ORIGINAL

Diagnostic technology assessment in Iran: A grounded theory study

Evaluación de la tecnología diagnóstica en Irán: Un estudio de teoría fundamentada

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Abstract

Introduction: Evaluation and selection of efficient medical equipment have always been among the concerns of health system managers.

Methods: The purpose of the present study was to present a model of diagnostic technology assessment in Iran based on a Grounded theory approach. The present qualitative Grounded Theory-based study was conducted in 2019. The participants in this study were medical equipment managers and health technology assessment experts working in university hospitals.

Results: The results showed that the Committee model is the most commonly used model of diagnostic technology assessment in Iran's university hospitals; it was also indicated that the organizational, economic, technological, clinical, and legal properties of diagnostic technologies are considered important in the assessment process.

Conclusion: Medicines, Treatment, and Medical Equipment Committees in Iran's hospitals can create an appropriate platform for diagnostic technology assessment, while the support and cooperation of managers play a decisive role in this process.

Keywords: Equipment and Supplies, Health, Ancillary Services Hospital.

Resumen

Introducción: La evaluación y selección de equipos médicos eficientes siempre han estado entre las preocupaciones de los gestores del sistema de salud.

Metodología: El propósito del presente estudio fue presentar un modelo de evaluación de la tecnología de diagnóstico en Irán basado en un enfoque de la teoría fundamentada. El presente estudio cualitativo basado en la teoría fundamentada se llevó a cabo en 2019. Los participantes en este estudio fueron gerentes de equipos médicos y expertos en evaluación de tecnología de la salud que trabajan en hospitales universitarios.

Resultados: Los resultados mostraron que el modelo de Comité es el modelo más comúnmente utilizado de evaluación de tecnología de diagnóstico en los hospitales universitarios de Irán; también se indicó que las propiedades organizativas, económicas, tecnológicas, clínicas y legales de las tecnologías de diagnóstico se consideran importantes en el proceso de evaluación.

Conclusiones: Los comités de medicamentos, tratamientos y equipos médicos de los hospitales iraníes pueden crear una plataforma adecuada para la evaluación de las tecnologías de diagnóstico, mientras que el apoyo y la cooperación de los gestores desempeñan un papel decisivo en este proceso.

Palabras clave: Equipos y suministros, salud, Servicios técnicos en salud.

Introduction

The diversity of the equipment market and the increase of demands and expectations of physicians and patients for the selection and application of new technologies have led to an unbridled increase in the use of new health technologies in Iran¹. Over the last few years, the availability of a new generation of diagnostic and therapeutic medical devices has caused a significant increase in the use of such devices in Iranian hospitals, while hospitals' authorities are still looking forward to having more of these new devices in their hospitals².

The results of studies in other countries show that hospitals and medical research centers spend about \$500,000,000 to \$1, 000,000,000 on medical equipment per year (plus 15-20% annual increase). It can be said that medical equipment plays the most important role in the increase in health care spending in different parts of the world^{3,4}. In Iran, more than one-third of the total spending of various educational, medical, and health care centers is allocated to medical equipment⁵.

Therefore, managers are always faced with decision-making situations concerning the selection of the most appropriate technologies⁶. Due to the diversity of products and organizations' authority to select products based on their needs, identifying factors affecting the decision-making processes in a competitive environment and using scientific methods to select appropriate products and services are of particular importance in medical settings⁷.

Health Technology Assessment (HTA) has emerged mainly in response to the increasing health care costs and to ensure the efficiency of resources used in health systems⁸. Most studies on HTA have been conducted in high-income countries, and the HTA statuses in middle-income and low-income countries remain unattended⁹. Iran's current Gross Domestic Product (GDP) has been estimated at \$454.01 billion, making it a middle-income country based on the World Development Indicators (WDI)¹⁰.

In Iran, HTAs are performed at national level and there is no active HTA program at hospital level. Therefore, the present study was executed to identify the parameters considered in Iranian University Hospitals (UHs) when assessing diagnostic medical equipment. This study also presents a model of HTA in Iranian UHs based on the Grounded Theory. Considering the limited resources of the health system, the high cost of diagnostic medical equipment, and the effect of medical equipment on proper and timely treatment, the proposed model in this study can play an effective role in the optimal and nondiscriminatory selection of scarce medical resources and lead to improved service quality.

Methodology

This qualitative study was conducted based on a Grounded Theory approach. The data were collected through unstructured interviews; the statistical population of this study consisted of medical equipment managers and HTA experts working in Iranian UHs; the data collection began in June 2019 and ended in August 2019. The demographic characteristics of the participants are presented in **table I**. Data saturation was reached after 15 interviews.

