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Abstract

Purpose – According to the great importance of community health as well as the ever-increasing development of health technologies, the importance of designing an interactive model of factors affecting health technology assessment (HTA) can be highlighted. The purpose of designing and implementing the framework of health information system assessment is to ensure that the required accurate data which are necessary to measure the main health indicators are available. The purpose of this paper is to design an interactive model of factors affecting HTA.

Design/methodology/approach – This is a cross-sectional, descriptive-analytic study conducted in the Iran Ministry of Health and Medical Education in the second half of 2017. A sample of 60 experts and professionals working in the field of health technologies are selected using purposive and snowball sampling methods. Two researcher-made questionnaires are used to collect the required data. The collected data are analyzed using decision-making trial and evaluation laboratory (DEMATEL) and MATLAB R2013a.

Findings – The results showed that "Legal dimension," "safety," "Effectiveness" and "Social dimension" were the affecting factors and net causes, and "Current application," "Knowledge of technology," "Ethical dimension," "Costs" and "Organizational dimension" were the affected factors and net effects in the interactive model. Furthermore, "Legal dimension" with the coordinates C: [1.88, 1.27] and "Ethical dimension" with the coordinates C: [1.75, −75] were known as the most affecting and most affected factors in the interactive model, respectively.

Originality/value – The DEMATEL model is an appropriate tool for managers and policy makers to structure and prioritize factors influencing the HTA. Policy makers and decision makers can use this model for identifying relationships among factors and prioritize them. Because health policy makers and managers have a major role in formulating the regulations and guidelines related to the HTA, they should pay more attention to the legal considerations in their decisions and use the management tools to move the available resources toward implementing and enforcing rules and guidelines related to the HTA.

Keywords Health care quality, Qualitative research, Health policy, Information technology, Organizational development for effective clinical governance, Health economics

Paper type Research paper

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Introduction

The concept of health technology assessment (HTA) was introduced in 1976 and then increased dramatically. The health system of each country reflects the history, culture, values and preferences of that country. This is also related to the HTA, which is part of the health system. Therefore, any final conclusion about the HTA may be gradual, and excessive dependence on details is wrong. People who assess the health technologies have not made the HTA concept clear, and thus it is difficult to give a proper description of HTA activities.

"Technology" can be defined as a systematic application of scientific knowledge, and also "Health Technology" can be defined as "medications, devices, and medical and surgical procedures used in health care, as well as organizational and supportive systems in which such care is provided" (Banta and Jonsson, 2009).

Health technologies create continuous challenges for health systems because their uses may require additional resources (not just financial resources) or may re-distribute resources in the health system. Therefore, it is essential to ensure that the health technologies are evaluated properly and used efficiently and effectively for health care. For optimal use of available resources, the most effective technologies should be promoted and used in the context of organizational, social and ethical issues (Naser Hamze Khanloo and Bazyar, 2010). Moreover, limited health care budgets have increased the need for rational allocation of public resources. As a result, most health care providers often ask the drug manufacturers to express the benefits of their new drugs before paying for them. Health policy guidelines and payment decisions are often made by the HTA agencies. These agencies assess the therapeutic value and the cost effectiveness of health technologies (Allen *et al.*, 2017).

The health system technologies include medications, biological substances, devices, equipment and supplies, medical and surgical procedures, support systems, management and organizational systems. The technologies can be classified according to their health care objectives into prevention, screening, diagnosis, treatment and rehabilitation. Also, the areas studied in the HTA are technology applications, technical features, safety, performance, effectiveness and economic aspects. Therefore, it is essential to ensure that health technologies are evaluated properly and then used in the health care provision effectively. The HTA can reduce the use of technologies that are unsafe, inefficient or those technologies whose costs are too high in relation to their interests (Naser Hamze Khanloo and Bazyar, 2010).

HTA is a multidisciplinary process for analyzing information on medical, social, economic and biological issues used by policy organizations (Wortley *et al.*, 2016). On the other hand, HTA is required to prioritize and allocate the health care resources. Many Asian countries use HTA in the decision-making processes, especially in the face of expensive technologies. These countries need HTA due to the aging population which causes increased health risks (Ngorsuraches *et al.*, 2017).

