

Quality of ethical analyses in health technology assessment reports up to 2020: the experience of a developing country

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Abstract

Background: Health technology assessment (HTA) is a conventional method in many countries for evaluating reasonable use of health technologies.

Aims: To investigate the ethical dimension as an inseparable aspect of HTA studies in Iranian HTA reports.

Methods: For quality assessment of ethical analysis, all HTA reports published by the HTA Office up to 2020 were reviewed using 2 valid assessment tools, the HTA Core Model and the Q-SEA questionnaires.

Results: We evaluated 91 reports for quality of ethical analyses. In the process dimension, the research question, literature search and inclusion/exclusion criteria were included in 91.2%, 83.5% and 82.4% of the HTA reports, respectively. The perspective of the analysis was explicitly stated in only 13.2% of the reports and the ethics framework in 6.6%. Maximum compliance with completeness, bias, policy implications, other implications, conceptual clarification and conflicting values was considered in only 2.2%, 4.4%, 9.9%, 9.9%, 14.3% and 2.2% respectively of all reports.

Conclusions: Iranian HTA reports require a coordinated and integrated framework acceptable to all stakeholders.

Keywords: health technology assessment, medical ethics, quality, Iran

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Introduction

Concerns about nonassessed benefits and the high cost of health care interventions have led to the establishment of health technology assessment (HTA), a policy-oriented interdisciplinary process to inform decision-making (1–3), into the system. Similar schemes have been devised throughout the world via establishing agencies or HTA units in health systems (1,4–6). The focus of HTA has been on the medical, economic, social and ethical outcomes; development; distribution; and use of health technologies (4–11), and most national and international HTA organizations have emphasized these aspects. The ethical aspect is, however, often less developed and less considered than other aspects such as clinical characteristics and economic effectiveness (8,12–15).

In the HTA process, the ethical analysis can be considered an assessment of ethical issues caused by technology or related to the HTA process (16–21). Health technologies incorporate ethical values and properties that can affect moral values on a personal or society level (22). Ethical analysis can be used as a basis for public participation and research on the values and preferences of stakeholders (11,23–27).

Although almost all HTA experts have reached consensus on conducting ethical analysis, the methods proposed for addressing ethical issues differ markedly in terms of philosophical approach, structure and comprehensiveness. However, a “one size fits all” approach is probably not the best option to evaluate ethical considerations about health care technologies (12,28).

Examining HTA reports on the analyses of ethical aspects may improve the quality of the reports.

In the Islamic Republic of Iran, HTA is not very old, only being introduced in the late 1990s. The HTA activities began in 2007 in the Department of Health Economics at the Center for Network Development and Health Promotion within the Ministry of Health and Medical Education. In 2010, changes in the structure of the Ministry of Health and Medical Education led to the separation of the deputies of hygiene and curative affairs. At the same time, the HTA Office began its activities in the Health Technology Assessment, Standardization, and Tariffs Office under the supervision of the Deputy of Curative Affairs and with a new structure. The vision of the HTA Office was to establish HTA within the health system, and thus, all forthcoming decisions and policies would be based on scientific evidence obtained from HTA reports (29–31).

Since, as a developing country, the Islamic Republic of Iran is exposed to modern health care technologies, this study aimed to examine and evaluate the quality of ethical analyses of all HTA reports.

Methods

This study is a type of grey literature review of HTA reports. All the reports from the Iranian HTA Office up to 2020 were retrieved from the website (<http://ihta.behdasht.gov.ir>). We used 2 assessment tools, the HTA Core Model questionnaire (32) and the Q-SEA questionnaire (8), to examine the quality of ethical analyses of all HTA reports. Two appraisers carried out the assessment and rating at the same time; in case of any disagreement, discussion continued until a consensus was reached, so that eventually complete agreement was reached on the rating.

