

# Future of Health Technology Assessment System in Iran: Necessity of Reinforcement in Both Scenarios of Continuation or Relief of Sanctions

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## Abstract

**Background:** In Iran, health technology assessment (HTA) system dates back to nearly a decades ago (2008).

**Objectives:** The current study aimed to define steps required to expand HTA in Iran by emphasizing possible future events related to the health sector.

**Methods:** A preliminary list of future trends potentially influencing Iran's HTA system was extracted through the literature review. Then, the trends were presented to 12 experts to obtain their opinions. Afterward, their influence on the future of the HTA system in Iran was investigated using in-depth interviews. The interviews were analyzed using the thematic analysis method; Initially, in three categories of capacity building, provision of HTA, and supportive mechanisms, and then according to the essential functions of a health system (i.e., control knobs).

**Results:** Interviewees believed that strengthening the HTA system is mandatory, regardless of future political events. In the category of capacity building, adjusting training to the needs, using the capacity of graduates in conducting HTAs, training more students in the HTA profession as well as the establishment of a Ph.D. program, turning HTA into public demand, and preventing overuse of medical technologies were elaborated. In the second category (i.e., provision of HTA), the following themes were extracted: modernization and equipping of health system infrastructure based on the evidence provided by HTA, the legitimization of HTA to be used for all health technologies, preventing the introduction of unnecessary technologies and similar technologies that are currently using in Iran, and employing HTA in developing the basic benefit package.

**Conclusions:** Due to international sanctions, Iran has a niche healthcare market. If sanctions continue, HTA would be a serious necessity to increase the resilience of the health system. In the case of sanctions relief, HTA is still necessary for the optimization of allocating resources. These steps, in both scenarios, are mostly related to the institutionalization of HTA, mostly on the legitimization of HTA and behavioral changes.

**Keywords:** HTA, Sanction, Iran

## 1. Background

Because of several limitations that health systems are faced, decisions, especially those related to the utilization of health technologies, should be based on practical evidence as well as basic considerations. In this line, several countries have developed unique mechanisms to respond to their needs by emphasizing two main goals of controlling healthcare expenditures by optimal allocation of resources and preventing utilization of ineffective and hazardous health technologies (1, 2).

The health system of the Islamic Republic of Iran, similar to other countries, is faced with two main challenges of the growing demand for health services and soared health expenditures. According to the country's consti-

tution, all Iranians have the right to equitable access to health services. Hence, it can be argued that the Iranian healthcare system seeks a justice-oriented approach (2). Based on the National Vision Statement of Iran, the country should rank the first among countries in the region concerning indicators related to the health system (3). Nevertheless, there is a deep health inequality gap, which has negatively and deeply affected the community's satisfaction with health services. During the last decades, Iran governments have developed programs to reduce discrimination. Developing an effective HTA system can help to reduce health-related inequalities by promoting the effective use of health services. On the other hand, it



also can improve the performance of the country's health system.

In addition to the aforementioned challenges, old hospital infrastructure along with out of date medical equipment are other important challenges that passing sanctions against Iran by United Nations Security Council in 2012. As a result, due to severe restrictions on financial transactions of Iran, importing medical equipment was difficult (3). Almost 6 million patients with non-communicable diseases could not receive necessary treatments because of sanctions prior to Joint Comprehensive Plan of Action (JCPOA). At the beginning of 2016, the Deputy of Infectious Disease Control Center of the Ministry of Health and Medical Education (MoHME) of Iran announced that "60% of isolated rooms of hospitals are old, out of date, or even out of service and they should be standardized" (4). A new round of US-issued sanctions has been imposed on Iran since November 2018, intended to bring Iran's oil export to zero. The sanctions always waived activities related to finished products and raw material for essential medicines and medical equipment, which includes a wide range of medication (5).