While HTA is often carried out at the national or international level, many local health service providers and hospitals believe that assessment should be done close to the care point, where the costs, effects and benefits of the technologies can be directly evaluated. Because many decisions related to the health technologies, including prioritization, investment, etc., are made at the local or hospital level (Gagnon *et al.*, 2014), most HTAs are still focused on clinical medicine, especially on medications, and are less focused on public health interventions (PHIs). The results of a study conducted in 2010 in five countries showed that only 5 percent of HTAs were focused on public health (Mathes *et al.*, 2017). The goal of HTA is to help the health policy and health technology decision-making processes. HTA is a strong basis for research on what affects health and the wide impacts of using technologies in health care (Garrido, 2008). Another goal of HTA is to ensure that the values and benefits of the technologies are higher than their costs of purchase (Akehurst *et al.*, 2017).

There is a greater awareness of the need to integrate ethics into the HTA process. This need is due to the recognition of ethical issues which result in more transparency, accountability and,

ultimately, better health care decisions. The health technology assessors, in addition to the results of economic assessments, are highly concerned with issues of environmental norms and value judgments. Integrating ethical issues into the HTA is very challenging. One of the key challenges is the multiplicity of ethical practices, which should be understood by the experts in this field. The next challenge is the systematic review of available evidence which HTA agencies often refuse to accept and follow these ethical guidelines because of their complexity and their need for skilled and expert manpower, other resources and time (Assasi *et al.*, 2016).

The results of Naser Hamze Khanloo and Bazyar's (2010) study indicate that HTA has been used in many countries to rationalize technologies, control costs and prevent the entry of low safety and effectiveness technologies into the market.

The results of Makady *et al.* (2017) study on six European HTA agencies showed that policies for real-world data (RWD) use in relative effectiveness assessments of drugs were different across contexts and between HTA agencies. They finally concluded that more alignment of policies were necessary for facilitating the use of RWD for HTA across Europe (Makady *et al.*, 2017). Morton (2017) in a study performed two tests for multi-criteria decision analysis (MCDM) models in HTA and investigated why models may fail such tests and, finally, made some suggestions as to how practice should be improved. In another study, Oortwijn *et al.* (2017) presented a framework for evaluating the comprehensiveness level of the HTA process in a country and, according to this framework, they offered some recommendations on how the HTA community could change into a more integrated decision-making process using HTA.

In recent years, the use of health technologies for diagnosing and treating diseases has been expanded. However, in the use of such technologies, it should be noted that they, while helping to diagnose and treat diseases, may be increase the costs of the health system through the inaccurate assessment and evaluation and lack of setting priorities. All health technologies should be evaluated by health care organizations (Bridges and Jones, 2007). Therefore, policy and decision makers need to use scientific decision-making methods. In some studies conducted in Canada, the analytic hierarchy process and multi-criteria decision-making methods have been used to prioritize health technologies (Goetghebeur *et al.*, 2010; Husereau *et al.*, 2010). Another study suggests that there should be a good link between decision making and HTA (Pichon-Riviere *et al.*, 2018). Careful assessment of health technologies requires reliable data (Downey *et al.*, 2018). Today, decision makers use different methods to make decisions, one of which is decision-making trial and evaluation laboratory (DEMATEL). DEMATEL is one of the group decision-making techniques used to structure factors affecting a phenomenon or system, and prioritizes factors and divides them into two affecting and affected groups (Bahadori and Ravangard, 2013), understanding the priorities of a system, as well as identifying factors affecting that provides a good opportunity for making the right decisions and formulating appropriate strategies. In the field of HTA, by the use of the DEMATEL model, priorities for decision making are set. The present study aimed to identify factors influencing HTA, prioritize them and determine the most influential factors. Therefore, what is important in this model and can be helpful is that in Iran, health technology policy makers should pay attention to these priorities when deciding on new health technologies. Other health care organizations can also use this method to prioritize.

Methods

This was a cross-sectional, descriptive-analytic study conducted in the Iran Ministry of Health and Medical Education in the second half of 2017 in order to investigate the health technology experts' viewpoints on the analysis of systematic relationships among factors affecting the HTA and provide an interactive model in Iran. A sample of 60 experts and professionals working in the field of health technologies were selected using purposive and snowball sampling methods. Their specialties were Medicine, Health Policy, Health Services Management, Health Economics, Business Management and Information Technology.

Two researcher-made questionnaires were used to collect the required data. The first questionnaire consisted of two parts. The first part contained items related to the participants' demographic data, and the second part included items related to nine factors of HTA. A five-point Likert scale was used in which 1 referred to "strongly disagree" and 5 to "strongly agree." In this questionnaire, a schematic representation of the primary model and its description was provided for the experts to get their viewpoints on this model. The second questionnaire consisted of 36 items, in which each two factors of the model were compared mutually. In this questionnaire, the relative importance of factors was determined using the pair-wise comparisons with a scale of 1 (equal importance) to 9 (extreme importance).