The HTA Core Model questionnaire encompasses 6 domains and 12 issues, including principal questions about the ethical aspects of technology, autonomy, human dignity, human integrity, beneficence/non-maleficence and justice/equity. The reason for using the HTA Core Model for ethical analysis in HTA reports is that most Iranian HTA researchers use this model for their assessments. The second tool used, the Q-SEA questionnaire, has 2 domains. The process domain has 5 elements: research questions, literature search, inclusion and exclusion criteria,

perspective and the ethics framework. The outputs domain also has 5 elements: completeness, bias, implications, conceptual clarification and conflicting values (8).

Ethics clearance was obtained from the ethics board of Kerman University of Medical Sciences (ethics clearance certificate number IR.KMU.REC.1397.381).

Results

A total of 101 Iranian HTA reports were retrieved. One report was excluded due to duplication, another 3 were excluded since they were not HTA reports, and 6 were excluded due to the lack of access to their full text. Therefore, 91 reports were included in the final ethical analyses.

Regarding the ethical aspect of the HTA reports based on the Q-SEA tool, in the process aspect, 91.2% of the reports included the research question, 83.5% included the text search and 82.4% included the inclusion/exclusion criteria. The analysis perspective was only explicitly mentioned in 13.2% of the reports, and only 6.6% included an ethics framework in their analysis. Maximum compliance was poor, with completeness considered in 2.2% of the reports, bias in 4.4%, policy implications in 9.9%, implications differentiated by stakeholder in 9.9%, conceptual clarification in 14.3% and conflicting values in 2.2%. The details for the description of items included in the HTA reports based on the Q-SEA tool are presented in Table 1.

Using the HTA Core Model questionnaire (Table 2), we found that 80.2% of reports noted that this was a modern technology in the health field for the Islamic Republic of Iran, adding to, or replacing, the existing health standards. Whether the evaluated technology could affect the religious and cultural beliefs of some groups was only noted in 4.4% of reports and just over 60% mentioned the hidden or unintended consequences of technology.

The impact of technology on patients' autonomy was considered in 9.9% of the reports; 5.5% mentioned the impact of the studied technologies on human dignity and 3.3% mentioned integrity. The consequences of implementing/not implementing the technology on justice in the health care system were mentioned in only 4.4% of reports. The description of the items included in the HTA reports from the Islamic Republic of Iran based on the HTA Core Model are presented in Table 2.

Discussion

In reviewing the process aspect of the Iranian HTA reports using the Q-SEA tool, the focus has been on evaluating the quality of the elements of that process in achieving ethical analysis, and this study showed that 100% of the HTA reports included the ethical aspect as a part of their systematic review. However, the ethical aspect was not responded to in the PICO format as a systematic review of clinical evidence, as suggested by McCullough et al. (33).

Our review on the clinical aspects and effectiveness of the Iranian HTA reports used a search strategy for choosing the appropriate information sources. However, none of the reports reviewed mentioned the search for content related to the philosophical and ethical issues of technology. The inclusion and exclusion criteria were clearly stated in 82.4% of the reports and ethical issues were also noted in the inclusion criteria.

Because most researchers working on HTA projects believed that other aspects of HTA cover the ethical aspect, they refused to conduct a separate study for ethical analysis. Therefore, in terms of inclusion and exclusion criteria, they also referred to studies on technology-related ethical issues and have noted the study of such issues as inclusion criteria.

The fact that the analysis and assessment were conducted from an impartial perspective was only clearly defined in less than 15% of the HTA reports we studied. It should be noted that, when investigating the ethical aspect of technology, certain other methods are commonly utilized, for example convening an expert panel or focus group discussions, where clinical experts and decision-makers in the relevant field are included.

A wide range of ethics frameworks, such as the Socratic approach, fundamentalism, coherence analysis or participatory HTA approaches, have been used to analyse the ethical aspect of HTA based on the HTA Core Model (34). In contrast, we found that only some reports noted that the technology aspects were investigated based on the HTA Core Model. There was no transparency in this regard, and the perception of the studied technologies from the stakeholders' point of view was not examined.

