

Stakeholder Perspectives and Experiences of Implementation of Accreditation and the ISO 9001 Programs in Hospitals of Iran: A Qualitative Study

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Abstract

Background: Accreditation and ISO 9001 programs in hospitals are widely adopted for quality control and quality improvement in healthcare.

Objectives: The objective of this study is to identify stakeholders' perspectives and experiences regarding the implementation of accreditation and ISO 9001 programs in hospitals affiliated with the Social Security Organization in Alborz Province, Iran.

Methods: In this qualitative study, participants were selected based on purposive sampling. For data collection, semi-structured one-to-one interviews were conducted with hospital staff in different positions (n = 30). All interviews were digitally recorded, transcribed verbatim, and analyzed using thematic analysis.

Results: Based on the analysis, 10 primary themes and 88 subthemes were identified. The 10 primary themes were categorized as experiences, strengths, weaknesses, effective factors, and recommendations for the implementation of accreditation and ISO 9001 programs in hospitals. Proper planning, benchmarking, physician involvement, increased resources, and more training are suggested for the successful implementation of accreditation in hospitals. Additionally, fostering a positive culture, focusing on the executive dimension, changing managerial attitudes, training, and supporting and motivating staff are the most important recommendations for the implementation of the ISO 9001 program.

Conclusions: The results provide important insights into the dimensions of implementing accreditation and ISO programs in hospitals, which can be used by health policymakers and managers to improve the implementation of these programs in Iranian hospitals.

Keywords: Accreditation; ISO 9001; Hospital; Iran

1. Background

Healthcare services in hospitals are essential for any society and indisputably receive public and societal resources (1). Despite the importance of hospitals, these centers constantly face challenges from variable internal and external forces, including changes in technology, the healthcare market, economic conditions, and amendments to the healthcare system (2). To promote health, hospitals should be places of safety for patients, staff, and the general public, and focus on the quality of health services as their primary goal (3). Nowadays, it is not enough to merely provide and deliver services; recipients expect them to be of high quality (4), which is of great interest

to many stakeholders, such as governments, non-governmental organizations targeting healthcare and social welfare, professional organizations, patient organizations, and shareholders of companies providing healthcare services (5). Healthcare organizations should improve the quality of health services through various strategies. Two main strategies contribute to the implementation and establishment of a quality system, including the standards of accreditation and the quality management system (QMS) and international ISO 9001 standards (6). Accreditation is defined as an evaluation mechanism that enhances the performance of healthcare organizations



by adapting them to standardized and pre-designed targets for continuous quality improvement rather than maintaining minimum levels of performance (7). Therefore, the main aim of an accreditation program in hospitals is to promote the quality of health services, which is necessary for hospitals to move toward those standards (8). The ISO 9001 certification is an external compliance assessment mechanism or control mechanism to ensure and regulate quality and safety in healthcare (9). It is also defined as an international standard that specifies the requirements of the QMS; by using these standards, organizations can continuously provide products and services that meet the needs of their clients (10).

In Iran, the Control and Accreditation Office of the Ministry of Health and Medical Education (MOHME), in line with its main responsibility, has substituted the evaluation of healthcare centers with an accreditation model since 2007 (11). During the hospital evaluation, the evaluators at universities of medical sciences visit the hospitals and evaluate their performance according to a checklist (12). The governance structure and management of hospital accreditation should be independent and reliable, but the method of accreditation evaluation in Iran is limited to self-evaluation and field evaluation by evaluators (13). The accreditation method of Iranian hospitals is faced with challenges such as inaccurate evaluations, low experience and skill of evaluators, a lack of transparency in the accreditation process, and inappropriate interaction between hospitals and evaluators (12). Additionally, the ISO 9001 standard is accepted in Iran as a model for quality assurance, and medical centers' certification is performed in accordance with this standard (14).

The findings of a study showed that promoting a culture of quality management and patient safety can resolve many problems in the accreditation program. This cannot be achieved without a proper working knowledge of accreditation and a strategy to diminish ambiguities about the program among the staff (4). The results of a quantitative study in Iran showed that the accreditation program was perceived as successful in improving patient safety (3.80 out of 5), patient compliance (3.72 out of 5), and error reduction (3.53 out of 5) (15). Another study in Iran on the benefits of the ISO 9001-2008 QMS for changing the quality indexes' effectiveness showed that using an integrated quality management model that can offer a program for continuous improvement of quality can identify the exact quality needs in medical and healthcare fields and affect the medical indicators of quality effectiveness in hospitals (16).

Despite the emphasis on better implementation of accreditation programs and ISO 9001 programs in Iranian hospitals, only a few studies have been conducted on the advantages and disadvantages of these programs in Iran.

