

Research Article

Designing a Model for Implementing Clinical Guidelines in Iran

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Abstract

Background

Clinical guidelines refer to a developed scientific statement to help physicians and patients for decision-making about the best care for special clinical conditions which can be an important document to shape evidence-based medicine.

Objective

This study has been conducted with the aim of designing a model for implementing clinical guidelines in Iran to enhance the quality of services.

Methods

The current research which has been of descriptive analytical type has been performed through combined quantitative-qualitative method in 2018. The statistical population consisted of 400 health managers and experts, and it was conducted through multistage sampling method in five regions of the country (North, South, Center, East, and West). Overall, 20 academic experts were chosen from each university. For data collection, a researcher-made questionnaire was used, and to measure the face and content validity, Content Validity Ratio (CVR) was used, while for determining the reliability, test-retest method as well as Cronbach alpha coefficient with a correlation of 0.934 was utilized. Also, to determine the validity of the items, exploratory factor analysis with Varimax rotation as well as Lisrel 8.8 and SPSS 24 was employed. Finally, to determine the fitness of the model, fitness indices were used.

Results

Out of the 63 factors identified in the questionnaire, based on CVR, 47 factors were confirmed by the experts. In the exploratory factor analysis, six economic (with seven components), organi-

zational (with nine components), organizational culture (with eight components), the clinical guidelines feature (with eight components), insurance (with seven components), trusteeship of the healthcare system (with eight components) were identified as the main dimensions, accounting for 52.35% of the total variance of the variables. The economic dimension had the maximum effect on implementing clinical guidelines (0.90), while the clinical guidelines feature (0.63) and organizational culture (0.63) showed the minimum extent of effect on implementing clinical guidelines. After performing Confirmatory Factor Analysis (CFA), all factors were shown to lie within a desirable range and the model indicated goodness of fit and was confirmed.

Conclusion

Alongside the trend of corresponding and developing CPG, their usage should be planned. Evidently, imposing the mentioned interventions with the ultimate goal of sustainable behaviour change in providing healthcare services requires contribution of all practitioners, presentation of suitable facilities for implementing clinical guidelines based on evidence, time and personnel management, training methodology and planning, developing the necessary infrastructure, supervision, and developing professional and legal motivation.

Keywords: Clinical guidelines; Evidence-based medicine; Facilitator; Implementing clinical guidelines; Obstacles

Introduction

Background

The main reason of the different performance in healthcare is the gap between knowledge generation and its consequences. To fill this gap, in recent years, evidence-based method has attracted a great deal of attention [1,2]. Evidence-based method is an international priority in an attempt to improve the quality of healthcare and has been defined as integrating clinical experience with high quality evidence and patient priority [3,4]. Clinical guidelines refer to a developed scientific statement to help the patient and physician for decision-making about the best care for special clinical conditions, which can be an important document to shape evidence-based medicine [5,6]. Development and implementation of instructions aim to organize and present the best available evidence to support clinical decision-making in order to improve the health care quality, outcome of patients, effectiveness, and reduction of costs [7-11]. Accordingly, through different ways, clinical instructions help the executors to improve professional performance, quality of care, and the outcome of patients [12].

In countries such as USA and the Netherlands, around 30-40% of patients do not receive evidence-based healthcare. About 20% or more of the patients receive the treatments that are not required or are even sometimes harmful. Indeed, there is a gap between what is currently available and the best evidence-based medical treatment [13]. Not following instructions may result in inessential diagnosis and inadequate or unfocused treatment [14]. Evidence clearly suggests that there are many obstacles against the use of evidence and

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its implementation. The major obstacles include lack of time, lack of knowledge, lack of medical resources, negative attitude to evidence, and financial constraints [15]. In the investigation by Kabana et al, it was found that lack of awareness, limited familiarity, and disagreeing with clinical guidelines are the main obstacles in approving clinical guidelines. Furthermore, this investigation concluded that the main obstacle can be attributed to the simple fact that sometimes physicians are not aware of the existence of special clinical guidelines [12]. In addition, the findings of a qualitative study indicated that the obstacles for creating, developing, and implementing clinical guidelines include the context of practice, evidence-based healthcare systems, professionalism of individuals, supportive policymakers and political context, innovation, and patients [16].

A study in Tehran indicated that only 31.8% of physicians were aware of clinical instructions for presenting health care services. The obstacles against implementation, according to these people, included lack of awareness of development of clinical instructions and evidence-based performance (37%), long way for employing clinical instructions (70%), unavailability (60%), lack of skill of physicians in using clinical guidelines (31%), and eventually absence of the necessary conditions and facilities (65%) [17]. Furthermore, the authors developed a framework in which these obstacles were categorized into three main groups: the obstacles related to physician's knowledge (e.g. lack of awareness and unfamiliarity), obstacles affecting the attitude of physicians (e.g. absence of agreement and lack of motivation), and external factors (patient associated factors, the feature of guidelines, and environmental factors) [6,18,19]. Furthermore, the results obtained from a study in Iran showed that 39% of the participants had very little familiarity with EBM databases, and only 12.7% of these databases were very familiar [20].