In this study, the "Current application" included the epidemiology of diseases, the burden of diseases on the individual and society, the variety of technologies used in different countries, regions and programs, how to manage diseases, the need for disease management based on guidelines, alternative and evidence-based interventions, technology development stage, status of international technology approval, technology coverage in other countries and technology manufacturers.

The "Knowledge of technology" included the characteristics of technologies, the capital and tools necessary for technology application, and the training and information needed for technology application.

The "Safety" included the identification and evaluation of injuries, effects of injuries, minimizing injuries and environmental safety.

The "Effectiveness" included the mortality, morbidity, quality of life and patients' satisfaction.

The "Costs" included the utilization of resources, unit costs, indirect costs, outcomes and cost effectiveness.

The "Ethical dimension" included the religious beliefs, authority, humanity and dignity, human perfection, harmfulness of technologies and equity.

The "Organizational dimension" included the structure, process and management.

The "Social dimension" included the important issues of patient's life, patients and other stakeholders' perceptions, and patients and other stakeholders' knowledge.

The "Legal dimension" included the patients' privacy, security, market rules, and existing and required rules of new technologies.

The validity of the first questionnaire was approved using content validity ratio (CVR) and content validity index (CVI) ($CVR = 0.75$, $CVI = 0.76$). Their reliability was also confirmed using Cronbach's alpha coefficient ($\alpha = 0.76$ and 0.85, respectively).

For collecting the required data, the first author referred to the Ministry of Health and Medical Education and explained the aim and methods of the study to the Director of HTA unit and studied experts and participants, and then the questionnaires were completed in person or through sending via the studied experts' e-mail. The data collection took a month.

For analyzing the descriptive data collected using the first questionnaire, SPSS 21.0 and descriptive statistics, including mean, standard deviation, frequency, etc., as well as one-sample T-test were used and the mean scores were compared with 3.75. If the average score of the answers for each question received 75 percent of the total score, it meant that the studied experts were agreed on the question. Given that the score of each answer was between 1 and 5, the 75 percent of the total score, i.e. 5, was equal to 3.75. Therefore, $H_1 = \mu \geqslant 3/75$.

To analyze the data collected by the second questionnaire, DEMATEL was used. DEMATEL is one of the scientific techniques used for structuring the factors influencing a phenomenon, which, in an interactive structure, divides the factors into two categories of affecting and affected factors. These collected data were analyzed using MATLAB R2013a. In general, the steps of applying DEMATEL technique were as follows:

(1) identifying the relationships among the factors using a pair-wise comparison questionnaire completed by the studied experts;

(2) forming the matrix of the intensity of relationships (matrix M);

(3) forming the matrix of the relative intensity of the direct relationships ($M = \alpha \times M$; the maximum sums of matrix rows = Mα);

(4) forming the matrix of the available relative intensity of direct and indirect relationships (matrix M(1−M)−1); and

(5) identifying the hierarchy of factors (with a diagram) (Bahadori and Ravangard, 2013).

In DEMATEl graph, R (the highest sum of rows) represents the order of factors affecting other factors. J (the highest sum of the columns) represents the order of factors affected by other factors. $R–J$ represents the position of a factor along the vertical axis. If it is positive, the factor is definitely an affecting factor and, if negative, this will be definitely an affected factor. $R + J$ represents the sum of the intensity of a factor along the horizontal axis, both in terms of being affecting and being affected. In other words, each factor has a length and a width whose length is $R + J$ and its width is $R–J$.

Obtaining oral-informed consent from participants before conducting the study, retaining anonymity, ensuring confidentiality of responses and observing the participants' rights of withdrawing from the study at any time were some of the ethical considerations in the present study.

Results

The results showed that most participants were male (66.7 percent), in the 35–45 age group (40 percent), had a PhD degree (60 percent), studied in the Health Services Management (33.3 percent) and had five to ten years' work experience (80 percent). Also, the results showed that the mean score of all proposed factors were significantly more than 75 percent of the total score. Therefore, the studied experts were agreed on all of the proposed factors (Table I).

Moreover, the results showed that "Legal dimension," "safety," "Effectiveness" and "Social dimension" had been placed above the horizontal axis of the coordinate system because their $R–J$ was positive. Therefore, they were known as the affecting factors and net causes in the interactive model.