2. Objectives

The present study aimed to analyze the hospital accredi-

tation programs and ISO 9001 programs in hospitals affiliated with the Social Security Organization in Alborz Province, Iran, as well as to identify stakeholders' perspectives and experiences about their strengths, weaknesses, affecting factors, and recommendations for implementation.

3. Methods

3.1. Study Design

This was a qualitative study with a phenomenological approach, conducted in 2020. To collect the information, semi-structured interviews with open-ended questions were conducted with 30 participants. We were intimately involved with them and their social context in data collection, allowing for some degree of mutual influence. Four known steps in performing this phenomenological study were followed, including bracketing, intuiting, analyzing, and describing. We also used the standards for reporting qualitative research (SRQR) to describe the design and findings of this study, aiming to improve the transparency of all aspects of qualitative study by providing clear standards for reporting qualitative studies (17).

Data were collected from governmental hospitals in Alborz province, situated northwest of Tehran, selected on the basis of convenience and also as they had the experience of both quality improvement strategies, making them suitable cases for this study. These hospitals have been established since 2000 and are affiliated with the Iran Social Security Organization.

3.2. Data Collection

Participants who met the inclusion criteria were enrolled in the study. Purposive sampling was performed in this qualitative study, which is a form of non-probability sampling where researchers rely on their judgment when choosing members of the population to participate in their surveys. The population comprised accreditation experts, all supervisors of clinical wards, and clinical and office workers who had fully participated in both accreditation and ISO 9001 programs at the hospitals. The inclusion criteria were having at least three years of work experience at the hospital, a university degree (at least a BSc degree), and volunteering to share informative experiences. The exclusion criteria were having non-Iranian nationality, being younger than 25 years of age, and lacking verbal skills to present a reliable image of the study phenomenon.

In this study, 40 people were invited by e-mail for interviews, and interviews were continued until reaching data saturation, with 30 interviews completed. The number of interviews was thus determined by the research team's view based on making a fair balance between the obtained information and the number of interviewees during the study design for data saturation. Theoretical saturation occurred in this study, and the researchers stopped the interview process when no new information

was obtained by continuing the interviews (18).

The topic guide for interviews is presented in Table 1. The interview guide was prepared and finalized based on the primary literature review, the research objectives, the opinions of the research team, and a pilot interview with experts. All interviews were conducted in Persian. Participants were invited via email, and the time and place of the interview were coordinated with them. To create a comfortable environment, all interviews were conducted in

friendly and stress-free settings. During the interview, participants were also asked to complete a socio-demographic information form. Face-to-face interviews helped collect rich data. For participants who provided an informed consent form, the interview was conducted at a convenient date and place. All interviews were recorded by a digital audio recorder and transcribed verbatim. Each interview lasted between 40 and 60 minutes.

Table 1. The Interview Guides

Interview Guides	
Please tell us about your general and experiences of accreditation program in hospital.	What are your views on the strengths and weaknesses of the accreditation program? What are the factors affecting the implementation of the accreditation program? What are your recommendations for improvement the implementation of accreditation program?
Please tell us about your general and experiences of ISO 9001program in hospital.	What are your views on the strengths and weaknesses of the ISO 9001program? What are the factors affecting the implementation of the ISO 9001program? What are your recommendations for improvement the implementation of ISO 9001 program?

We have talked about the accreditation program and ISO 9001 program in the hospitals.

Please feel free to add anything that you think is necessary in order to improve their implementations.

3.3. Data Analysis

Thematic analysis was applied to identify common themes from the range of views provided during the interviews. All interview transcripts were analyzed using thematic analysis, which consisted of six stages: Familiarizing oneself with the data, generating initial codes, searching for themes, reviewing themes, refining and defining themes, and producing the report (19). At the familiarization stage, the research team actively read each transcript to identify initial patterns. In the initial coding stage, lines of each transcript were categorized with specific codes that conveyed meaning related to the research purpose. In the searching for themes stage, categorized codes were grouped according to their similarity to themes. At the reviewing themes stage, themes and codes identified in previous transcripts were reviewed and applied to subsequent transcripts. In the refining and defining stage, a matrix was created for each participant, and cells were populated with data from the transcripts. Finally, at the producing the report stage, results were reported for each theme using a narrative synthesis of the responses with supporting quotations. To preserve bracketing, researchers set aside their own beliefs and assumptions to avoid misrepresenting participants' intended meanings and experiences.