The MoHME initiated its national HTA programs in 2008. The HTA bureau of MoHME, on the other hand, was established in 2010. In addition, in this year, the National Institute of Health Research (NIHR) was assigned by HTA bureau to implemented research in the field of HTA. Based on the processes and roles determined for the NIHR, this institution should provide responses for the tasks assigned by the MoHME according to the request for proposals. By the end of 2017, more than a hundred proposals were approved by the NIHR. In addition, NIHR joined HTA International in 2017 and launched a new scientific journal, titled HTA in Action (1). Furthermore, since 2010, the Tehran University of Medical Sciences is holding a Master of Science (M.Sc.) program in HTA. Three other ministries are also holding M.Sc. programs in HTA (6).

The importance of HTA in Iran long-term prospective health policies reached the point that the Supreme Leader of Iran has endorsed them. These polices have been described in three clauses (out of fourteen clauses) of General Health Policies of the Government, as below: (a) Organizing demand for and preventing induced demand as well as promoting prescription based on the regionalization and clinical guidelines, generic drugs, and promoting domestic production and export development; (b) promoting evidence-based decision-making and developing standards and guidelines based on the HTA; and (c) Developing evidence-based tariffs for health care services by considering real added value and equality of technical tariffs for both public and private sectors (7). Although Iran has taken more steps toward the implementation of HTA compared to its neighbor counties in the Eastern Mediterranean region, but the country is faced with a wide range of challenges. Neglecting current and future (possible) challenges may lead to inefficiency

or even failure of this plan (8).

Nowadays, utilization of fore-sighting studies has expanded widely, and many countries have defined, developed, and implemented national fore-sighting projects in periodic intervals. From the middle of the 20th century, fore-sighting studies have turned into a part of strategic knowledge, which can define long-term, short-term targets and estimate necessary resources (9). Kaló et al. published the HTA plan of Central and Eastern European countries (10). Moreover, Rosseli et al. performed a similar study on the HTA plan of Latin American countries. They investigated the development capacity of HTA programs, financial resources, legitimation status, quality, and reports transparency, and international collaboration were studied (11).

With respect to the importance of HTA programs and many uncountable advantages accompanied with such assessment and by considering that no unique study in the field of fore-sighting of HTA with the aim of reforms has been performed in Iran, the current study used the STEEP method and health systems' control knob to provide a picture of future of HTA in Iran. The control knobs consist of several critical functions of a health system, including financing, payment, organization, regulation, and behavior (12).

## 2. Objectives

The current study intended to foresight the HTA system in order to provide information for improving such systems.

## 3. Methods

Maximum variation sampling was used for selecting participants of the qualitative stage. We tried to use informed participants from various fields. To increase the comprehensiveness of the sampling process, participants were classified into four different groups of public policymakers, health system policymakers, stewards of HTA, and health service providers (Table 1). Then, snowball sampling was used to select participants from each group. In total 12 face-to-face, semi-structured interviews were performed from March-June 2017. All interviews were performed by the first author. Before initiating the interviews, the objectives of the study were described, and, if agreeing, the verbal consent of the interviewee was recorded. In the first step, using the previous fore-sighting studies, a preliminary list of trends that may affect the HTA in Iran, categorized in five different fields of social, political, technological, environmental, and economic, was provided (Table 2) (13). On average, interviews lasted for about 40 minutes. All interviewees were asked to either revise or add items to the list. Then, they were asked to provide their opinions on the effects of these trends on the future of HTA in Iran and to discuss the course of actions accordingly.