Also, "current application," "Knowledge of technology," "Ethical dimension," "Costs" and "Organizational dimension" had been placed below the horizontal axis of the coordinate system because their $R–J$ was negative. Therefore, they were considered as the affected factors and net effects in the interactive model (Table II).

Furthermore, "Legal dimension" with the coordinates C: [1.88, 1.27] and "Ethical dimension" with the coordinates C: [1.75, −75] were known as the most affecting and most affected factors in the interactive model, respectively (Figure 1).

Table I. The studied experts' viewpoints on the proposed factors affecting the HTA in Iran

	The studied experts' responses							
Factors affecting the HTA	Strongly agree	Agree	No comment	Disagree	Strongly disagree	Mean	SD	p-value
Current application	24	30	6	2	0	4.2	0.76	< 0.001
Knowledge of technology	24	34	2	2	0	4.26	0.69	< 0.001
Safety	42	18	0	0	0	4.7	0.46	< 0.001
Effectiveness	44	16	0	0	0	4.73	0.4	< 0.001
Costs	38	20	2	0	0	4.6	0.56	< 0.001
Ethical dimension	36	32	10	0	0	4.13	0.68	< 0.001
Organizational dimension	22	26	10	2	0	4.13	0.81	< 0.001
Social dimension	28	36	8	2	0	4.03	0.71	< 0.001
Legal dimension	28	24	8	0	0	4.33	0.71	< 0.001

Discussion

Significant growth of health technologies in the fields of equipment, medicine, telemedicine and diagnostic tools in recent years has made considerable advances in improving health, providing care and treatment, as well as improving quality of life for all people (Barbash and Glied, 2010). Indeed, health product manufacturers, physicians, patients, hospital managers, payers, political leaders and others, in order to support their decisions, are increasingly seeking information collected appropriately on how to implement and use technologies, how to allow technology supply in the market, how to get technologies, how to pay for technologies, etc. (Abbasi and Arbalo, 2012). Because of the limited comprehensive studies on the factors affecting HTA, the present study aimed to design an interactive model of such factors and review and prioritize them in order to support future decisions in the health care system.

Considering that various decisions are taken at all levels of the countries' health care systems about the use of technologies, which often lead to a kind of coordination among

Table II.
The hierarchy of affecting and affected factors of the HTA in Iran from the studied experts' viewpoints

Factors	*R*	*J*	*R+J*	*R–J*
Current application	0.6318	1.3633	1.3633	–0.7315
Knowledge of technology	0.7168	0.8973	1.6141	–0.1805
Safety	1.0670	0.4532	1.5202	0.6138
Effectiveness	1.1567	0.5887	1.7454	0.5680
Costs	0.6305	1.0718	1.7023	–0.4413
Ethical dimension	0.4978	1.2557	1.7535	–0.7579
Organizational dimension	0.7897	1.1733	1.9630	–0.3836
Social dimension	0.8256	0.7859	1.6115	0.0397
Legal dimension	1.5815	0.3082	1.8897	1.2733

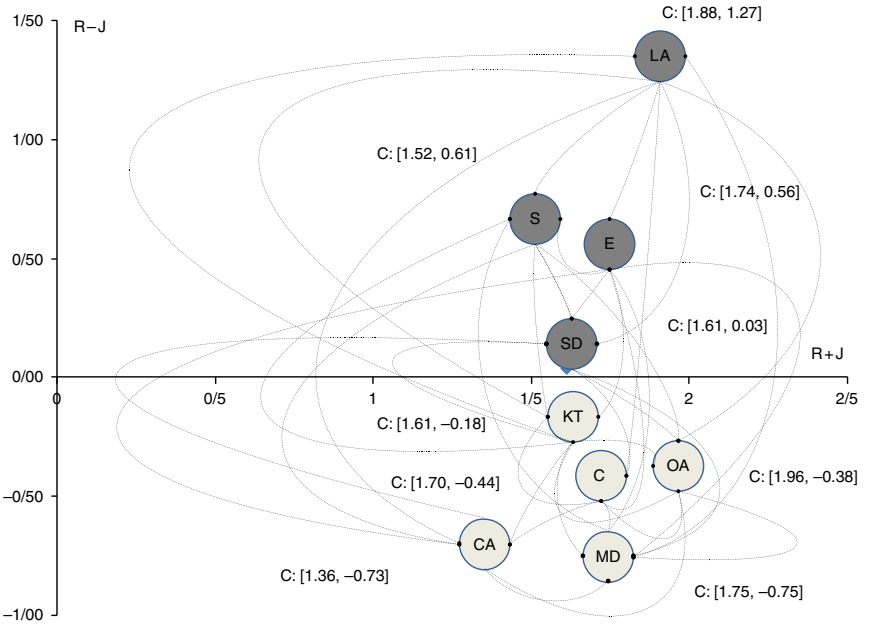

Figure 1.
The relationship of factors affecting the HTA in Iran from the studied experts' viewpoints