The results relating to the output domain of the tool evaluating the quality of the output components (i.e. the ethical analysis as the outcome of the process) showed that only 2.2% of all

reports acknowledged ethical gaps. This finding is significant, indicating the absence of a number of approaches that many researchers use to ensure the completeness of any ethical analysis (8,19,35,36).

Brief reference to any possible biases during the ethical analysis was made in only 4.4% of the reports, and the policy- and other stakeholder-related implications were discussed in less than 10%. Therefore, from this point of view, Iranian HTA reports were not found to be of good quality, did not explicitly identify various ethical issues and offered no suggestions for stakeholders.

In terms of conceptual clarification, the reports were poorly presented. Although the systematic review does not provide any transparent assessment of conceptual topics, the authors of those reports implicitly proposed several explanations, such as: it does not affect human dignity, it does not damage patient autonomy, or the studied technology leads to justice in access.

An interesting point about the reports referring to the ethical aspect is the use of issues such as benefits and loss balance, autonomy and human dignity, indicating that these are the most important ethical issues that could present a risk for health technology. This issue is exactly what Bellemare et al. noted in a systematic review (14) and what Strech and Sofaer noted in an ethical analysis of 7 reports on the European HTA Network (37).

The issues of justice, safety, human integrity, human dignity and free choice were discussed in only a few Iranian HTA reports. None of the issues discussed around ethics were based on ethical studies; they were based on the opinions of experts and specialists in the technology field.

Although most reports use the HTA Core Model, the lack of a standard model in HTA in the Islamic Republic of Iran can be seen in the ethical analysis of technology-related issues, which has also been highlighted in previous research (14). Most of the reported Iranian HTAs were conducted by only 1 or 2 people; in none of them was a medical ethics expert involved, but this was not mentioned in the reports. This issue shows the significant weakness of knowledge related to complex philosophical theories, ethical arguments and lack of expertise in the perception of ethical justification methods in HTA studies. The technology-related ethical goals

have been discussed in only a small number of reports; these were not very transparent and nor did they use any of the various approaches to ethical analysis.

Over more than a decade since the establishment of the HTA Office in the Islamic Republic of Iran, many activities have been carried out to promote HTA, an indication of the serious determination to develop a dynamic and active HTA system. However, our findings show that, although an appropriate structure has been prepared for HTA, there are systematic weaknesses for an integrated and coherent HTA system, especially for the ethical aspect. This issue highlights the need for a standard model for ethical analysis of technology-related issues, training of ethics experts in the field of health, and fostering the knowledge of experts in understanding ethical theories.

Conclusion

In this study, we used 2 important tools to check the quality of Iranian HTA reports. The results show that the ethical dimension of health technologies, one of the most important aspects of an HTA, has not been properly investigated in HTA studies in the Islamic Republic of Iran, and that there is a huge gap between what is and what can be. We believe, therefore, that a review of the critical appraisal of the ethical dimension of the HTA reports is necessary to eliminate the existing gaps.

