do ethical considerations influence any in HTA reports? A review of reports

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### Abstract

**Background:** Dealing with ethical considerations is a major component of Health Technology Assessment (HTA) definitions.

**Objectives:** Present study aimed to explore and describe the manner of ethical analyses in HTA reports and the effects it had on HTA-related decision making around the world.

**Methods:** By considering the contextual milieu of reports and searching for ethical themes and subjects in HTA full reports, a descriptive analysis of HTA reports' contents and related processes was conducted. The review focused on all English HTA reports issued in a year. All ethical aspects, criteria, approaches, and also decision-making related ethical issues were described and summarized in retrieved reports. The inclusion of ethical aspects in final decision-making criteria of HTA reports was also considered.

**Results:** Eighty-nine HTA reports issued in one year were included in this review and analyzed for ethical considerations. There was no trace of any ethical issues in 60.7% of retrieved HTA reports. Dimensions of equity in resource distribution, stakeholder engagement, social values, essence and nature of technology, and ethical issues about the method of assessment for decision making, and physician-patient relationship were raised and discussed in 38.2%, 3.4%, 3.4%, 3.4%, 34.8% and 3.4% of reports respectively. Those issues were also included in 44.1, 5.9, 2.9, 2.9, 0 and 2.9% of final reports, respectively. In overall, only in 16 cases (17.9%) of all 89 reports, ethical issues were included in HTA decision-making orientations.

**Conclusion:** This review shows that ethical issues are occasionally raised and discussed in HTA reports. More importantly, the inclusion of ethical concerns as a decision criterion in HTAs is few and insufficient.

**Keywords:** Health Technology Assessment, Ethical considerations, Ethical analysis, Decision process.

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### Introduction

Health Technology Assessment (HTA) is an effective policy tool in the evidence-based evaluation of health care technologies. One of the most important components of any HTA is its focus on ethical considerations of technologies. This matter is both discussed as decision criteria and also as an ethical or value basis for all decision makings (1-4). Previous studies, however, have shown that despite being completely stipulated, ethical issues are less considered in HTA reports. The difficulty and subjectivity inherent in ethical analyzes

might be a reason for such a negligence (5). Nevertheless, there have been great efforts to develop numerous tools to consider ethical aspects in HTAs (6-11).

Whether those tools are used or not is a worthy question to ask. This study intends to review HTA reports to describe methods of considering ethics in HTAs. Such a consideration may range from propounding of ethical issues to effects they might have on final decisions; i.e. approaches and methods adopted, principles referred to and goals and objectives sought by ethical analysis and also the extent to which these have

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been exposed during decision-making process.

### Methods

First, to reach to HTA reports we searched and found HTA institutions around the world. So, our study focused on HTA reports accessible by the internet and was limited to electronic sources in English. To this end, we used Google™ search engine by applying the following general terms:

Health “Technology Assessment” OR HTA OR “Technology Appraisal.”

To be more sensitive and to assume that in addition to aforementioned terms, there might be other relevant concepts and words too, we used other queries in refining and revising search strategies and efforts. After finding relevant HTA websites, the content of their accessible documents was searched through further. Thus, HTA full reports in English published in 2011 and with available and accessible were selected out.

In the next stage, Lehoux and Williams-Jones’ model and the map were used to conduct a content analysis of HTA reports. The model and map apply for social and ethical issues that might emerge out of conditions inherent to technology use; issues like doctor-patient relationship, direct or indirect effect on other stakeholders, broader societal issues (such as conflict with social values and arrangements, human integrity and dignity), or issues concerning assessment methods (such as choice of end points, moral consequences of the HTA) and, finally, issues of resource implications of technology dissemination (such as distribution of and access to health care services and equity) (6-11). Authors assumed that based on a report contents, influence and implication of ethical considerations would be traceable if the issues raised could change the final decisions made, or affect the decision-making process (e.g. observing “accountability for reasonableness” as a moral approach to decision making), or add an ethical point to executive summary.

Content analysis of HTA reports was conducted by only one of involved researchers. Then it was peer reviewed, summarized, and tabulated by others. The general approach of the HTA institutions to ethical aspects in HTA based decision making was also analyzed.

### Results

In overall, 89 HTA reports were analyzed in our study. Most reports belonged to the United States and the UK and a few ones to Sweden and Ireland.

No ethical issue was brought up in 55 reports (61.8%). Amongst the rest 34 reports, ethical issues about the nature of the technology, issues of doctor-patient relationship, issues relating to other stakeholders, social values, assessment methods, and equity were discussed in 3, 3, 3, 4, 0 and all 34 reports respectively. According to the text report, those ethical considerations influenced documented dialectics of decision making or final decision in 1 (33%), 1 (33%), 2 (66%), 1 (100%), 0, 15 (44%) reports respectively. Also, influencing final recommendation in terms of ethical points added to executive summary was boldly detectable in 16 reports (Table 1). However, it was not investigated whether other cases were relevant for a due consideration and change in decision making. The most common ethical assessment considered was equity-related issues, though inadequately and incompletely. Nevertheless, equity concerns were not even brought forth in 55 reports (61.8%). Amongst countries, these ethical aspects were fully assessed and considered in all reports issued in Ireland and Sweden, with obvious effects on final decision statement (Table 2).

