

Challenges of implementing health technology assessment in the Iranian pharmaceutical industry

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Abstract

Background: Health technology assessment remains underdeveloped in the Islamic Republic of Iran, with limited systematic application in the pharmaceutical sector.

Aim: To identify the challenges facing the development and implementation of health technology assessment in the Iranian pharmaceutical industry.

Methods: Between August and November 2024 we conducted in-depth interviews with 15 experts who have experience in implementing health technology assessment, on the development and implementation of health technology assessment in the pharmaceutical sector of Islamic Republic Iran. We used MAXQDA version 12 for data management and analysed the data using the Braun and Clarke's 6-step thematic analysis.

Results: The major challenges identified were the absence of centralised health technology assessment governance for pharmaceuticals, insufficient and unstable funding, resistance to change, limited awareness about health technology assessment, limited health technology assessment capacity, absence of a legal enforcement framework, political interference, and the strong influence of pharmaceutical companies. Participants noted the availability of international partnerships on health technology assessment.

Conclusion: Several complex and multilevel barriers hinder the development and implementation of health technology assessment in the Iranian pharmaceutical industry. There is a need for actions to strengthen health technology assessment in the country to support evidence-based policymaking, resource optimisation and equitable access to essential medicines.

Keywords: health technology assessment, pharmaceutical industry, health policy, Islamic Republic of Iran

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Introduction

Health technology assessment (HTA) is a multidisciplinary process that evaluates the medical, social, economic and ethical implications of health technology. By providing evidence on effectiveness, cost-effectiveness and broader impacts, HTA plays a critical role in guiding decision-making (1). In the pharmaceutical industry, HTA supports evaluation of new drugs and therapies, informing decisions on development, pricing and reimbursement (2). It helps ensure that limited resources are directed toward high-value interventions, while promoting innovation and equitable access to drugs (3). For insurers, HTA offers a framework for sustainable financing and resource prioritization, while also shaping health benefit packages that align with population needs and advance Universal Health Coverage (UHC) (4).

In the Islamic Republic of Iran, HTA adoption is still limited, especially in the pharmaceutical sector, and major gaps remain despite early integration efforts (5).

Fragmented governance, insufficient funding and lack of standardized guidelines limit effective use of HTA in drug evaluation and reimbursement (6). Strengthening HTA frameworks is essential for improving cost-effective access to quality drugs and advancing UHC goals (7). In resource-constrained settings like the Islamic Republic of Iran, where economic instability and budget limitations remain critical, HTA can optimize pharmaceutical spending and enhance patient access to essential drugs (8). By promoting transparency and evidence-based decision-making, HTA builds trust among policy-makers, providers and patients, supporting a more equitable and sustainable healthcare system (9).

Recent studies from other countries have similarly highlighted the pivotal role of HTA in promoting efficient resource allocation and informed pharmaceutical policies (10,11). These studies have demonstrated that strong institutional capacity, stakeholder engagement and clear policy frameworks are critical for successful

integration of HTA into national health systems. This study investigated key structural, institutional and policy barriers to developing and implementing HTA in the Iranian pharmaceutical sector, addressing a notable gap in the literature. By comparison with international studies, we highlight how systemic constraints hinder HTA institutionalization and identify strategies to strengthen frameworks, support evidence-based decision-making, and advance UHC through more efficient resource allocation.

Methods

Study design and data collection

This study used qualitative, semi-structured interviews and content analysis to identify key patterns and challenges in developing HTA in the Iranian pharmaceutical sector. Given the national focus, a qualitative approach effectively captured diverse expert perspectives influencing HTA implementation.

Purposive sampling recruited 15 HTA-related experts from academia, health policy and health insurance. There were 11 males (73.3%) and 4 females (26.7%), with an average age of 45.9 years and an average work experience of 15.5 years (Table 1). Participants from the public sector averaged 16.4 years of experience, while those from the private sector averaged 14.6 years. Participants were chosen for national roles in major universities, regulatory bodies, insurance organizations and policy units, ensuring a broad perspective. All invitees agreed to participate. Although interviews occurred in specific institutions, these experts influence national decisions, aligning recruitment with the national focus of the study.

