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Short research communication

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Abstract

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

Aims: To investigate the ethical soundness of HTA studies in Islamic Republic of Iran.

Methods: All HTA reports published by the HTA office until 2020 were reviewed using the HTA Core Model and the Q-SEA questionnaires.

Results: We evaluated 91 reports for ethical soundness. The research question, literature search and inclusion/exclusion criteria were included in 91.2%, 83.5% and 82.4% of the HTA reports, respectively. Only 13.2% of the reports explicitly stated the objective of the analysis and 6.6% stated the ethics framework. Only 2.2%, 4.4%, 9.9%, 9.9%, 14.3%, and 2.2%, respectively, of the reports, complied with the completeness, bias, policy implications, other implications, conceptual clarification, and conflicting values.

Conclusions: HTA reports in the Islamic Republic of Iran require coordinated and integrated framework acceptable to all stakeholders to ensure their compliance with sound ethical requirements.

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

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Introduction

Concerns about unassessed benefits and the high cost of healthcare interventions have led to the establishment of health technology assessment (HTA), a policy-oriented interdisciplinary process to inform decision-making (1–3). Similar schemes have been devised throughout the world by 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, 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 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 for evaluating ethical considerations about healthcare technologies (12,28). Examining ethical considerations in HTA reports may help improve the quality of reports.

In the Islamic Republic of Iran, HTA is not very old, it was introduced in the late 1990s. 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 healthcare technologies, this study examined the quality of ethical analyses of all HTA reports in the country.

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 Iranian government 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 the reports. Two appraisers carried out the assessment and rating at the same time; in case of any disagreement, discussion continued until a consensus agreement was reached on the rating.

The HTA Core Model questionnaire contains 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. We used the HTA Core Model for ethical analysis of HTA reports because most Iranian HTA researchers use this model for their assessments. The second tool used, the Q-SEA questionnaire, has 2 domains, the process domain and the outputs domain. 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).

Ethical 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 because it was a duplicate, another 3 were excluded because 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%. A description of items included in the HTA reports based on the Q-SEA tool is presented in Table 1 .

Using the HTA Core Model questionnaire (Table 2), we found that 80.2% of the 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. The relationship between the evaluated technology and the religious and cultural beliefs of some groups was only noted in 4.4% of the 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 healthcare system were mentioned in only 4.4% of the reports. A 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 development of the Iranian HTA reports using the Q-SEA tool, the focus has

been on evaluating the quality of the process regarding ethical analysis, and this study shows that 100% of the HTA reports included ethics in their systematic review. However, they did not respond to ethics in the patient, intervention, comparison, outcome (PICO) format as a systematic review of clinical evidence, as suggested by McCullough et al. (33).

Our review of the clinical aspects and effectiveness of the Iranian HTA reports used a search strategy to choose 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 noted in the inclusion criteria.

Because most researchers working on HTA projects believed that other aspects of HTA cover the ethical aspect, they did not conduct a separate ethical analysis. Therefore, in terms of inclusion and exclusion criteria, they also referred to studies on technology-related ethical issues and noted the study of such issues as inclusion criteria.

Less than 15% of the HTA reports we studied clearly stated that their analysis and assessment were unbiased. It should be noted that, when investigating the ethical aspect of technology, certain other methods are commonly used, for example convening an expert panel or focus group discussions that include clinical experts and decision-makers in the relevant field.

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 aspects of HTA based on the HTA Core Model (34). In contrast, we found that only some reports noted that the technologies were investigated using the HTA Core Model. There was no transparency in this regard, and stakeholders perceptions of the studied technologies were not examined .

Results relating to the output domain of the tool, which evaluated 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 the 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 has no effect on human dignity", "it does not affect patient autonomy", or "the studied technology enhances justice in access".

An interesting point about the reports that referred to ethical issues is the use of concepts 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 was also noted by Bellemare et al. in a systematic review (14) and Strech and Sofaer 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 used 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, although this was not mentioned in the reports. This shows the significant weakness of knowledge related to complex philosophical theories, ethical arguments and a lack of expertise in ethical justification methods for HTA studies. The technology-related ethical goals were discussed in only a few reports; these were not transparent and did not 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 enhancing the knowledge of experts in 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 critical appraisal of the ethical dimension of HTA reports is necessary to eliminate the existing gaps.

Acknowledgements

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Competing interests: None declared.

Validité éthique des rapports d'évaluation des technologies de la santé en République islamique d'Iran

Résumé

Contexte : L'évaluation des technologies de la santé (ETS) est une méthode conventionnelle permettant d'évaluer l'utilisation raisonnable des technologies de la santé dans de nombreux pays.

Objectif : Examiner la validité éthique des études ETS en République islamique d'Iran.

Méthodes : Tous les rapports d'évaluation des technologies de la santé (ETS) publiés jusqu'en 2020 par le bureau chargé de ces évaluations ont été examinés à l'aide du modèle ETS principal et des questionnaires Q-SEA.

Résultats : Nous avons évalué la validité éthique de 91 rapports. La question de recherche, la recherche dans la littérature et les critères d'inclusion et d'exclusion étaient inclus dans 91,2 %, 83,5 % et 82,4 % des rapports ETS, respectivement. Seuls 13,2 % des rapports mentionnaient explicitement l'objectif de l'analyse et 6,6 % en indiquaient le cadre éthique. Parmi les rapports, seuls 2,2 %, 4,4 %, 9,9 %, 9,9 %, 14,3 % et 2,2 %, respectivement, étaient conformes aux exigences en matière d'exhaustivité, d'impartialité, d'implications par rapport aux politiques ou autres, de clarification conceptuelle et de valeurs conflictuelles.

Conclusion : Les rapports ETS en République islamique d'Iran nécessitent un cadre coordonné et intégré qui soit acceptable pour toutes les parties prenantes, afin de garantir leur conformité avec des exigences éthiques bien fondées.

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WHO EMRO | Ethical soundness of health technology assessment reports in Islamic Republic of Iran

: قيّمنا 91 تقريرًا عن السلامة الأخلاقية . وأُدرج سؤال البحث، والبحث فيالنتائ ج
المؤلفات، ومعايير الإدراج / الاستبعاد في 91.2%، و 83.5%، و 82.4% من تقارير تقييم
التكنولوجيات الصحية، على التوالي . وأوضحت 13.2% فقط من التقارير صراحةً هدف
التحليل، وذكرت 6.6% منها إطار الأخلاقيات . وقد امتثل فقط 2.2%، و 4.4%، و 9.9%، و 9.9%،
و14.3%، و 2.2% من التقارير، على التوالي، للاكتمال، والتحيز، والآثار المترتبة على
السياسات، والآثار الأخرى، والإيضاحات المفاهيمية، والقيم المتضاربة .

: تتطلب تقارير تقييم التكنولوجيات الصحية في جمهورية إيران الإسلاميةالاستنتاجات
إطارًا منسقًا ومتكاملًا، ويكون مقبولًا من جميع أصحاب المصلحة لضمان امتثالهم
للمتطلبات الأخلاقية السليمة .

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