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References

1. Lafortune L, Farand L, Mondou I, Sicotte C, Battista R. Assessing the performance of health technology assessment organizations: a framework. *Int J Technol Assess Health Care*. 2008 Winter;24(1):76–86. doi:10.1017/S0266462307080105
2. Banta D, Oortwijn W. Health technology assessment and health care in the European Union. *Int J Technol Assess Health Care*. 2000 Spring;16(2):626–35. PMID:10932427
3. Henshall C, Oortwijn W, Stevens A, Granados A, Banta D. Priority setting for health technology assessment. Theoretical considerations and practical approaches. Priority setting Subgroup of the EUR-ASSESS Project. *Int J Technol Assess Health Care*. 1997 Spring;13(2):144–85. doi:10.1017/s0266462300010357
4. Velasco-Garrido M, Busse R. Health technology assessment: an introduction to objectives, role of evidence, and structure in Europe. Copenhagen: World Health Organization Regional Office for Europe, European Observatory on Health Policies; 2005.
5. Hanney SR, Gonzalez-Block MA, Buxton MJ, Kogan M. The utilisation of health research in policy-making: concepts, examples and methods of assessment. *Health Res Policy Syst*. 2003 Jan 13;1(1):2. doi:10.1186/1478-4505-1-2
6. Drummond M, Banta D. Health technology assessment in the United Kingdom. *Int J Technol Assess Health Care*. 2009 Jul;25(Suppl. 1):178–81. doi:10.1017/S0266462309090618
7. Banta D. What is technology assessment? *Int J Technol Assess Health Care*. 2009 Jul;25(Suppl. 1):7–9. doi:10.1017/S0266462309090333
8. Scott AM, Hofmann B, Gutiérrez-Ibarluzea I, Lysdahl KB, Sandman L, Bombard Y. Q-SEA—a tool for quality assessment of ethics analyses conducted as part of health technology assessments. *GMS Health Technol Assess*. 2017;13:Doc02. doi:10.3205/hta000128
9. EUnetHTA, Mäkelä M. HTA Core Model® for Medical and Surgical Interventions 1.0 R. Copenhagen: European Network for Health Technology Assessment (EUnetHTA); 2008 (<https://corehta.info/model/HTA%20Core%20Model%20for%20Medical%20and%20Surgical%20Interventions%201.0r.pdf>, accessed 15 February 2023).
10. Goodman CS. HTA 101: introduction to health technology assessment. Bethesda: National Library of Medicine; 2014 (https://www.nlm.nih.gov/nichsr/hta101/HTA_101_FINAL_7-23-14.pdf, accessed 15 February 2023).
11. NaserHamzeKhanloo M, Bazayr M. Role and necessity of health technology assessment (HTA) in health system. *J Health*. 2010;1(2):59–68 (https://healthjournal.arums.ac.ir/browse.php?a_id=143&sid=1&slc_lang=en, accessed 15 February 2023).
12. Hofmann BM. Why ethics should be part of health technology assessment. *Int J Technol Assess Health Care*. 2008 Fall;24(4):423–9. doi:10.1017/S0266462308080550
13. Leys M. Health care policy: qualitative evidence and health technology assessment. *Health Policy*. 2003;65(3):217–26. doi:10.1016/s0168-8510(02)00209-9