The participants were asked to describe the process of assessing diagnostic devices at hospitals where they were working. They were also asked to specify what they usually consider when assessing diagnostic medical devices? And what questions do they pose concerning those devices?

Data analysis was a regular and continuous process of data comparison, done in three stages of open coding, axial coding, and selective coding. In open coding, the transcribed version of the interviews was read several times, the main themes were extracted and recorded as codes; then, categories were developed by grouping similar codes. In axial coding, categories were linked to their subcategories to provide more accurate explanations of the phenomenon. Moreover, the primary categories, which were formed in the open coding stage, were compared and similar categories were placed on a common axis. Selective coding is the process of integrating and refining theme categorization; therefore, the present study's researcher harmonized and arranged different categories to present and form a theory. In the selective coding stage, while integrating and purifying the categories, it was decided to have a main theme; then, using the model paradigm, all themes were linked to the main theme. Throughout the study, methods were used to ensure the validity and reliability of the data. Four criteria have been proposed to ensure the trustworthiness of qualitative studies: credibility, dependability, confirmability, and transferability. Making long contacts with the participants, providing them with information about the project objectives to gain their trust throughout the interviews, continuously reviewing the data, audio recording each interview and transcribing it immediately after it finished, and using its feedbacks in subsequent interviews, the researchers tried to improve the study's credibility. Data dependability was tested by asking the participants and observers to review the transcribed interviews and express their corrective opinions. To test the transferability of the study, the study findings were sent to some medical equipment experts, who did not participate in the current study, to compare them with their own experiences.

Table I: Demographic Characteristics of the Participants.

Variables		Frequency	Percentage
Educational Level (Academic Degree)	Bachelor's Degree	3	20
	Masters' Degree	9	60
	Ph.D./Ph.D. Candidate	3	20
Organizational Status	Medical Equipment Manager	13	86.7
	Master of HTA	2	13.3
Gender	Female	9	60
	Male	6	40

Table II: Main categories and themes of diagnostic technology assessment in Iranian UHs.

Number	Main categories	Themes	
1	Clinical Properties	Disease burden Alternative methods Attending to clinical standards Attending to the needs of specific groups of patients	
2	Economic Properties	Primary cost Secondary cost Utilization of available resources Refund	
3	Organizational Properties	Accreditation requirements Meeting the needs of special groups of patients in UHs (Education & Research Affairs) Accountability requirements	
4	Technological Properties	Production feature Technical feature Setup requirement	
5	Legal Properties	Medical Equipment Office Department of Laboratory Affairs Atomic Energy Organization Etc.	
6	Asswessment Model	Committee Model Mini-HTA Model no Model	

Results

The results showed that, in line with the Ministry of Health and Medical Education instructions, the Medicines, Treatment, and Medical Equipment Committees have been formed in all Iranian UHs. In other words, the technology assessment of medical devices in Iranian UHs is performed via the internal committee method. The results indicated that five main properties are considered when assessing health technologies in Iranian UHs (Table II).

Step 1. Open Coding

Clinical properties

Clinical properties are determined based on the results of scientific studies and evidence for the effectiveness and safety of medical technologies. These properties also involve the impacts of technologies, such as their side effects and advantages in terms of safety and treatment. Moreover, meeting the needs of special patients, including those with viral infections such as AIDS, is considered here.

Economic properties

The economic value of the clinical effects of certain technology and its associated costs is determined

through various types of economic analyses, such as cost-minimization analysis, cost-benefit analysis, etc.

Organizational properties

Organizational properties are related to health institutions' operational processes and infrastructures, such as institutional expertise, educational features, types of relationships between work teams, workflow, potential barriers, and meeting accountability and accreditation requirements.

Technological Properties

Assessing technological properties includes examining a medical device in terms of mechanical and electrical safety, proper application, required accessories, equipment, space, maintenance, and storage.

Legal Properties

Legal properties include regulations (laws, resolutions & enactments) and all legal requirements before and after the application of a specific technology.

Assessment Model

The method each hospital uses to obtain information and assess a specific diagnostic technology.

Step 2: Axial Coding

In the present study, five main categories of clinical properties, organizational properties, technological properties, economic properties, and legal properties were identified. Focusing on interviews, categories, themes, and reminders, "HTA characteristics in the domain of diagnostic medical equipment" was identified as the main variable in the selective coding step; this variable related all categories and themes to each other. A brief explanation of each of those categories and themes will be presented in the following sections

Step 3: Description of the Theorizing Stage (Selective Coding)

As mentioned, the goal of fundamental theorizing is to produce a theory, not merely describing a phenomenon. To turn analyses into a theory, categories must be adequately related to each other.