3.4. Trustworthiness

In this study, Lincoln and Guba's criteria for trustwor-

thiness—credibility, transferability, dependability, and confirmability—were used. These criteria were applied through several months of engagement with the research setting, providing thick descriptions illustrating participants' experiences, peer debriefing, member checks (participants attended a peer review to establish initial coding), recording the decision trail throughout the data analysis process, and transcribing interviews immediately after each interview. To enhance credibility and dependability, transcripts and translated texts were read multiple times by research team members. To expand transferability, participants' quotes were closely translated to English and presented. Researchers maintained insight into their own biases at all stages of decision-making as the study progressed. Standards of rigor were used to ensure trustworthiness and integrity within the data analysis process, including the use of computer software, peer review, audit trail, and negative case analysis.

4. Results

The characteristics of participants were described in Table 2. The age range of participants was 26 to 67 years old, and most of them were female, married, and had a bachelor's degree. Data analysis led to the identification and classification of primary themes and subthemes. The primary themes included the experience of the accreditation and the ISO 9001 programs, the strengths and weaknesses of these programs, factors affecting their

implementation, and recommendations for improving the implementation of these quality improvement programs in hospitals. Table 3 lists the themes, subthemes,

and participants' quotations that emerged from the study, categorized based on the two quality improvement programs.

Table 2. Characteristics of Participants

Qualitative Variables	No. (%)
Gender	
Male	12 (40)
Female	18 (60)
Age (y)	
< 40	15 (50)
40 - 49	13 (43.3)
> 50	2 (6.7)
Marital status	
Married	21 (70)
Single	9 (30)
Educational level	
Bachelor	22 (73.3)
Master	7 (23.3)
PhD	1 (3.4)
Work experience	
1 - 10	7 (23.3)
11 - 20	13 (43.3)
> 20	10 (33.4)
Organizational position	
Accreditation executive experts	4 (13.3)
Supervisors of clinical wards	10 (33.4)
Clinical staff	3 (10)
Office workers	13 (43.3)

Table 3. Primary Themes, Subthemes and Quotations

Variables	Primary Themes	Subtheme	Quotation
Accreditation	Experiences of accreditation program implementation	Positive consequences on effectiveness and efficiency	A female supervisor who worked in clinical wards explained: "As I said, the overall safety of our hospital was not bad, but there were parts that were worn out and needed to be rebuilt, and this accreditation program improved the safety of the emergency department. 47-year-old female office workers stated the following: "I think this is a good program that has improved the routine; tasks are done more easily and faster than before, and the patients are more satisfied because the work is done fast."
		Accelerate hospital affairs	
Increase orbital law			
Renovation of old structures			
Maintain of facilities and equipment			
Strengths of accreditation program	Facilitate processes		
Considering the standards and guidelines			
Improve employees' attitudes			
Help to hospital performance			
Making hospitals competitive			
Improve patients' safety			
Improve system integration			
Improving the quality of medical services			
Creating commitment in hospitals			
Improving a team spirit			

	Weaknesses of accreditation program	Lack of infrastructure	Another Supervisors of clinical wards stated: "Another problem is that some of the documentation is really redundant and takes up our time. Although the final result of the program seems to be the best inspector, this may lead to bias, and the results are not really fair."			
		Poor participation of physicians				
		Lack of culture building				
		Too much documentation				
		Poor training of units and evaluators				
		Weakness in indicators				
		Injustice and taste rating				
		Time consuming				
		Ambiguity of measures				
		Poor attention to information systems				
	Factors affecting the implementation of the accreditation program	Attitudes of organizational managers	One accreditation executive expert pointed out that: "The head and managers of the hospital have the most impact on this program. Because, generally, everything is hierarchical, and if a superior orders something, the subordinates must follow. In fact, the head and managers at the top of the pyramid can tell employees what they want them to do."			
		Reviews of accreditation experts				
		Existence of justice in the organization				
		Managers training programs				
		Holding regular meetings and committees				
		Financial incentives				
		organization culture				
		Environmental factors				
	Recommendations for improve-ment the implementation of accreditation program	Reduce the interval between accreditation periods	A man of office workers reported that: "I don't know why doctors do not participate in the accreditation program. They must participate so that this program can run well. Therefore, the best advice that can be given to help this program is to increase the participation of doctors in its implementation."			
		Apply proper planning				
		Following the example of successful countries				
		More involvement of physicians				
		Electronic system integration				
		Include accreditation in the personnel job description				
		Increase human and financial resources				
		More training of evaluators				
ISO 9001	Experiences of ISO 9001 program implementation	Increase the work process	Another clinical staff member who participated in the study stated that: "This program has defects and cannot fit our hospital. The ISO didn't improve patients' conditions, nor did it affect the structure of the hospital."			
		Lack of tangible effect due to defects in implementation				
		Not affecting the structure of the hospital				
		Problems with documentation				
		Staff resistance				
		Problems in applying ISO				
		Time-consuming				
				Strengths of ISO 9001 program	Compliance with international standards	A hospital office worker explained that: "In my opinion, the good thing about ISO is that it is available, and whenever you have any doubts, you can refer to it and find an answer to your question; that, in itself, is a good advantage. ISO also gives our organization a standard for work, and everyone has a clear definition of their work based on it."
					Improve staff skills	
					Unification of processes	
Improve the services quality						
Creating a working standard						
Codified and accessible						
Increase patient and staff satisfaction						
Understandable						
Existence of control measures						
Help to problem-solving						