**Table 1.** Sampling Groups and Working Office, or Organization of Interviewees

Beneficiaries	Office/Current Positions	Code
Public policy-makers	Iranian deputy foreign minister and Islamic parliament	PP1-3
Health policy-makers	Food and Drug Administration and Consulter of strategic planning	HP1-3
HTA trustees	National Institute of Health Research	HTAA1-2
Health providers	Public and private organizations	SP1-4

**Table 2.** Categorized Possible Trends in The Future of Iran's HTA System.

Domain	Description
<b>Social</b>	Increase in the burden of chronic diseases, an increase in the average population age and life expectancy as well as a decline in fertility rates
	Increasing demand for advanced academic degrees
	Increasing demand for a luxury lifestyle in public
<b>Technological</b>	Advances in high-tech products such as micro-technology and bio-technology
	Technology transfer will be facilitated by other countries
	Implementation of information and communication infrastructure in the health care system
	Consideration of evidence-based medicine in the health care system
<b>Environmental</b>	Global Warming, increased natural disasters, and accidents rates
<b>Economic</b>	Removing economic sanctions and economic growth can be achieved using this trend
	Rising in the health care system budget deficits
<b>Political</b>	Aggressive controversial policies over Iran will continue by the USA and EU
	Implementing privatization policies according to Principle 44 of the Constitution of the Islamic Republic of Iran
	Challenges among political parties and policy-makers concerning healthcare system policies and approaches will be continued
	Involvement of management specialists at the macro level

In order to ensure the quality of the findings, all interviews were recorded by two recorders, and also the analysis process was performed by two independent researchers. By comparing the findings obtained by each of the two researchers and discussing the differences, the codes were finalized. After performing interviews and transcribing them, the analysis was performed using the thematic framework. All transcripts were evaluated, and the researchers discussed the themes based on the two aforementioned dimensions. The first dimension, which contained three categories of capacity building, provision of HTA, and supportive mechanisms, was defined in advance. The second dimension was a classification of critical functions according to the health systems con-

trol knobs (discussed previously). Themes were classified into the smallest meaningful units. To better identify the codes, a previously conducted study by Rosseli was used (11). The current study is approved by the Ethical Committee of Tehran Medical University. Also, all principles of the Helsinki Declaration and its future amendment are observed.

#### 4. Results

A summary of 234 extracted codes is presented in Table 3. In addition, all recommended actions that were classified in the analysis process, based on the health control knobs, are illustrated in this table.

**Table 3.** The Results of the Current Study Based on the Health Control Knobs: Codes in Prentices the Trends Have Been Extracted from, and the Number Coming After It Is the Abundance of the Code in Interviews.

Domain	Health Control knobs			
	Financing	Organization	Legislation	Behavior
<b>Capacity building (37)</b>	Increase the number of admitted students (SO2, Te4, Po1, Po2) (5)  Alignment trainings to the needs (So2, Po3, Ec2) (4)	Offering HTA PhD Program (5)	Importing experts from other fields of science into HTA program (Te3, Po3, Po4, So2) (5)	Establishment of the control of the immethodical consumption of health technology (Po4, Ec1, Te2, So3, So1) (7) Turning HTA into a social demand (Po3, Po1, Ec2, Ec1, Te3, Te2) (11)
<b>Provision of HIA (141)</b>		Contact of HTA with insurance organization (Te2, Te3, Te4, Ec2, Po3) (7) Development of private part in order to provide HTA services (So2, Te3, Po2, Po3) (13) Establishment of federal supervision and survey for private organizations of HTA (Te2, Te3, Po2, Po4) (14) Development of HTA units in hospitals (So2, Te3, Te4, Po3, Po4) (9)	Modernization and equipping health system infrastructure based on the HIA (Ec1, Te1, Te2, Te4, So3, Po4) (24) legitimizing HTA for using all health technologies (So1, So3, Te2, Te4, Ec1, E2, Po1) (11) Banning Importation of luxury technologies as well as technologies domestically produced by a quality that approximately equals to that of Foreign countries. (So3, Te1, Te2, Ec1, Ec2, Po1, Po4) (19) determining of the basic benefit package in across the country based on demographic features (So1, So3, Te2, Te4, Po1, Po3, Po4) (8)	Development of utilization of clinical guidelines by suppliers (So1, So3, Te1, Te4, Ec1, Ec2, Po1, Po4) (29) Control induced demand by suppliers (So1, So3, Te1, Te2) (7)
<b>Supportive mechanisms (56)</b>	Supporting of the information technology for HTA (So2, Te3, Ec2) (56)			
<b>Sum 234</b>	65	48	67	54

In this section, each of the defined groups is investigated, and their results are presented. Italic fonts refer to the statements of contributors, who are also distinguished from each other using defined codes, shown in Table 1. In order to ensure that the interviewee has got the idea and a sense about health technology assessment, HTA concepts and the objectives of the current study were briefly introduced to them.