The Paradigmatic Model of Diagnostic Technology Assessment in Iran's Public Hospitals

This theory presents mechanisms through which the target population (decision-makers in the domain of diagnostic medical equipment) identifies its needs and better assesses the diagnostic medical equipment; on the other hand, hospitals allocate their resources efficiently and nondiscriminatory. A general model is presented to develop and extend the theory of diagnostic technology assessment (within hospitals affiliated with medical sciences universities).

Description of the Paradigmatic Model

Hospitals are always faced with different kinds of requests from doctors, nurses, and other medical staff for applying diagnostic medical equipment and providing patients with better care. One of the most critical decision-making situations that managers always face is selecting the most appropriate technologies. Limited resources, organizational limitations, and the country's policies in the health domain are among the factors involved in these decision-making situations. Thus, it would be appropriate to use methods that accurately and properly take into account the ambiguity of human judgment when deciding over such issues.

In the present study, the researchers sought to identify the most important factors in the assessment of diagnostic technologies in Iranian UHs. The results of this study led to the formulation of useful and practical ideas for the current condition of the country. Considering the findings of the present study, the following theory was developed:

When selecting a diagnostic technology, Medicines, Treatment, and Medical Equipment Committee is formed based on the requirements of hospitals' accreditation rules, and the committee examines a technology from different dimensions and finally makes a decision.

One of the most important issues in such decisions is the hospital's ability to provide "primary" and "secondary" costs of diagnostic technology. In many cases, when a hospital is not "economically" capable to pay the costs of a certain technology, other dimensions of the technology will not be assessed. "special needs patients", "alternative diagnostic methods" and "clinical standards" are also considered in decision-making situations; in fact, clinical issues are of great importance in the decision making process. Each hospital's grade is determined based on the Ministry of Health and Medical Education's accreditation assessments, which has a direct impact on hospitals' revenues. Therefore, medical equipment experts and hospital managers usually consider this when selecting diagnostic technologies. In addition to accreditation requirements, due to the accountability requirements, if regulatory institutions (e.g. the State Inspectorate Organization, municipalities, provincial governments, Ministry of Health and Medical Education, Medical Council of the Islamic Republic of Iran, Department of Environment, etc.) have expectations from the hospitals, they usually try to purchase the desired technologies. In other words, considering the "organizational properties" of a hospital is evident in every decision.

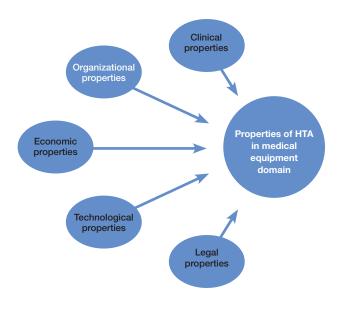
When deciding to purchase a medical device, its "technological properties" play vital roles in its "setting up". The "quality", organizations' capacity to provide "after-sales-services" ... are of great importance in "brand selection".

Furthermore, compliance with the current "regulations" in the domain of medical equipment was among the main features that were considered in the assessment of diagnostic technologies in Iranian UHs.

It can be said that the issues considered in HTA practices in Iranian UHs depend on various factors, the most important of which are "clinical", "organizational", "technological", "economic" and "legal" properties. Taking into account all of these properties in decision-making situations will optimize hospitals\ budget allocations; it also helps provide doctors with the facilities they need to meet the needs of the community and minimize possible human misjudgments.

The following figure (**Figure 1**) is the basic conceptual model of HTA in Iranian UHs:

Figure 1: Basic conceptual model of HTA in Iranian UHs.



Discussion

Hospital-based HTA consists of specific hospital needs¹¹. This approach considers the local organizational conditions in which health technologies are used¹². Studies have shown that many initiatives have emerged

in the area of hospital-based HTA in the world^{13,14,15}. In 2008, the Health Technology Assessment International (HTAi) proposed four models of HTA at hospital level:
1) Ambassador Model; 2) Mini-HTA Model; 3) Internal Committee Model, and 4) HTA Unit Model^{16,17}. The results of the present study showed that Iranian UHs use Internal Committee and Mini HTA models of HTA; moreover, it was indicated that clinical, organizational, economic, technological, and legal properties of medical devices are considered important factors in the assessment of diagnostic medical technologies in Iranian UHs.

Research shows that clinical and economic aspects of medical devices are considered very important in hospital-based HTA¹⁸, which is in line with the presets study's findings.

Besides, previous studies have reported that legal properties had been considered in only 23% of their examined hospital-based HTA documents19, while those properties were quite widespread in the context of Iranian UHs.

In line with the present study's findings, the technological properties of medical technologies have received considerable attention in previous studies, including the one conducted in France²⁰.

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