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Design and psychometric properties of a questionnaire to assess quality management of health care services: a sequential exploratory study

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ABSTRACT

Background: Quality management is one of the most effective programs for improving the performance of healthcare systems.

Aims: This study aimed to develop and assess the psychometric properties of a questionnaire to assess the quality management of healthcare services in Iranian hospitals.

Methods: This study is a mixed sequential (Qualitative-Quantitative) exploratory study. This study was conducted in the two phases of identifying and designing the items and evaluating the psychometric properties of the instrument. In the preliminary phase, quality management models in healthcare systems were reviewed. In the second phase, the psychometric evaluation of the instrument was done using face and content validity, construct validity, and reliability.

Results: A total of 293 completed questionnaires were returned. Six main dimensions and 30 variables were identified according to the factor loadings. The dimensions of the final questionnaire included leadership, human resources, financial resources, planning, control, and process approach. Cronbach's alpha coefficients for each subscale were acceptable, ranging from 0.85 to 0.93, and for the total scale, it was 0.96. Confirmatory factor analysis by Amos software was performed afterwards to confirm the relationship between each of the variables and the main dimensions. Confirmatory factor analysis demonstrated a five-factor model, all of whose fit indices were acceptable, except for the goodness-of-fit index and normed fit index (Normed chi-square [$\chi 2/df$] = 2.35, RMSEA = 0.066, TLI = 0.907, CFI = 0.906, AGFI = 0.899).

Conclusion: The dimension of leadership has the greatest impact on the quality management of healthcare services in Iran. It seems that with continuous planning on the quality of management at the ministry level in the Iranian health system, this dimension can significantly contribute to improving the quality of healthcare services.

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Keywords: *Healthcare, Quality Management, Questionnaire*

INTRODUCTION

In the 21st century, healthcare delivery is focused on enhancing the quality of care. This is due to seemingly irrelevant international events, such as creativity in finance and differences in healthcare provision over the last hundred years, the mid-18th to 19th centuries (Sheingold and Hahn 2014).

Products and services through quality management (based on the report of the World Health Organization (WHO) in 2013), for achieving a public health goals, it is necessary to provide quality services in terms of prevention, treatment, and rehabilitation (Al-Ibrahim 2014). Accordingly, the health system should formulate and implement structural, procedural, and outcome requirements to improve the quality of healthcare services by selecting an appropriate quality management model (Dehnouyeh, et all. 2018).

For the healthcare system, quality management will lead to quality improvement. The key factors in quality management include changing safety culture and oversight by senior leaders and focusing on the workforce as well as patients (Campbell et all. 2020). A study in 2018 showed that the dimension of quality improvement has a great impact on patient loyalty and satisfaction (Gong and Yi 2018).

To advance the goals of quality improvement in the health system, factors such as supporting senior managers, formulating goals of continuous quality improvement in strategic planning, creating and reviewing processes, training human resources and working as a team, establishing a quality culture in the organization, and creating sustainable financial resources factors, are influential.(Mosadegh Rad and 2015).

However, due to the specific characteristics of health services and the challenges in managing health services, such as dependence on technological advances in diagnosis and treatment and the cost of resources, including equipment and specialized manpower, deploying these models have not had a notable impact on improving the quality of services provided, especially in the developing countries (Antony et all. 2018).

In Iran, the quality management system began in the mid-1990s. Models such as TQM, ISO, clinical governance, models of excellence (EFQM), and recently the implementation of national accreditation standards tool have been established in the Iranian healthcare system (Moradi et all.2015).

However, so far, this tool has not been able to have good results at implementation time. In a study conducted to evaluate the accreditation tool, the level of satisfaction of hospital managers with the results of the implementation of accreditation tool standards was reported to be moderate to low (Mossadegh Rad et all. 2018). Hospital managers face a lack of resources and several challenges to implement accreditation standards (Mossadegh Rad 2017a). As a result, due to the impact and moderate satisfaction with the existing results, the costs incurred by the Ministry of Health were not justified.(Mosadegh Rad et all. 2017b,2019) Nonetheless, there are challenges in the Iranian healthcare system such as poor use of models, lack of agreed quality management indicators, barriers in manpower, lack of senior managers' support, and instability in the establishment of standards(Dehnouyeh et all. 2018).