Weaknesses of ISO 9001 program	Lack of culture building	One supervisor of clinical wards, who has a 17-year experience in the hospital, stated that: "Given my many years of experience in the hospital, I have to say that the ISO program identifies risks, but the big drawback is that it does not have a plan to manage these risks."
	Non-compliance with hospital standards	
	Weakness in knowledge management	
	Poor risk management in all settings	
	Lack of strategic attitude	
	Lack of complete executive records	
	Not paying attention to creative and capable people	
	Being dictated	
	Being ceremonial	
	Too much documentation	
	Time-consuming	
	Lack of familiarity of consultants with the treatment department	
	Lack of compulsory training courses	
	Inconsistency in execution	
	Tasteful results	
Factors affecting the implementation of the ISO 9001 program	Attitudes of senior managers	Another supervisor of clinical wards (49-year-old female) stated that: "ISO has the same condition as other programs, that is, its good performance requires the support of the upper hand. The most important person who can help is the hospital manager."
	Pressure from the presidency	
	Financial incentives	
	Organization culture	
	Existence of educational programs	
Recommendations for improvement the implementation of ISO 9001 program	Creating a positive culture in the organization	An accreditation executive expert with a master's degree stated that: "Our conditions impose great psychological pressure on personnel. The personnel have many concerns that reduce their motivation to participate properly in programs such as ISO 9001."
	Pay more attention to the executive dimension instead of documentation	
	Changing the attitude of the managers of the organization	
	Training of program managers and staff	
	More management supports	
	Insert ISO in the job description of employees	
	Need to Motivate the staff	
	Integration of ISO and accreditation	

5. Discussion

The findings of this study identified the hospital stakeholders' perspectives and experiences with accreditation and ISO 9001 program implementation, the strengths and weaknesses of the program, factors affecting its successful implementation, and recommendations for improving its implementation in hospitals. The findings of this study explore new aspects in hospitals affiliated with the Social Security Organization and show that the implementation of ISO 9001 and accreditation programs, despite having strengths, also has weaknesses and challenges in implementation and results that should be considered by managers. Although the impact and outcome of accreditation and ISO 9001 programs in hospitals remain debatable, this study provided a rich understanding of the programs associated with the results and processes taking place in hospitals affiliated with the Social Security Organization in Iran.

The strengths of the program included facilitating processes, paying attention to standards and guidelines, changing employees' attitudes, improving hospital performance, ranking the hospitals and making them competitive, improving system integration, enhancing the quality of medical services, making a commitment, and creating team spirit. Most of these results are similar to the findings of Karimi et al. demonstrating the positive effects of accreditation, such as improving health service quality and infrastructure, creating performance guidelines, promoting patients' education, and paying attention to the staff (20).

In hospitals, forming a good team improves performance, data sharing, and working toward the shared objective, thereby helping the staff provide safe health services to society. However, the findings of Moradi et al. revealed that the accreditation program had little effect on teamwork and commitment in hospitals, which is in contrast with the findings of our study (21). One of

the strengths expressed for accreditation in this study is changing the attitude of employees to help the organization, which is an important issue because Alkhenizan and Shaw systematically reviewed health staff attitudes toward accreditation and mentioned negative attitudes of healthcare professionals about accreditation (22).

The subthemes of accreditation indicated the perspectives of interviewees about the experiences and weaknesses of the accreditation program in hospitals. The results of the interviews showed that accreditation standards are more ambiguous in terms of indicators. In a study by Ahmadi et al., it was found that fundamental errors in the wording of accreditation indicators and their incompleteness could lead to different interpretations, and the questions were not clear, hence resulting in ambiguity for evaluators and the hospital staff (23). The structural, contextual, and procedural changes involved in accreditation put too much stress on hospital managers and employees. Therefore, it is necessary to pay attention to the implementation of such programs so as not to create problems for the managers and staff of the hospital (12).