Interviews were held at convenient locations such as workplaces, private offices and universities. To address logistic constraints, 9 interviews were conducted in

person and 6 online. Privacy was ensured, and only participants and the interviewer were present. These settings represented major national institutions involved in pharmaceutical decision-making, further supporting the national relevance of the study.

An interview guide with open-ended questions was pre-tested, and all interviews were conducted by the principal investigator – an experienced health policy researcher with no relationship with participants. Interviews (65–105 minutes) were recorded with consent, supported by field notes, and continued until saturation. Preliminary findings were validated by member checking. Data were collected between August and November 2024.

Data analysis

Data were analysed using Braun and Clarke's 6-step thematic analysis (12): familiarization with transcripts; generating codes; organizing codes into themes; reviewing, defining and naming themes; and producing the final report. Coding was conducted iteratively by 2 researchers to ensure reliability, with discrepancies resolved by consensus. MAXQDA version 12 supported data management. The analysis followed an inductive approach, allowing themes to emerge from the data while remaining conceptually informed by the study aim. Although the study aim guided the focus of the analysis, no predefined coding framework was imposed; instead, the inductive strategy ensured that the themes were grounded in participants' experiences. Methodological triangulation involved several researchers in coding and theme development. A coding tree was created to organize themes and subthemes. This inductive thematic analysis was compatible with the qualitative content analysis framework, as it enabled flexible interpretation of participant narratives while maintaining a structured analytical process consistent with the conceptual focus

Table 1 Demographic and professional characteristics of study participants

Participant No.	Gender	Specialty	Employment sector	Interview method	Years of experience	Age (years)
1	Male	Pharmacist	Private	In-person	20	50
2	Female	University professor	Public	Online	18	48
3	Male	Researcher	Public	In-person	15	45
4	Female	Policymaker	Public	Online	17	47
5	Male	Medical specialist	Private	In-person	22	52
6	Female	Pharmacist	Private	Online	16	46
7	Male	University professor	Public	In-person	19	49
8	Female	Insurance manager	Private	Online	14	44
9	Male	Researcher	Public	In-person	21	51
10	Male	Policymaker	Public	Online	13	43
11	Male	Medical specialist	Private	In-person	12	42
12	Male	Pharmacist	Private	Online	11	41
13	Male	University professor	Public	In-person	10	40
14	Male	Pharmacist	Private	Online	9	39
15	Male	Researcher	Public	In-person	8	38

of the study. The identified themes reflected barriers to HTA implementation and informed the development of recommendations for strengthening HTA in the Iranian pharmaceutical industry. Preliminary findings were shared with participants for validation, thus enhancing credibility.

Rigour and trustworthiness

To ensure trustworthiness, several strategies were applied. (1) Credibility: member checking through sharing preliminary results with participants. (2) Dependability: independent coding by 2 researchers, with disagreements resolved collaboratively. (3) Confirmability: maintenance of an audit trail documenting analytical decisions. (4) Transferability: provision of detailed context and participant characteristics to enable assessment of applicability to other settings. The study followed the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist to ensure rigour and transparent reporting. Direct quotations from participants, identified by number, were used to illustrate themes, with both major and minor themes presented for consistency.

Ethics considerations

The study was approved by the Ethical Committee at Lorestan University of Medical Sciences (IR.LUMS.REC.1402.310). All the respondents had the study explained and were asked to sign informed consent before confirming their participation. The study procedures and methods were conducted in accordance with the ethical principles and guidance in the Declaration of Helsinki.

Results

Analysis of the interviews revealed 7 inter-related themes, which were mapped against established HTA development and policy implementation frameworks (13,14): structural and institutional challenges; economic and financial barriers; cultural and perceptual barriers; technical and methodological barriers; legal and ethics issues; political and stakeholder influence; and international collaboration and influence.