Therefor, in order to assess the quality of providing health services and make appropriate policies, as well as to recognize the related challenges, it is necessary to provide a suitable tool and identify the effective factors(Simbar et al. 2020). In this regard, few tools have been designed to measure the quality management of health care services in Iran. Thus, this study sought to fill this gap in the existing knowledge and evaluate the psychometric properties of a questionnaire to assess the quality management of health care services in Iran. This study aimed to assess the psychometric properties of a questionnaire to assess the quality management of healthcare services in Iranian hospitals.

METHODS

Study Design

This was a mixed sequential exploratory study to develop a valid and reliable questionnaire to assess the quality management of healthcare services in Iranian hospitals. Therefore, the study was conducted in two phases (qualitative and quantitative), using Waltz steps(Walts 2012) for tool development(Creswell et al. 2017).

Phase 1: Development of the tool

In the first stage, researchers reviewed the related literature for identifying the current status of quality management in health services around the world. They studied quality management models, such as TQM, EFQM, ISO, and Clinical Governance, and theories of reputable scientists in quality management such as Juran, Crosby, and Deming. Information was collected through valid and relevant articles to identify and compare the dimensions and variables affecting quality management and the official website of the WHO.

In the next stage, the countries were selected for review study with criteria such as having a quality management model in the healthcare system, the availability of the required information, and the possibility of modeling and implementation according to the current situation in Iran. These countries included the United States, Egypt, Japan, and Malaysia. In the qualitative method, the data were collected from articles, related doctoral dissertations, rules and regulations in the Ministries of Health in the selected countries, and the website of the WHO. Based on a comparative study, the conceptual model of the research was extracted in six main dimensions (i.e., human resources, leadership, planning, process approach control, and finances).

Quantitative phase: psychometric assessment of the tool

In this part, the researchers designed the tool based on the review study and conceptual model in 40 items. In the quantitative part, the psychometric properties of the questionnaire, including quantitative and qualitative content validity and reliability, were assessed.

Content validity

To establish the content validity and reliability of the tool, a survey was conducted through 20 professors in the field of health services management with at least 10 years of teaching experience at university. To validate the questionnaire, the relative content validity ratio (CVR) and content validity index (CVI) was used along with Cronbach's alpha coefficient to measure reliability. The CVI was calculated by dividing the sum of scores for each item (options: 1- relevant but in need of review, 2- relevant, and 3- fully relevant) by the total number of specialists. To measure the CVR, experts were asked to review items based on a three-point scale of "necessary", "useful but not necessary" and "not necessary".

Evaluation of its psychometric properties

Reliability: To measure the questionnaire reliability, Cronbach's alpha coefficient was calculated through SPSS version 20. In this method, the correlation between the score of each item and the total score of the instrument is captured. In this method, people who achieve a certain score in a certain item are expected to do the same in other items, as all items have been designed to measure a specific feature. The total reliability through Cronbach's alpha was equal to 0.946, which indicated that the questionnaire has sufficient and appropriate reliability. In the study of the following components of the research, it was observed that the degree of reliability in all methods was appropriate.

At this stage, the validated questionnaire was sent to the statistical population of the research via email. The questionnaire was in two parts: i) demographic information and ii) 31 questions about factors affecting quality management in healthcare. The statistical population consisted of 320 quality improvement specialists in the Iranian healthcare system in 2020 who were selected through simple random sampling (the

number of samples was based on 5 to 10 times the number of questionnaire questions).