complex medical issues, patient-related issues and organizational, economic and ethical factors, reviewing the interactions, division of labor and collaboration among health professionals, decision makers and health care managers is very important (Farnoudi, 2009). In short, it can be said that HTA is as a bridge between the world of research and the world of decision and policy making (Barbash and Glied, 2010). On the other hand, health is a universal right and international organizations and governments emphasize it. According to the great importance of community health as well as the ever-increasing development of health technologies, and economic, social, political and ethical issues associated with the deployment of these technologies, the importance of prioritizing the assessment of health technologies can be highlighted (Abbasi and Arbalo, 2012).

Leys (2003) in a study has stated that some assessment agencies only need data of effectiveness, while others need cost-effectiveness evidence. This can be complemented by evidence of organizational, social and ethical issues of a product (Leys, 2003). Abbasi and Arbalo (2012), in their study, have mentioned that technology assessment is a comprehensive form of policy research that examines the short-term and long-term social consequences of technology use. They also believe that HTAs are not carried out in the vacuum, but always are conducted in a social and value context (Abbasi and Arbalo, 2012).

In the present study, nine factors affecting the HTA were studied. The results of the current study showed that "Legal dimension," "safety," "Effectiveness" and "Social dimension" were known as the affecting factors and net causes in the interactive model. Oortwijn *et al.* (2017) in their study concluded that in middle-income countries, the focus was on increasing standardization of methods and developing guidelines, and there was often no clear legal framework for implementing and using HTA results in the decision-making processes. Ham (1997) also in a study shows that, in addition to the prioritization of health care services, decision-making processes need to be more accountable and more transparent, and the governments have used various strategies to address such issues, mainly through laws and regulations and financing projects. In Koohpaei *et al.*'s (2011) study, it has been indicated that usually rules and regulations, instead of facilitating works and activities, have become a factor for impediments and slowness.

Perry *et al.* (1997) in their study conclude that National Institute for Clinical Excellence addresses issues of efficiency, safety, efficacy and costs during its HTAs. Naser Hamze Khanloo and Bazyar (2010) in their study show that safety and side effects of technologies remain long unknown, and this leads to the increases in the health sector costs and, therefore, it is essential to ensure that health technologies are evaluated properly and used efficiently and effectively for health care. They finally suggest that for optimal use of available resources, the most effective technologies in terms of organizational, social and ethical issues should be promoted and used (Naser Hamze Khanloo and Bazyar, 2010). Mathes *et al.* (2017) in their study believe that HTA can help the health managers at different levels of health systems in their decision making in terms of efficiency and effectiveness. They also conclude that, in general, the approaches used for carrying out the HTAs of PHIs appear to be broader and more flexible than those used for clinical interventions, and the desire to identify the components of interventions and other factors affecting the effectiveness is great (Mathes *et al.*, 2017). Kanavos *et al.* (2010) in their study conclude that safety is considered by all organizations. However, it seems at different levels that agencies and organizations have different emphases on the outcomes in terms of efficiency, effectiveness and safety (Kanavos *et al.*, 2010). Arab Zozani *et al.* (2014) in their study have shown that the selected strategies used in the UK, Sweden and Wales to empower HTA outcomes have included collecting information about equity, social benefits and patients' preferences.

Considering that in the present study, "Legal dimension," "Safety," "Effectiveness" and "Social dimension" were recognized as the factors affecting the HTA, paying more attention to the costs and economic evaluations, as well as ethical and organizational dimensions is necessary.

In the current study, "Current application," "Knowledge of technology," "Safety," "Ethical dimension," "Costs" and "Organizational dimension" were considered as the affected factors and net effects in the interactive model. Naser Hamze Khanloo and Bazyar (2010) in their study have stated that HTA is used in many countries for the rational use of technologies, cost control, and prevention of introducing low safety and efficiency technologies. Aminpoor and Sadooghi (2011) have mentioned in their study that some believe that organizational and social factors constitute the main elements of health information systems. In recent years, the outcomes of comprehensive HTA projects have been seen in countries such as Denmark, Germany, Sweden, the Netherlands, Finland, France and the UK (Abbasi and Arbalo, 2012).