NICE (National Institute for Health and Clinical Excellence) of England had the highest number of HTA reports accessible (26 reports). Equity-related issues, as a distinct component, were considered in all of NICE Technology Appraisals; “equality impact assessment” influenced final decision statement in 10 reports. Although issues of assessment methods were not con-

sidered in any report, NICE process for HTA-based decision making (Technology Appraisal) conformed with principles of “accountability for reasonableness”, which have 4 conditions for the legitimacy of a decision-making process: publicity, relevance, appeals, and enforcement (12).

Among HTA reports in which ethical issues were somehow raised (i.e. 38% of all reports in 2011), equity issues were considered in 100% of the reports; issues concerning societal values in 11.8%; and issues of technology itself, of doctor-patient relationship, and of other stakeholders in 8.8% of

Table 1. Raised ethical issues and their influence on HTA reports; a summary of 34 relevant reports

Technology	Country	Institute	Ethical issues concerned						Issues Phrased In The Text Of Drafts But With Little Influence On Final Decision	Issues Influenced That Final Decision Or Stated In Executive Summary
			1) Issues about the technology itself	2) Issues of doctor-patient relationship	3) Issues related to other stakeholders	4) Issues concerning social values	5) Issues concerning assessment methods	6) Equity/ equality related issues		
1 Ticagrelor (Acute coronary syndromes)	England	NICE (13)						✓	-	Issue 6
2 Donepezil, galantamine, rivastigmine and memantine (Alzheimer's disease)								✓	-	Issue 6
3 Golimumab(Ankylosing spondylitis)								✓	-	Issue 6
4 Tocilizumab (Arthritis- juvenile idiopathic, systemic)								✓	Issue 6	-
5 Bevacizumab in combination with a taxane								✓	Issue 6	-
6 Fulvestrant (metastatic Breast cancer)								✓	Issue 6	-
7 panitumumab (metastatic Colorectal cancer)-terminated appraisal								✓	-	Issue 6
8 retigabine (adjuvant for partial Epilepsy)								✓	Issue 6	-
9 Everolimus (the second-line treatment of advanced renal cell carcinoma)								✓	Issue 6	-
10 Bendamustine (lymphocytic Leukaemia)								✓	Issue 6	-
11 Erlotinib (non-small-cell Lung cancer, advanced /metastatic-maintenance)								✓	Issue 6	-
12 Rituximab (follicular non-Hodgkin's Lymphoma)								✓	Issue 6	-
13 Ranibizumab (diabetic Macular oedema)								✓	Issue 6	-
14 Dexamethasone (Macular oedema - retinal vein occlusion)								✓	Issue 6	-
15 Bortezomib and thalidomide (Multiple myeloma-first line)								✓	Issue 6	-
16 Azacitidine (Myelodysplastic syndromes)								✓	Issue 6	-
17 Bivalirudin (Myocardial infarction - persistent ST-segment elevation)								✓	Issue 6	-
18 Mifamurtide (Osteosarcoma)								✓	-	Issue 6
19 Trabectedin (relapsed Ovarian cancer)								✓	Issue 6	-
20 Cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate (Peripheral arterial disease)								✓	Issue 6	-
21 Golimumab (Psoriatic arthritis)								✓	-	Issue 6
22 Pazopanib (Renal cell carcinoma - first line metastatic)								✓	-	Issue 6
23 Abatacept (2nd line - Rheumatoid arthritis)								✓	-	Issue 6
24 Golimumab (Rheumatoid arthritis- after the failure of previous anti-rheumatic drugs)								✓	Issue 6	-
25 Aripiprazole (Schizophrenia)								✓	-	Issue 6
26 Romiplostim (Thrombocytopenic purpura)								✓	-	Issue 6