Data analysis

The collected data was transferred into SPSS version 20 for exploratory factor analysis. The dimensions and variables of the research model were identified and named. Internal consistency and item analysis were assessed by calculating Cronbach's a coefficient. In the last stage, the validity of the model extracted from the exploratory factor analysis was confirmed through confirmatory factor analysis using structural equation modeling by Amos version 24. The strength of the model was assessed using the Chi-square goodness-of-fit ($\chi 2$), normed Chi-square ($\chi 2/df$), root mean square error of approximation (RMSEA), Tucker-Lewis index (TLI), comparative fit index (CFI), goodness-of-fit index (GFI), normed fit index (NFI), and adjusted goodness-of-fit index (AGFI). It is interpreted as acceptable when normed $\chi 2 < 3$, RMSEA < 0.08, CFI > 0.90, GFI > 0.85, AGFI > 0.85, and NFI > 0.90. The $\chi 2$ should have a P-value of > 0.05 (Kakemam et all 2021, Hu and Bentler 1999).

RESULTS

Phase 1: - Development of the tool

In a review study in the selected countries, 40 items were found. According to the experts' opinions, nine questions were removed from the questionnaire in the validation stage. Then, in this stage the primary tool with 31 items was extracted.

Phase 2 - Quantitative Study: Survey

The research tool is a 31-item questionnaire rated on a 5-point Likert scale. The statistical population was 320 specialists in the quality improvement unit of health centers who worked in the Ministry of Health and the Social Security Organization in 2020 in Iran. A total of 201 questionnaires were returned, some of which were incomplete and could not enter the statistical process. Finally, 293 complete questionnaires were analyzed. The results of the descriptive analysis showed that the average age of the respondents was 40.58 years, and their average work experience was 14.15 years. Also, out of 293 people, 49% were women, and 51% were men, with the undergraduate and postgraduate groups claiming the highest number (39%).

TABLE 1: Descriptive data of the target population

Variables	Age	work experience	Gender		Education		
Mean	40.58	14.15	Woman	Man	P.H.D	Postgraduate	Undergraduate
Standard deviation	8.23	4.52					
Percentage			0.49	0.51	0.22	0.39	0.39

Table 1 reports the mean, standard deviation, skewness, and kurtosis of the research variables. Based on the results, the skewness and kurtosis values of the variables are between -2 and +2, indicating that the data distribution is almost normal.

In this research, to identify the research factors and classify research questions in each factor, the principal component analysis method was used. According to the results, the sampling adequacy index (KMO) for the questionnaire was greater than 0.70, showing that the data are sufficient for factor analysis. Also, the level of Chi-square (significance level) of Bartlett index for all the variables and their dimensions was calculated (0.000), which was lower than the error levels of 0.05 and 0.01, suggesting that the data are

continuous. The factor analysis method has been approved, and the validity status is appropriate.

According to the results, the factors whose eigenvalues were less than one were excluded. The first six factors (i.e., financial resources, leadership, human resources, process approach, control, and planning) explain 61.433% of the variance. Note that in rotating the remaining factors, a proportion of the total changes has been explained by these six factors.

TABLE 2: Rotating Agents Matrix

	Planning	Factor load	Control	Factor load	Process Approach	Factor load	Human Resources	Factor load	Leadership	Factor load	Financial Resources	Factor load
Verified variables	Q22	0.690	Q19	0.671	Q29	0.826	Q9	0.735	Q4	0.695	Q17	0.751
	Q21	0.688	Q20	0.650	Q30	0.780	Q8	0.654	Q2	0.651	Q16	0.743
	Q23	0.615	Q18	0614	Q31	0.724	Q10	0.588	Q1	0.636	Q15	0.536
	Q24	0.523			Q26	0.627	Q12	0.580	Q5	0.633		
					Q27	0.607	Q11	0.573	Q3	0.582		
					Q28	0.596	Q13	0.508	Q6	0.581		
							Q14	0.500	Q7	0.557		

According to Table 2, each variable is placed in a factor with which it has a high correlation. Item 25 was removed from the model due to a lack of correlation with factors. After identifying the items for the main factors of the research, confirmatory factor analysis was used to ensure the existing factor structure.

Confirmatory factor analysis measures the relationships between independent and dependent variables, which can show the direct and indirect effects as well as the total effects of independent variables for dependent variables. Factor loading indicates the effect of variables on each other. In this study, we considered the acceptance factor equal to 0.5.