The other major weaknesses were the poor participation of physicians, excessive documentation, and wasting the time of the personnel. The accreditation program requires extended documentation, which increases the workload of hospital personnel and is time-consuming. In a study, Brubakk et al. stated that the increased workload of personnel when implementing accreditation was a challenge (24). The weaknesses identified in this study are in agreement with the results of the Bogh et al. study that examined staff experience and perception of hospital accreditation in Denmark and staff stated the hospital's accreditation as meaningless, difficult, and confusing (25).

The results of our study showed that hospital managers play a key role in the successful implementation of accreditation. Similar to our findings, the results of a study showed that managers value positive external evaluations during accreditation, which might explain the level of tension in order to achieve such a positive assessment (26). Also, in a study by Ng et al., the results revealed that various stakeholders (the government, society, patients, and healthcare providers) influence the implementation of accreditation programs (27).

Our findings also revealed that, similar to the accreditation program, the implementation of ISO 9001 affects the hospital's performance, which highlights the importance of the ISO 9001 program. Similar to our findings, the findings of a 2014 study in Iranian regional hospitals showed that there was a significant relationship between the implementation of ISO 9001-2008 QMS and some indicators of quality effectiveness (16). Patient satisfaction is an important and commonly used indicator for measuring the quality of healthcare and the success of hospitals. Likewise, consistent with our findings, the results of previous research among healthcare managers and

accreditation executive experts revealed that the implementation of ISO 9001 in hospitals ensures patient satisfaction in the delivery of high-quality healthcare (28).

Yousefinezhadi et al. mentioned that ISO 9001 also improved patient satisfaction and safety, cost-effectiveness, and the hospital admission process and reduced the percentage of unscheduled returns to the hospital (29). In the field of healthcare, ISO 9001 is an essential tool for the management of the services offered to patients, but the results of the interviews in this study demonstrated that the implementation of this program has some weaknesses.

Accreditation and ISO 9001 programs have a positive effect on improving hospital performance as long as they are well implemented. The results of our study showed that various factors are effective in the regular implementation of these programs, and recommendations have been provided in this regard. These programs can be implemented and used well in hospitals with effective activities such as providing training, offering management support, improving staff motivation, involving physicians, and following the example of successful countries. In their study to improve the condition of hospitals through ISO 9001, Raeissi et al. recommend that creating work teams, continuously evaluating processes, comparing programs with external patterns, and providing accurate data can help improve processes (28). The International Society for Quality in Healthcare (ISQua) has some basic requirements for the healthcare accreditation programs, including the accreditation body, standards, and surveyor training, which can be used for benchmarking and improving the Iranian hospital accreditation program (30).

5.1. Implications for Policy, Practice, and Research

The study has provided evidence that makes clear the experiences of implementation of the accreditation program and the ISO 9001 program in hospitals affiliated with the Social Security Organization in Alborz Province, Iran. Also, this comparison led to the identification of strengths, weaknesses, and affecting factors, and provided recommendations for the proper use of these programs. These new guidelines and principles about accreditation and the ISO 9001 program led policymakers to become more aware of these programs and implement them in hospital settings. Accreditation and ISO 9001 programs seek to improve the quality of care and patient safety in the hospital, which must be properly implemented.

Given the extent of Iranian hospitals and to expand the generalizability of the findings related to accreditation and ISO 9001, it is recommended that wide-ranging studies be conducted with a variety of methods. Future research can examine the strategies for involving physicians in accreditation programs and ISO 9001. Finally, it is worthwhile to study the dimensions of accreditation

programs and ISO 9001 from the perspective of health policymakers and managers of MOHME to promote these programs.

One of the important strengths of this study was the vastness of the subject and the wide range of issues identified about accreditation and ISO 9001 programs that led to the in-depth exploration of the issue. Moreover, the most important limitation of this study was the lack of access to the managers of the MOHME due to the problems caused by the COVID-19 pandemic. Also, according to the demographic characteristics of the participants, the quality of the results of this study may be affected. Of course, an effort was made to guarantee the quality of research results through diversity in sampling.

5.2. Conclusions

The present study highlighted the dimensions of implementing the accreditation and ISO programs in hospitals. These findings can be used by hospital managers to improve the implementation of this program in Iranian hospitals. Also, various stakeholders' involvement should be encouraged in implementing the accreditation and ISO programs. Finally, promoting the organizational culture, physicians' involvement, and human and financial resources will resolve many problems of the accreditation and ISO 9001 program, and this will be achieved with proper education, more management support for this program, and enhancing the hospital personnel's motivation.

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Authors' Contribution:

It was not declared by the authors.

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The authors declare that there is no conflict of interest in this research.

Data Reproducibility:

Datasets are available through the corresponding author upon request.

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