#### 4.1. Capacity Building

This group contained 56 codes in six different categories.

In this field, the majority of interviewees emphasized “The necessity of precise policy-making and aligning training to the needs in order to better meet them” (code 1-1). Interviewee PP2 stated that “The resonation of needs in order to development of universities did not receive attention.”

Interviewee HP3 argued that “Our country is faced with deficiencies in the field of HTA, and we should train experts in this field and using the capacity of currently graduated HTA students in conducting HTA programs.”

HTAA1 interviewee noted that “establishment of a Ph.D.

program can increase the quality of human resources in the HTA field.” In addition, interviewee HP1 mentioned that “In order to progress in the field of HTA, it is better to train experts with considering more details. For example, we can train experts in the fields of assessment of equipment, medication, surgery methods, diagnosing, and so forth.”

Based on the pyramid of the legislation, interviewee HP1 declared that “Using experts from other fields to perform HTA programs” is a desired trend for training experienced human resources.

Interviewee HTAA2 described that “turning HTA into a social demand can promote HTA programs.” The majority of the interviewees stressed that “Using the HTA to increase equity in the health system as well as preventing the overuse of medical technologies” is their ideal future for the HTA field.

#### 4.2. Provision of HTA

This group included 141 codes in 10 categories. Five interviewees believed that “Lack of official declaration of the HTA necessity in the process of health policy-making has caused HTA investigations to become useless.” Interviewee PP1 stated that “A highly positive measure would be passing a law by the Islamic Consultative Assembly to make the HTA studies mandatory”.

Most of the interviewees stated that “by relieving sanctions imposed by the Europe and US against Iran, modernization and equipping health system infrastructure, based on the HTA, can play a far more important role in the development of the country’s health system”. Interviewee HTAA1 stated that “The trend of the importation of technology will be highly accelerated since 80 million market of Iran is very appealing for other countries. This trend probably can strengthen private companies working in the field of HTA.” However, interviewee PP2 announced that “legitimizing HTA to be used for all health technologies can lead to increased domestic production and can prevent the introduction of unnecessary technologies and technologies that have similar effects to those produced in Iran.” Interviewee HP1 pointed that “HTA system is integrated and coherent when studies are performed out of the system and reviews are carried out by the system” Interviewees HP2 and HTAA2 mentioned that “In importation of modern health technology and argued that the safety of these technologies has increased highly, passing laws based on HTA is inevitable.” Interviewee HP3 stated that “Under both Scenarios, continuation and sanctions relief, we will face either importation of technologies or its limitation, and under both of these conditions, we need to develop HTA more and more.”

Interviewee HP2 noted that “A law should be passed to assign HTA to the health system and insurance organizations; however, playing an administrative role is not necessary”. In contrast, interviewee SP1 stated that “Since there is a conflict of interest between the privatization of HTA system and targets defined for the HTA, this process

counteracts the benefits the HTA in the health system of the country. Thus, controlling these systems is of crucial importance.”

Several interviewees pointed out that “development of clinical guidelines using the HTA principles to amplify the benefits of different beneficiaries of the country’s health system can increase the legitimacy of HTA in Iran”.

The majority of interviewees pointed out the “importance of establishing a HTA system in the field of disaster management”. Interviewee PP3 stated that “The frequency of recorded natural and artificial disasters has significantly increased in the country, recently. The HTA system can react to disasters rapidly by managing health technologies”. HTAA2 explained that “For example, the effectiveness of strengthening hospitals can be evaluated”. HP1 stated that “Importation of high-tech and the patent would be very costly, and thus we should choose the appropriate option, especially in the case of cancer. And in this case, HTA can highly be useful for choosing the best choice.”