TABLE 3: Factor loadings and t-values of the main model dimensions

	Factor In estimation mode Standard	Factor In non-standard estimation mode	t-value	p Value	Condition
Leadership	0.953	1.000	8.512	0.000	Confirmed
Human Resources	0.942	1.182	9.084	0.000	Confirmed
Financial Resources	0.705	0.776	6.046	0.000	Confirmed
Control	0.797	1.029	8.292	0.000	Confirmed
Planning	0.831	1.183	8.546	0.000	Confirmed
Process Approach	0.743	0.861	7.533	0.000	Confirmed

TABLE 4: Factor loads and t values of the sub dimensions

Variable	Variable badge	Load factor in state Standardized	Load factor in state not standardized	T statistic value	p Value	
Condition						
1-Leadership participation	Q1	0.600	1.000	11.233	0.000	Confirmed
2.Continuous quality improvement policies	Q2	0.622	1.011	12.269	0.000	Confirmed
3. Scheduled goals	Q3	0.575	0.991	8.288	0.000	Confirmed
4.Organizational quality culture	Q4	0.591	0.986	8.501	0.000	Confirmed
5. Participatory management	Q5	0.705	1.049	9.602	0.000	Confirmed
6. Developing shared values	Q6	0. 697	1.058	9.501	0.000	Confirmed
7. Senior Management Commitment	Q7	0.619	1.025	8.773	0.000	Confirmed
8. Staff participation	Q8	0.696	1.000	9.896	0.000	Confirmed
9. Scientific and operational capability of staff	Q9	0.710	0.881	9.881	0.000	Confirmed
10. Staff commitment	Q10	0.710	0.998	11.495	0.000	Confirmed
11.Forming working teams	Q11	0.710	1.015	11.495	0.000	Confirmed
12. Effective inter-organizational communication	Q12	0.698	1.031	11.204	0.000	Confirmed
13- Delegation of power	Q13	0.695	1.020	11.129	0.000	Confirmed
14. Assessment of staff performance	Q14	0.856	0.856	10.062	0.000	Confirmed
15- Funding from public sources	Q15	0.535	1.000	12.235	0.000	Confirmed
16. Identify and protect income centers	Q16	0.780	1.423	7.706	0.000	Confirmed
17. Identifying capabilities and limitations on internal resources	Q17	0.725	1.294	7.639	0.000	Confirmed
18. Internal Audit	Q18	0.698	1.000	9.653	0.000	Confirmed
19. Monitoring stakeholder requirements	Q19	1.065	1.065	11.439	0.000	Confirmed
20. Internal Independence	Q20	0.627	0.921	9.420	0.000	Confirmed
21- Planning the selection of future managers	Q21	0.706	1.000	12.526	0.000	Confirmed
22- Setting standards of Functional Goals	Q22	0.765	1.027	12.231	0.000	Confirmed
23. Organizing and analyzing documented information	Q23	0.764	0.941	11.685	0.000	Confirmed
24. Evidence-based decision making	Q24	0.655	0.773	10.074	0.000	Confirmed
26. Identifying the interrelationships of processes	Q26	0.636	1.000	10.235	0.000	Confirmed
27- Developing a process-oriented attitude	Q27	0.588	0.944	12.332	0.000	Confirmed
28- Organizing activities	Q28	0.747	1.271	10.904	0.000	Confirmed
29- Removing activity overlap	Q29	0.800	1.227	11.196	0.000	Confirmed
30. Assessing the risks and consequences of stakeholder activity	Q30	0.791	1.338	11.060	0.000	Confirmed

According to tables 3 and 4, with the significance tested at 0.05 level of error, all factor loadings were significant since the t-value statistic was higher than the critical values of 1.96 and -1.96.