Theme 1: Structural and institutional challenges

A major challenge was the absence of centralized governance in HTA for pharmaceuticals. Participants consistently highlighted fragmentation among key actors, including the Ministry of Health, insurance companies and private evaluators, leading to inefficiency and duplication. As Participant 3 explained:

"One of the biggest problems is that there's no central authority overseeing health technology assessment in the pharmaceutical sector. We have different organizations... each operating with its own agenda, which creates inefficiency and duplication of efforts."

Participant 8 added:

"Sometimes one agency approves a drug based on its own standards, while another questions its cost-effectiveness."

This misalignment confuses pharmaceutical companies and delays patient access to innovative treatments."

Participants called for a national HTA body to set standards, monitor processes and ensure consistency and transparency. They noted weak policy frameworks and short-term planning. Participant 10 observed:

"Policies guiding HTA in the pharmaceutical industry are not well defined. They seem reactive rather than proactive... This short-term focus is a major obstacle to effective HTA implementation."

Participant 6, a pharmaceutical industry representative, noted:

"Every stakeholder seems to interpret HTA in their own way because there are no clear national guidelines. One organization might prioritize cost-effectiveness, while another focuses on clinical efficacy."

Overall, participants emphasized that poor governance and lack of standardized processes undermine the credibility and policy influence of HTA.

Theme 2: Economic and financial barriers

Participants consistently reported insufficient and unstable funding as a major barrier. Participant 1 remarked:

"Implementing HTA requires significant financial resources, and unfortunately, there's no dedicated funding. Government budgets are already stretched thin, and HTA often gets sidelined."

Participant 5 added:

"Many HTA initiatives start with enthusiasm but fail to achieve their goals because the funding runs out. For example, data collection often stops because there's no money left to hire qualified analysts."

Economic instability, inflation and fluctuating exchange rates were cited as major obstacles. As Participant 4 explained:

"The economic instability in Iran makes it incredibly challenging to conduct reliable HTA. With inflation and fluctuating exchange rates, the cost data we collect today might be completely irrelevant in 6 months."

Participants noted that smaller pharmaceutical companies struggle to cover HTA-related costs. Participant 7 stated:

"HTA is an expensive process... Many smaller pharmaceutical companies simply can't afford to participate, which limits the scope and inclusiveness of evaluations."

Theme 3: Cultural and perceptual barriers

Resistance to change and limited awareness about HTA were recurring issues. Participant 2 noted:

"In our system, there is a deeply ingrained resistance to change. Many decision-makers feel threatened by new approaches like HTA because it challenges the traditional way of doing things."

Participant 12 added:

"Innovation is often perceived as an added burden rather than an opportunity. The mindset here is more about maintaining the status quo."

Participant 9 highlighted misconceptions about the role of HTA:

"Many stakeholders... don't fully understand what HTA is or how it can benefit them. They see it as a bureaucratic hurdle rather than a process that could help improve their competitiveness."

This limited understanding reduces support for HTA adoption among policy-makers and providers.

Theme 4: Technical and methodological barriers

Participants frequently mentioned a shortage of skilled HTA professionals and limited technical capacity. Participant 13 explained:

"There is a serious shortage of experts trained in HTA methodologies. Most people working in this field have limited knowledge of advanced cost-effectiveness analysis or health outcome modeling."

Participant 11 added:

"HTA relies on high-quality, reliable data, but our healthcare system doesn't have the infrastructure to collect and store such data... Most of the time, we're working with fragmented or outdated information."

Participants reported poor data sharing and lack of standardized methods across organizations. Participant 14 said:

"Every organization seems to have its own approach to HTA, which creates inconsistencies... Without standardized methodologies, it's hard to compare outcomes or make informed decisions."

Theme 5: Legal and ethics issues

Ethics dilemmas and the absence of legal enforcement mechanisms were widely mentioned. Participant 15 reflected:

"HTA often raises ethics questions, especially when it comes to prioritizing treatments. How do you justify denying a potentially life-saving drug because it's not considered cost-effective?"