14. Bellemare CA, Dagenais P, Suzanne K, Béland J-P, Bernier L, Daniel C-É, et al. Ethics in health technology assessment: a systematic review. *Int J Technol Assess Health Care*. 2018 Jan;34(5):447–57. doi:10.1017/S0266462318000508
15. Weinstein BD. What is an expert? *Theor Med*. 1993 Mar;14(1):57–73. doi:10.1007/BF00993988
16. Clausen C, Yoshinaka Y. Social shaping of technology in TA and HTA. *Poiesis & Praxis*. 2004;2(2–3):221–46. doi:10.1007/s10202-003-0046-1
17. Hofmann B. The technological invention of disease. *Med Humanit*. 2001 Jun;27(1):10–9. doi:10.1136/mh.27.1.10
18. Reuzel RP, van der Wilt GJ, ten Have HA, de Vries Robbé PF. Interactive technology assessment and wide reflective equilibrium. *J Med Philos*. 2001 Jun;26(3):245–61. doi:10.1076/jmep.26.3.245.3015
19. Popay J, Rogers A, Williams G. Rationale and standards for the systematic review of qualitative literature in health services research. *Qual Health Res*. 1998 May;8(3):341–51. doi:10.1177/104973239800800305
20. ten Have H. Ethical perspectives on health technology assessment. *Int J Technol Assess Health Care*. 2004 Winter;20(1):71–6. doi:10.1017/s0266462304000819
21. Reuzel R, Oortwijn W, Decker M, Clausen C, Gallo P, Grin J, et al. Ethics and HTA: some lessons and challenges for the future. *Poiesis & Praxis*. 2004;2(2–3):247–56. doi:10.1007/s10202-003-0054-1
22. Hofmann B. On value-judgements and ethics in health technology assessment. *Poiesis & Praxis*. 2005;3(4):277–95. doi:10.1007/s10202-005-0073-1
23. Hutton J, McGrath C, Frybourg J-M, Tremblay M, Bramley-Harker E, Henshall C. Framework for describing and classifying decision-making systems using technology assessment to determine the reimbursement of health technologies (fourth hurdle systems). *Int J Technol Assess Health Care*. 2006 Winter;22(1):10–8. doi:10.1017/s0266462306050781
24. Braunack-Mayer AJ. Ethics and health technology assessment: handmaiden and/or critic? *Int J Technol Assess Health Care*. 2006 Summer;22(3):307–12. doi:10.1017/s0266462306051191
25. Gauvin FP, Abelson J, Giacomini M, Eyles J, Lavis JN. “It all depends”: conceptualizing public involvement in the context of health technology assessment agencies. *Soc Sci Med*. 2010 May;70(10):1518–26. doi:10.1016/j.socscimed.2010.01.036
26. Daniels N, Sabin J. The ethics of accountability in managed care reform: recent efforts at reforming managed care practices have one thing in common: a call for accountability to consumers. *Health Aff (Millwood)*. 1998 Sep–Oct;17(5):50–64. doi:10.1377/hlthaff.17.5.50
27. Hofmann B, Cleemput I, Bond K, Krones T, Droste S, Sacchini D, et al. Revealing and acknowledging value judgments in health technology assessment. *Int J Technol Assess Health Care*. 2014 Dec;30(6):579–86. doi:10.1017/S0266462314000671

28. Scott AM, Bond K, Gutiérrez-Ibarluzea I, Hofmann B, Sandman L. Quality assessment of ethics analyses for health technology assessment. *Int J Technol Assess Health Care*. 2014 Dec;30(6):579–86. doi:10.1017/S0266462314000671
29. Arab-Zozani M, Sokhanvar M, Kakemam E, Didehban T, Hassanipour S. History of health technology assessment in Iran. *Int J Technol Assess Health Care*. 2020;36(1):34–39. doi:10.1017/S0266462319003489
30. Yazdizadeh B, Mohtasham F, Velayati A. Impact assessment of Iran's health technology assessment programme. *Health Res Policy Syst*. 2018 Sep 7;16(1):89. PMID:29471838
31. Mohtasham F, Yazdizadeh B, Zali Z, Majdzadeh R, Nedjat S. Health technology assessment in Iran: Barriers and solutions. *Med J Islam Repub Iran*. 2016 Jan 26;30:321
32. EUnetHTA. HTA core model version 3.0 for the assessment of diagnostic technologies, medical and surgical interventions, pharmaceuticals and screening technologies. Copenhagen: European Network for Health Technology Assessment (EUnetHTA); 2016 (<https://www.eunetha.eu/wp-content/uploads/2018/03/HTACoreModel3.0-1.pdf>, accessed 15 February 2023).
33. McCullough LB, Coverdale JH, Chervenak FA. Constructing a systematic review for argument-based clinical ethics literature: the example of concealed medications. *J Med Philos*. 2007 Jan–Feb;32(1):65–76. doi:10.1080/03605310601152206
34. Anttila H, Jacobsen CB, Koivisto J, Mortensen BB, Wiuff MB, Reiman-Möttönen P, et al. Social aspects. HTA core model for medical and surgical interventions 1.0 R: Copenhagen: European Network for Health Technology Assessment (EUnetHTA), FinOHTA; 2008:128–41 (<https://corehta.info/model/HTA%20Core%20Model%20for%20Medical%20and%20Surgical%20Interventions%201.0r.pdf>, accessed 15 February 2023).
35. Dixon-Woods M, Agarwal S, Jones D, Young B, Sutton A. Synthesising qualitative and quantitative evidence: a review of possible methods. *J Health Serv Res Policy*. 2005 Jan;10(1):45–53. doi:10.1177/135581960501000110
36. Strech D, Sofaer N. How to write a systematic review of reasons. *J Med Ethics*. 2012 Feb;38(2):121–6. doi:10.1136/medethics-2011-100096
37. Ekmekci PE, Güner MD. Evaluation of ethical analyses in seven reports from the European Network for Health Technology Assessment. *Int J Technol Assess Health Care*. 2019;35(4):273–9. doi:10.1017/S0266462319000485