TABLE 5: Confirmatory factor analysis fits for the quality management questionnaire (n = …)

Index	Index Criteria (n > 250)	Fit Index in Sample of study (n = 220
$\chi 2$ (df), p-value	$p < 0.05$	932 (396), $p < 0.001$
Normed chi-square ($\chi 2$/df)	<3	2.355
RMSEA (CI)	<0.08	0.066 (0.061, 0.072)

TLI	>0.90	0.907
CFI	>0.90	0.906
NFI	>0.90	0.912
GFI	>0.85	0.905
AGFI	>0.85	0.899

Model fit indices

The results represent the relative appropriateness of the indicators. Based on the output of Amos, the calculated value of $\chi 2$ was equal to 2.355, which compared to its degree of freedom (396), was less than 3. The low level of this index indicates a slight difference between the conceptual model and the observed research data. The RMSEA value was equal to 0.066. Also, GFI, NFI, and TLI indices were equal to 0.905, 0.912, and 0.907, respectively.

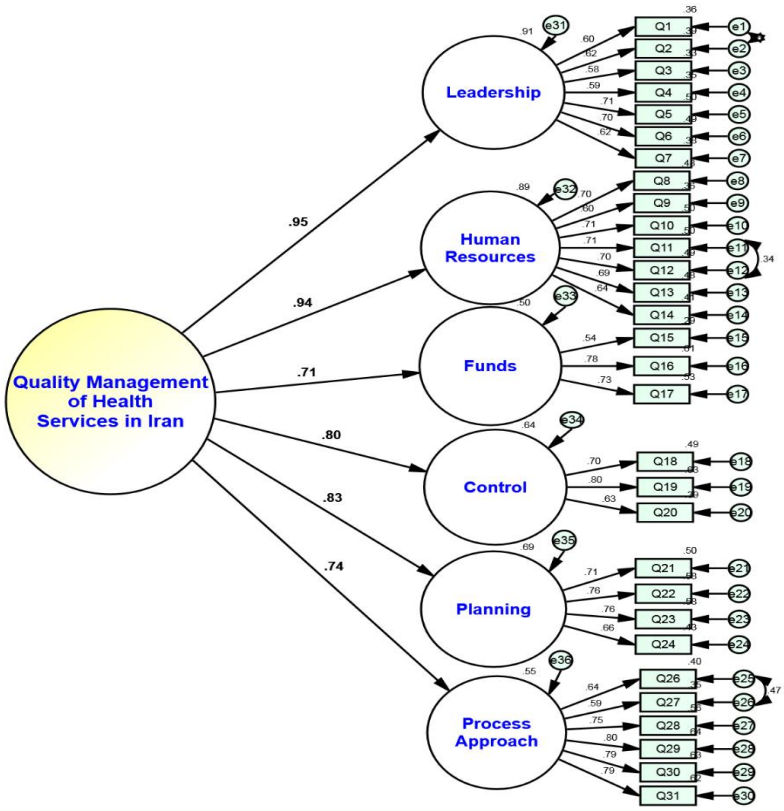

FIGURE 1: Factor loadings of the final research model in the standard estimation model

This figure presents a final model of quality management. The actual loading of each structure is shown in the official estimate. Note that in this figure, large circles represent latent factors, rectangles represent measurement metrics for those factors, and small circles indicate some undefined variance for each variable. The loading factor accepted in this section is 0.5.

DISCUSSION

This current study tried to develop and assess the psychometric properties of a questionnaire to assess the quality management of healthcare services in Iranian hospitals. According to the results of this study, the most effective dimensions in quality management in Iran include leadership, human resources, control, planning, and management process approach

along with variables such as leadership, participatory management, employee commitment and teamwork, and establishment and maintenance of revenue centers. Sustainability, monitoring the needs of stakeholders, setting performance goals, and eliminating overlapping activities are the most significant variables. These results seem to be very similar to the studies of researchers in this field.

The study conducted by Antony et al. (2018) revealed that leadership has a crucial role in quality management for organizations that have a customer-centric approach. Managers can simplify processes to achieve results in a short time.

Based on the results of a study by Carrasco et al. (2019), establishing accreditation standards as a quality improvement program can improve patient safety culture and patient care, but there are also negative consequences such as the effects of bureaucratic rules on clinical practice.