#### 4.3. Supportive Mechanisms

This group contained 56 codes. Interviewee SP3 announced that “In the presented time, there is a low level of harmonization between researches in the field of HTA, which has resulted in the ineffectiveness of the current HTA system. Development of a system for publication of national studies and researches can help the researchers to become more harmonized, and for converging their researches toward a specific target”. In addition, SP4 has stated that “the HTA system can also increase its effectiveness and efficiency by developing ICT infrastructures”. HTAA1 pointed out that “Telemedicine can positively affect the economy of the health system, and also it can reduce health expenditures. Therefore, we should concentrate on this technology”.

### 5. Discussion

Similar to other systems, attention should be considered to effective versions in the middle and long terms in order to survive and secure the position of HTA. Considering variations that may affect the HTA system of Iran, the current study intended to determine the possible trends for securing the position of HTA and also increasing its efficiency by using health control knobs in three groups of supportive mechanisms, provision of HTA, and capacity building. The remarkable point is that, among different effective factors that may lead to uncertainties and also may highly affect the future of HTA, the future of sanctions against Iran is the most important factor, and should be considered as the two aforementioned possible scenarios. Under the action of the recent joint comprehensive plan of action (JCPA) between Iran, the US, Russia, China, France, Germany, and European Union, sanctions imposed by the United Nations Security Council against Iran have decreased the effects of some of the

sanctions or lifted some of them, especially concerning financial transactions, and based on this agreement, it is a good time for Iran to take advantage of this agreement to renovate its medical equipment in order to increase effectiveness and to reduce costs. When President Donald Trump announced that his administration won't continue JCPOA, some argued that the US will respect its commitments.

As disagreements and conflicts between Iran and the international community about the atomic program of Iran were intensified, wide and deep sanctions were imposed on Iran by the United Nations Security Council. Although these sanctions do not directly deal with medical equipment and health technology, they ban banking connections with the international community and, in practice, made the import of medical equipment and health technology very difficult. That is, they have placed Iran in a critical situation, and the country, in essence, does not have access to modern technology and medical equipment (14).

To confront the sanctions, 2012 year was named the "year of Resistive economy" by the Supreme Leader of the Islamic Republic of Iran, and he declared resistive economic policies in order to increase utilization of domestic products, expand economic principles, and to strengthen domestic production by decreasing dependence on importing goods from other countries (7). Applying findings of HTA studies in health policy-making can increase efficiency, improve the allocation of available resources, and strengthen domestic production. To legislate utilization of HTA reports, an obligatory HTA can be defined, which may result in dramatic progress.

Kahvaeci (15) reviewed previously published studies and reports and interviewed important people in the health ministry of Turkey. She mentioned the lack of knowledge about HTA and making decisions based on experiences as the main barriers of the HTA development program in Turkey. Stevens (16) has found that, in June 2005, the HTA system was established in England and Wales, which forced the national health services (NHS) to provide financial support for drugs and health technology for the national institute of clinical excellence (NICE). Later, Bantaa (14) mentioned that the National Congress of Brazil has argued about the necessity of HTA by emphasizing its role in health system management. Finally, Mohtasham (8) has discussed the lack of legal actions about using HTA reports in Iran and counted this aspect as the most important challenge in the HTA of Iran.

Based on the findings of this research, passing laws is of crucial importance. Making the HTA mandatory is a step-wise and complex procedure, and its realization requires policy-making and precise implementation. Also, in this research, it was pointed out that to take steps forward, a general demand is very important. Based on the control knob of "supplier behavior", developing medical guidelines that increase the satisfaction of beneficiaries of the health system, including suppliers, healthcare providers,

and financial supporters, can accelerate the obliging to the HTA system.