Participant 10 noted:

"There is no legal mandate to integrate HTA into decision-making processes in the pharmaceutical industry. Without a strong legal framework, it's impossible to enforce HTA requirements or hold stakeholders accountable."

Theme 6: Political and stakeholder influence

Participants highlighted political interference and the strong influence of pharmaceutical companies. Participant 1 stated:

"Pharmaceutical companies in Iran hold significant power... They lobby for favourable decisions, sometimes

pushing for drug approvals or pricing structures that don't fully align with evidence-based evaluations."

Participant 4 added:

"Politics always plays a role... Sometimes, drugs are approved for political reasons without thorough evaluation."

Participant 9 noted:

"There are many competing interests among the different stakeholders involved in HTA... Each group has its own agenda, which makes it difficult to reach a consensus."

Theme 7: International collaboration and influence

International partnerships were viewed positively but with caution. Participant 8 said:

"International collaboration is vital... Collaborating with countries that have more experience in HTA helps us learn from their successes and mistakes."

However, reliance on external models was seen as problematic. Participant 6 explained:

"Because we lack comprehensive local data, we often have to rely on international sources... These external models might not always be suitable for our unique healthcare system."

Participant 2 added:

"Global pharmaceutical companies influence HTA adoption in Iran, sometimes steering it toward models favourable to their products."

Discussion

This study identified major structural, financial, technical, legal and political barriers to HTA development in the Iranian pharmaceutical sector. The findings align with the experiences of low- and middle-income countries (LMICs) while highlighting challenges specific to the Islamic Republic of Iran. Overall, the results show that fragmented governance and limited resources jointly constrained HTA institutionalization, underscoring the need for coordinated policy action.

A major barrier was the absence of centralized HTA governance, resulting in fragmented and inefficient decision-making. Similar patterns have been reported in India and Brazil, where the lack of a unified regulatory body has slowed HTA adoption (15–17). In contrast, countries with dedicated HTA agencies, such as the National Institute for Health and Care Excellence in the United Kingdom of Great Britain and Northern Ireland and the Canadian Agency for Drugs and Technologies in Health, benefit from standardized processes and leadership (18). Our findings reaffirm the importance of institutional leadership and suggest that a coherent HTA governance structure is essential for integration into national decision-making. Establishing a national HTA body in the Islamic Republic of Iran could improve coordination, foster collaboration and promote consistent methodologies. Establishment of a national HTA authority under the Min-

istry of Health operating with semi-autonomous status could enhance transparency, coordination and long-term planning (7). Embedding HTA units within major universities and teaching hospitals would further decentralize expertise while maintaining central oversight (4).

Limited funding and the high costs of HTA processes emerged as significant obstacles. Comparable financial challenges have been reported in South Africa and Malawi, where insufficient budgets limited HTA scope and quality (19,20). High-income countries, by contrast, invest heavily in HTA, enabling sustainable and robust evaluations. This finding supports the literature that links sustainable financing mechanisms to the institutional maturity of HTA systems (21). In the Iranian context of fiscal constraints and sanctions, new financing mechanisms could include earmarking a small percentage (e.g. 0.5–1%) of annual health insurance premiums for HTA research; allocating part of pharmaceutical import duties to HTA capacity building; or introducing performance-based financing in collaboration with domestic insurers. Establishing a dedicated HTA innovation fund, supported by public and private contributions, could promote sustainability (7).

Resistance to change and limited awareness of the benefits of HTA remain critical barriers. Similar issues in Turkey and Egypt have slowed adoption due to reliance on traditional decision-making practices (22,23). Conversely, the Republic of Korea has advanced HTA through awareness campaigns and training, fostering a culture of evidence-based practice. These comparisons suggest that cultural adaptation and knowledge transfer are as crucial as technical capacity building (24). To address this in the Islamic Republic of Iran, national awareness campaigns and mandatory HTA training within the curricula of medical and pharmacy schools could be introduced. Targeted workshops for members of parliament, provincial health managers and industry leaders would help shift perceptions and create a shared understanding of the role of HTA in rational policy-making (25).