The UK Health Services Research and Development unit in the definition of HTA has stated that HTA is paying attention to the technology costs. The health system technologies may have some benefits, however, it should be noted that to what extent the people's health is improved in comparison with the new technology costs (Naser Hamze Khanloo and Bazyar, 2010). Gagnon *et al.* (2014) in their study have stated that the costs, outcomes and benefits of technologies can be directly evaluated. Abbasi and Arbalo (2012) in their study emphasize that the spread and diffusion of health technologies has been accompanied by a sharp increase in the health care costs, and it has been considered for the first time as one of the reasons for cost increases, although the nature of this relationship is complex and evolving. In the current era which is accompanied with the rises in cost pressures, restructuring of payment systems and health care provision, and inadequate permanent access of millions of people to health care around the world, according to one technology commentator, an increase in this cost has become a health care opiate (Abbasi and Arbalo, 2012) Kanavos *et al.* (2010) in their study concluded that although there were some wanderings in clinical, safety and economic conditions, But with regard to the information provided by various HTA organizations, the economic dimensions of treatment are usually assessed through cost effectiveness (Kanavos *et al.*, 2010) Aminpoor and Sadooghi (2011) in their study have stated that some researchers believe that the framework of health information system assessment consists of three main factors, including human factors, organizational factors and technical factors.

In the present study, two factors of "Legal dimension" and "Ethical dimension" were identified as the first and last priorities and, in other words, the most affecting and the most affected factors, respectively. Naser Hamze Khanloo and Bazyar (2010) in their study have stated that the legal considerations have not much been considered in the HTA carried out in most countries. However, today, the need to address the legal dimension of technology assessment projects has well been known (Naser Hamze Khanloo and Bazyar, 2010). The legal dimension in the results of the present study had been considered by the studied experts as a factor which had the greatest impact on other factors related to the HTA, so that components such as patient rights (related to the informing about technology alternatives, obtaining informed consent before implementing technology indication and having enough time for decision making), equity in the health system, authority and security, market rules, patient privacy and legal issues related to the new technologies had the greatest effects on the technology selection and HTA. Because health policy makers and managers have a major role in formulating the regulations and guidelines related to the HTA, they should pay more attention to the legal considerations in their decisions and use the management tools to move the available resources toward implementing and enforcing rules and guidelines related to the HTA.

Limitation of study

The current study had a limitation which was the lack of transparency in the choice of technologies. This can exacerbate tension among stakeholders and may create challenges in the process of reviewing and revising the decisions. Without a transparent process, the

methods of prioritization of and decision-making on a specific technology may be assessed inappropriately or with error. This can distort the clinical policies and practices regarding the interventions which are not well evaluated and those for which there are less legal barriers.

The results of studies have also shown a wide gap between ethics and technology assessment, which have several reasons, some of which are: most technologies are considered ethically neutral by the HTA suppliers; the only issues that are considered appropriate are technical and economic issues; there are often difficulties in integrating ethical considerations into HTAs; and the training of health technology assessors and available resources for ethical analyses are often limited (Barbash and Glied, 2010). In the current study, "Ethical dimension" had been recognized as the most affected factor, so that the factors such as legal dimension, safety, effectiveness and social dimension could have the greatest effects on the studied HTA factors, human dignity and perfection, no harmful technology and equity, which are among the components of the ethical dimension.

The current study had a limitation. The issue of lack of transparency in the choice of technologies was not mentioned. This can exacerbate tension among stakeholders and may create challenges in the process of reviewing and revising the decisions. Without a transparent process, the methods of prioritization of and decision-making on a specific technology may be assessed inappropriately or with error. This can distort the clinical policies and practices regarding the interventions which are not well evaluated and those for which there are less legal barriers.

Conclusion

Significant growth of health technologies in the fields of equipment, medicine, telemedicine and diagnostic tools, as well as the health managers, political leaders, physicians and patients' needs for supporting their decisions on technology implementation and allowing their spread and diffusion in the health market have led them to seek related useful information. The DIMATEL model is an appropriate tool for managers and policy makers to structure and prioritize factors influencing the HTA. Policy makers and decision makers can use this model for identifying relationships among factors and prioritize them. Because health policy makers and managers have a major role in formulating the regulations and guidelines related to the HTA, they should pay more attention to the legal considerations in their decisions and use the management tools to move the available resources toward implementing and enforcing rules and guidelines related to the HTA.

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