In the study of Agrawal et al. (2018) regarding the application of quality management in health care, they emphasized that the training of future managers in healthcare requires defining a specific training program on quality management given the nature of health services.

According to a study on the Department of Health and Human Services in the US(2016), the vision of the Health Research Agency (AHRQ) researchers is to create a quality healthcare system that serves all human beings equally. Providing quality patient care at the right time and place using economic and financial resources upturns patient's safety. Meanwhile, in a study in the US on the effect of developing quality assessment indicators for service delivery, it was observed that in high-grade hospitals, the rate of neurosurgery admission had decreased (Lichtman et all.2018).

On the other hand, Ferreira and Mackays (2017) showed no significant relationship between restricted access to clinical safety in hospital services and patients' satisfaction, while it was more effective in neonatal mortality. They also believed that to improve the quality of healthcare delivery, organizations should work together as a team in planning and implementation. However, the same study stated that leadership's importance is less than the role of employees, which does not concur with the findings of the present study, which identified the leadership component as the most effective factor in establishing quality(Ferreira et all. 2017).

According to Seiedin et al. (2019) in order to improve the quality of hospital services, the participation of managers, staff commitment, development of a quality improvement program, progress in the culture of continuous improvement, and the creation and review of processes are essential.

Al-Shdaifat Emad (2015) discussed how to implement a comprehensive quality management model in Jordan. In this study, in line with the present study, it was stated that if senior management does not believe in improving the quality of healthcare and patient quality culture, it is meaningless to hope for the successful implementation of quality enhancement programs. This culture must be present in all components of the organization, including management and employees. According to them, efforts should be made to establish an efficient system for the inspection and accreditation of the healthcare system.

This result has also been found in a study conducted by Bahadori et al. (2018), who showed that the role of managers and employees in implementing accreditation standards and cost-effectiveness of programs is very crucial in improving quality.

In another study conducted by Dehnouyeh et al. (2018) the weaknesses observed in Iran's health quality management system included weaknesses in the performance of senior management, financial and human resources, and weaknesses in the use of laws and regulations along with the application of quality management models. According to the results found in the present study, these factors are among the effective factors in quality management in Iranian health services.

LIMITATIONS

Although the results of this study lend support for the development and assessment of the psychometric property of a questionnaire to assess quality management of healthcare services in Iranian hospitals, the quantitative survey with convenience sampling method limits the generalizability of the study results beyond the study sample.

CONCLUSION

The aim of this study was to determine the active factors in quality management in health services and evaluate the psychometric properties of a questionnaire to assess the quality management of healthcare services in Iranian hospitals. The results were obtained by reviewing the relevant literature, surveying experts and the statistical community, and presenting the final questionnaire.

Given the results of the study and the importance of commitment to the participation of managers in improving quality, the policies of the ministry of health should be in line with improving the quality of health services. Planning over a period of time, use of trained manpower, and the allocation of financial resources along with the control of results using audits and standard design at the level of service providers in health centers can dramatically improve the quality of services.

Availability of data and materials

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Abbreviations

AHRQ: Agency for healthcare research and quality; STROBE: Strengthening the reporting of observational studies in epidemiology; CFA: Confirmatory factor analysis; RMSEA: Root mean square error of approximation, CI: confidence interval, TLI: Tucker–Lewis index, CFI: Comparative fit index, NFI: Normed fit index, GFI: Goodness-of-fit index, AGFI: Adjusted goodness-of-fit index

Ethics approval

Refer to Islamic Azad University of Science and Research and receive ethics from the Faculty of Medicine- Islamic Azad University of Medical Sciences, Tehran, Iran, and approved by ethics code I.R.IAU.TMU.REC.1398.088.

Consent to participate

Not applicable

Conflict of Interest

The authors have no relevant financial or non-financial interests to disclose.

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Author contributions

V. Z., S J.T. planned the study; LR conducted the survey; MM. analyzed the data, VZ drafted the article and submitted it.

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