The main technical and methodological barriers to HTA in the Islamic Republic of Iran include a shortage of skilled professionals and limited access to reliable data, which are challenges also reported in many LMICs (26). Nigeria faces similar obstacles due to insufficient expertise and data systems (27). Conversely, France and the Netherlands have strengthened HTA by investing in training and data infrastructure (28). Our findings reveal that strengthening technical capacity and data integration should be considered foundational to HTA system development (29). The Islamic Republic of Iran could adopt a dual strategy: establishing an HTA academic consortium involving key universities to provide postgraduate training in pharmaco-economics and health policy; and integrating national health databases (e.g. insurance, prescription and hospital data) into a unified HTA data platform. Partnerships with the Statistical Center of Iran and the Food and Drug Organization could improve data accuracy and availability (4).

The absence of legal frameworks and ethics concerns regarding treatment prioritization was identified as a barrier. Similar issues have been noted in Colombia and Mexico, where weak mandates and ethical dilemmas have limited HTA uptake (30). In contrast, Scotland has adopted clear legal and ethics guidelines that promote transparency and accountability (31). The Islamic Republic of Iran could introduce legislation mandating HTA as part of the drug registration and reimbursement process. This reform would institutionalize HTA within the legal system and safeguard fairness in decision-making. Establishing a national ethics committee for HTA decisions comprising ethicists, clinicians and patient representatives would ensure fairness, transparency and social acceptability (32).

Political interference and pharmaceutical lobbying were reported as major barriers, reflecting findings from Egypt and India, where similar pressures have compromised HTA integrity (33). New Zealand has addressed such risks by ensuring independence through transparent processes and conflict-of-interest policies (34). This indicates that good governance and insulation from political and commercial pressures are prerequisites for credible HTA processes. For the Islamic Republic of Iran, clear conflict-of-interest declarations and publicly accessible HTA reports could mitigate undue influence. Establishing multi-stakeholder advisory boards, including civil society and academia, would further enhance transparency and accountability in decision-making.

While international partnerships were considered vital, participants highlighted difficulties in applying global data to local contexts. Similar findings were reported in Jordan and Egypt, where international collaborations advanced HTA capacity but created challenges when adapting methodologies (35). This study contributes to the global dialogue by emphasizing that international models should be contextually adapted, not directly replicated.

Future HTA development in the Islamic Republic of Iran requires systemic reform rather than isolated actions. Contextual adaptation of global tools, regional collaboration, stronger institutional capacity, and firm political and legal support are essential. Further research should assess governance, financing and capacity-building interactions.

Study limitations

This study had several limitations. Although interviews with 15 participants generated valuable qualitative insights, the small sample size limits generalizability. Purposive sampling captured diverse views but excluded some groups, especially patients. As highlighted by the reviewer, the absence of patients or potential beneficiaries means that end-user perspectives on health technologies were not represented. Future studies should involve larger and more inclusive samples. Reliance on self-reported data may have introduced recall or social

desirability bias. Using multiple data sources could improve reliability. Although the findings are context-specific and may not apply to settings with different political or economic structures, they offer useful indicators for LMICs developing HTA systems. Despite these limitations, the study benefitted from input across policy, regulatory, academic and insurance sectors, strengthening its credibility and relevance.

Conclusion

This study highlights major financial, technical, political and economic challenges in developing pharmaceutical

HTA in the Islamic Republic of Iran. Although the study provides important insights, its findings are not fully representative due to its qualitative design and the absence of groups such as patients. Strengthening HTA requires clearer governance, legislation, better data systems and capacity building. The conclusions reflect expert views rather than nationwide perspectives, and practical actions including improved coordination, data infrastructure, early industry engagement, and patient input can support more equitable HTA. Future work should assess these strategies within broader reforms.

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