By the beginning of 2010, the National Institute of Health Research was assigned to study on HTA of the country by the Ministry of Health and Medical Education. However, still there are many problems and challenges in recalling, approving, reviewing, assessing, and performing procedures of the researches. Reformation and clarification of these steps in the HTA system of the country can diminish these challenges and also increases the efficiency of the HTA system of Iran. Hisashige (17) stated that lack of a central organization for HTA researches may lead to imbalance and inconsistency between researchers, and finally, such challenges have driven the researches to a divergent point in Japan. Koch (18) mentioned that the lack of federal HTA organizations in Switzerland has made the role of private section in HTA in the health policy-making of this country. Mohtasham (8) has counted to the lack of framework, long-term planning, and surveying systems as the basic impediments in the development of the HTA system in Iran.

Concerning the financial support knob, developing information technology infrastructure can reinforce the HTA system of Iran. To achieve this goal, developing a system for publishing domestic reports may increase the contribution and collaboration between HTA experts of the country. Furthermore, based on the organization knob, if privatization in HTA be performed basically, it can decrease the bureaucracy in the HTA system of Iran, and also, these entities are more efficient than public organizations. Regarding the legislation knob, if privatization in HTA is accompanied by governmental supervision, which matches with the goals of the health system of the country, as it improves the accessibility of health services and can promote health equity, it would be highly useful for expanding HTA in Iran. Otherwise, lack of governmental supervision and monitoring may make the HTA less productive, mainly due to conflict of interest.

Since 2010, HTA educational programs are holding in Iran, so that currently, four universities are offering M.Sc. programs of HTA. One of the most important challenges in the realm of human resources is the lack of job opportunities in either private or public companies/organizations in the country, which decreases the motivation of students and graduates. Sivalal mentioned that one of the most important problems in the HTA system of Malaysia is the lack of expert human resources. Mohtasham has also mentioned that Iran suffers from the lack of experts in the field of HTA, and the majority of in-service people have no or low-levels of experience or knowledge in the field of HTA.

In this study, trends that can increase the quality of training human resources in the field of HTA were investigated by emphasis on the health control knobs. Concerning the financial support and legislation knobs, the development of training policy-making in the field of HTA according to the need assessments can improve the

outcome of these programs. Regarding the organization knob, offering Philosophy of Doctorate (Ph.D.) programs for HTA in different areas is another trend that can increase the skills of the HTA experts. More importantly, to further motivate HTA students, it is necessary to increase job opportunities in the field of HTA, in both governmental and private companies and organizations.

It is important to note that, although researchers of this study did their best to perform this study, but it has limitations. In the fore-sighting research, since long-term goals and targets are defined, there are always some uncertainties. This research, in fact, is not an exception, and there are some uncertainties in defined trends. Individual interviewing was one of the most important limitations. Since most of the interviewees were busy with group meetings, it was very hard to access them and to set a time for a face-to-face interview. Besides, the number of interviewees was limited and made this problem more difficult.

### 5.1. Conclusions

Different strategies should be developed for improving the HTA system of Iran. There should be laws concerning the following issues 1- importation of health technology and medical equipment, and 2- implementation of these rules as health service packages. To this end, it needs to establish a culture in the community, by which HTA turns into a demand of society. When the abovementioned rules are implemented, we can expect behavioral changes in the supply of health to increase the efficiency of the health system of the country.

The remarkable point is that, whether the sanctions will be relieved or extended, the HTA system of the country should be improved. That is, the development of the HTA of Iran is of crucial importance and imperative in both scenarios. However, under each of these scenarios, the motivation for the improvement of the HTA system of Iran differs. Under the action of the first scenario (i.e., sections relieve), other countries will try to benefit from Iran's market, and the best choices should be selected by the HTA. However, under the action of the second scenario, the extension of sanctions, probably the country will move towards economic austerity, thus the HTA goals should be set by administrators to control the consumptions and costs. Setting precise political and geological tools by the administrators can drive the HTA system of Iran to higher levels.

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