Table 1. Cntd

27	Clopidogrel versus Other Antiplatelet Agents (for Secondary Prevention of Vascular Events in Adults with Acute Coronary Syndrome or Peripheral Vascular Disease)	Canada	CADTH (14, 15)					✓	Issue 6	-
28	Robot-Assisted Surgery Compared with Open Surgery and Laparoscopic Surgery							✓	Issue 6	-
29	Genetic Testing for Hereditary Mutation of the von Hippel-Lindau (VHL)	Australia	MSAC (16)	✓	✓	✓	✓	✓	Issues 3, 4, 6	Issues 1, 2
30	Artificial Intervertebral Disc Replacement							✓	Issue 6	-
31	Prion filtration of red cell concentrates to reduce the risk of variant Creutzfeldt-Jakob disease transmission	Ireland	HIQA (17, 18)	✓		✓		✓	Issue 1	Issues 3, 6
32	Robot-assisted surgery in selected surgical procedures				✓		✓	✓	Issues 2, 4	Issue 6
33	Medical and Psychological Methods for Preventing Sexual Offences Against Children	Sweden	SBU (19, 20)				✓	✓	-	Issues 4, 6
34	Treatment of Hemophilia A and B and von Willebrand Disease			✓	✓	✓	✓	✓	Issues 1, 2, 4	Issues 3, 6

the reports. From extent-of-influence viewpoint, equity issues were stated in final document of 15 cases (44.1%); issues of other stakeholders in 2 final documents (5.9%); and issues of societal values, of technology itself, and of doctor-patient relationship in only one final document (2.9%).

Despite existence of various tools for consideration of ethical aspects in HTAs (6,7,21,22), no reference was made to them in all HTA reports retrieved in present study.

## Discussion

Although there are numerous studies that

Table 2. A summary of the review of HTA reports for ethical issues.

Country	Number of HTA reports retrieved N (%)	Number of reports with at least one ethical issue raised N (%)	Number of reports that considered ethical issues and incorporated it in final document n (%)	Ethical considerations in general approach to HTA-based decision-making
England	26 (100)	26 (100)	10 (38)	Establishment of a citizen's council for social value judgments as a separate structure for most important ethical issue; existence of an equality impact assessment; existence of a structure that comply with conditions of "accountability for reasonableness" for legitimate decision-making
Canada	15	2 (13)	0 (0)	Trivial dealing with equity and efficiency trade-offs in some HTA reports with no influence on final decisions; no structure to address all potentially relevant ethical issues
Australia	7	2 (29)	2 (29)	Detailed and special approach to ethical aspects for some relevant health care technologies without separate structure to deal with ethical issues in all technologies
Ireland	2	2 (100)	2 (100)	Detailed and special consideration to relevant ethical issues by ethics specialist for all health care technologies being assessed; a separate chapter on ethical and legal issues in all HTA reports
Sweden	2	2 (100)	2 (100)	Detailed and special approach to relevant ethical issues for all health care technologies; dealing with relevant ethical issues in a separate chapter of all HTA reports
Belgium	7	0 (0)	0 (0)	No explicit consideration of ethical aspects in HTA reports
America	30	0 (0)	0 (0)	No ethical issues are brought up in HTAs; transparency of decision making about health care technologies was only seen in one HTA institute

point to little attention to ethics compared to other aspects in HTA reports (23-26), more detail about local approaches to and influence of ethical considerations on final decisions in HTA reports is missing. Our study tried to answer the question that “to what extent each type of ethical issue was considered and implicated in HTA documents?” Findings showed that most attention was paid to equity issues while allocating the resources. Amongst the countries, the highest moral considerations concerning evaluation methods (ethical HTA process) was related to “accountability for reasonableness” for legitimate decision-making in the UK. According to literature, this might show that structural measures for moral decision-making process seem to be more effective. Some of this success might be attributable to the legal status of HTA system and related recommendations in public services as quasi-law statements (27). Therefore, it seems that institutionalization of ‘ethical HTA’ would not be possible only by adding a chapter on ethics to the HTA reports.

Again, it was observed that there are few HTA reports with a complete approach to all aspects of ethical consideration. Although there are some accessible tools of addressing ethical and / or equity issues in Health Technology Assessment, we could not judge on whether or not the tools was helpful and had any effect because no reports referred to them.

### Conclusion

While few number of ethical issues included in HTA reports has real influence on final HTA decisions, those ethical considerations defined in the form of planned and written policy and institutionalized in a systematic way, are of the great need to truly influence HTA decision makings.

It can be said in countries that are considering the ethical issues in their HTA reports (such as the UK, Sweden and Ireland), the approach is more focused on implications of equality and fairness in the allocation of resources.

### Limitations

The authors only managed to assess the content of HTA reports in one year, those with accessible electronic English documents; therefore, this sample may not represent all relevant HTA reports. Moreover, in a review of HTA based decision-making systems around the world, there might be some other mechanisms for ethical considerations that are not documented (as technical evidence) in the assessment phase of HTA reports. Those mechanisms could have a potential influence on decision-making about technologies under question. These limitations prevent us from generalizing the results.

Another limitation of the study relates to ethical issues considered. Our study only focused on assessment consequences and not on other ethical issues that might be relevant to HTAs. Indeed, the authors could not evaluate subjectivity of ethical concerns about the technologies assessed in the reports. For future studies, one can recommend that all the stages of assessment, especially scoping phase of the HTA project, should be documented and analyzed. A repeat of the present review for different years in order to assess the trend of attention to ethics in HTAs can be another recommendation.

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