Table 1. Frequency distribution of elements of the Q-SEA tool in Iranian health technology assessment reports published up to 2020

Element	Description	Rating					
		Yes		Partially ^a		No	
		No.	%	No.	%	No.	%
Process domain							
Research question	Was the research question clearly stated a priori ?	83	91.2	3	3.3	5	5.5
Literature search	Is the search for literature comprehensive?	76	83.5	8	8.8	7	7.7
Inclusion and exclusion criteria	Does the analysis clearly state inclusion and exclusion criteria?	75	82.4	10	11.0	6.0	6.6
Perspective	Is the analysis conducted from an impartial perspective? (i.e. considers how the technology impacts on various stakeholders : patients, health system, care providers, etc.)	12	13.2	25	27.5	54	59.3
Ethics framework	Does the analysis identify which ethics framework (s) it has adopted?	6	6.6	4	4.4	81	89.0
Output domain							
Completeness	Does the analysis acknowledge gaps in the ethical literature?	2	2.2	8	8.8	81	89.0
Bias	Are possible sources of bias identified?	4	4.4	6	6.6	81	89.0
Implications	Are policy implications identified?	9	9.9	16	17.6	66	72.5
	Are implications differentiated by stakeholder (e.g. patient, health professionals, policy-makers, health system, industry, etc.)	9	9.9	24	26.4	58	63.7
Conceptual clarification	Have key terms in the analysis been defined?	13	14.3	30	33.0	48	52.7
Conflicting values	Have potential conflicts of values been identified?	2	2.2	6	6.6	83	91.0

^aCan be inferred.

Table 2. Frequency distribution of elements of the core model questionnaire in Iranian health technology assessment reports published up to 2020

Topic	Issue	Rating					
		Yes		Partially		No	
		No.	%	No.	%	No.	%
Principal questions about the ethical aspects of technology	Is the technology a new, innovative mode of care, an “add on” to a standard mode of care or a replacement of a standard?	73	80.2	11	12.1	7	7.7
	Can the technology challenge religious, cultural or moral convictions or beliefs of some groups or change current social arrangements?	4	4.4	5	5.5	82	90.1
	What can be the hidden or unintended consequences of the technology and its applications for different stakeholders?	56	61.5	21	23.1	14	15.4
Autonomy	Does the implementation or use of the technology challenge patient autonomy?	9	9.9	1	1.1	81	89.0
	Is the technology used for patients/people that are especially vulnerable?	6	6.6	4	4.4	81	89.0
	Can the technology entail special challenges/risks that the patient/person needs to be informed of?	34	37.4	34	37.4	23	25.3
Human dignity	Does the implementation or use of the technology affect human dignity?	5	5.5	3	3.3	83	91.2
Human integrity	Does the implementation or use of the technology affect human integrity?	3	3.3	1	1.1	87	95.6
Beneficence/ non-maleficence	What are the benefits and harms for patients, and what is the balance between the benefits and harms when implementing and when not implementing the technology? Who will balance the risks and benefits in practice and how?	30	33.0	33	36.3	28	30.8
	Can the technology affected any other stakeholders?	7	7.7	5	5.6	79	86.8
	What are the consequences of implementing/ not implementing the technology on justice in the health care system?	4	4.4	7	7.7	80	87.9
Justice and equity	How are technologies presenting with relevantly similar (ethical) problems treated in health care system?	5	5.5	7	7.7	79	86.8