The implementation strategies should be based on the current knowledge about effective interventions and evaluating the potential obstacles to approve guidelines [21,22]. Evaluating the obstacles and facilitators to implement clinical instructions is the first step in adapting and approving localized evidence [23]. Clinical instructions can improve the quality of healthcare services, but currently there are a number of challenges in adopting and implementing the instructions [8]. Considering the legal necessity to produce CPG in Iran, localized clinical instructions are rarely used to offer clinical services [16,17]. Therefore, recognizing and investigating these obstacles to enhance the quality of services seem to be essential. On the other hand, developed and translated clinical instructions are sparse in Iran, and their distribution is also limited or has become stopped [16]. Therefore, given the investigations performed in Iran, there are problems in implementation of the guidelines including absence of adequate studies about the obstacles of implementation and unavailability of a suitable executive model. Therefore, to motivate the authorities to select development policies and use clinical guidelines, this study has been conducted with the aim of presenting a model for developing a system of producing and implementing clinical guidelines.

Objectives

This study has been conducted with the aim of designing a model for implementing clinical guidelines in Iran.

Methods

The present research which is a descriptive analytical study has been conducted by combined quantitative-qualitative method in 2018

across Iranian medical sciences Universities to achieve a suitable model for implementing clinical guidelines in Iran.

Setting

This study has been conducted in 2018 across medical sciences universities that are the executive of clinical guidelines in Iran.

Sample

The research population in the first stage was used from the common and available models regarding implementation of clinical guidelines as information resources. The second stage involved the professors of the fields of healthcare services management, the health economy, and the experts of developing clinical guidelines in Ministry of health and health policy-making. In the third and fourth stages, field study was done by academic professors, students, and executives of clinical guidelines as well as experienced experts in the field of healthcare system across the country. The sample size in the third and fourth stages consisted of 400 health managers and experts, chosen through multistage sampling method across five regions of the country (North, South, East, West, and East). Each region by allocating for universities and five quotas was chosen and then introduced into the cluster. Overall, 20 academic experts were chosen from each university.

Data collection

The required data were collected through investigating the literature of all related studies and performed on obstacles, facilitating factors, effective factors, awareness, and attitude in Iranian and global clinical guidelines in relevant databases. Further, collection of field data was performed using a researcher-made questionnaire to measure the influential factors in designing a model for implementing clinical guidelines. The questionnaire was designed in two sections. The first section included gender, age, and level of education, management background, workplace, and academic field. The second section consisted of 47 items about the influential factors in implementing clinical guidelines in the form of Likert scale ranging from absolutely agree [5], to absolutely disagree [1]. The responsiveness rate was 100%.

Validity and reliability

To determine the qualitative face validity, a 20-person specialized panel was formed with the presence of healthcare specialists and experts of developing clinical guidelines to resolve the ambiguities of factors, lack of fit of factors, the objective and presentation of comments, whose comments were applied in the questionnaire. To examine the content validity quantitatively, Content Validity Ratio (CVR) coefficient was used, where the minimum acceptable value of this index based on the number of assessors was 0.42. In this study, out of the 72 variables in the initial questionnaire, given the CVR value, 47 variables were introduced into the final questionnaire. In order to examine reliability along the questionnaire, test-retest method was used. Accordingly, the questionnaire was distributed among 20 specialists and experts in two stages and the data were collected. After completion, the data were introduced into SPSS 24. For reliability over time, the correlation of the responses of the experts along the two stages of data collection was calculated, which was obtained as 0.934.

Data analysis

The collected data were analysed using Exploratory Factor Analysis (EFA) to determine the main effective components for implementing clinical guidelines, while Confirmatory Factor Analysis (CFA) was utilized to confirm the model. In addition, to analyse the current item, principal components analysis method with vertical rotation using vari max technique was employed. By performing exploratory factor analysis for the questionnaire and through vertical rotation, six main factors were identified. To investigate the goodness of fit of the measurement instrument (questionnaire), CFA was utilized with covariance approach via Lisrel 8.8 software. In addition, to investigate the type of data distribution, skewness and kurtosis coefficients were used. Finally, to investigate the research questions and hypotheses, independent one sample t-test as well as Friedman ranking test was used by SPSS 24.

Ethical considerations

To perform the research, official permission was presented as introduction letter to the research Department of the universities of interest. Completion of the questionnaire was performed with complete consent of the subjects, while ensuring confidentiality of the identity of the individuals.

Results

The results indicated that the mean age of the participants was 40.53 years old with a standard deviation of 6.86. The maximum frequency in the variable of gender was related to men with 230 (57.5%) subjects, while the maximum frequency regarding the level of education was associated with medical subspecialty with 118 individuals (29.5%). Considering working background, the greatest frequency was related to the group of 15-20 years with a frequency of 105 (26.3%). Also, regarding management background, the maximum frequency was related to the group of 5-10 years with the frequency of 128 (32%). Finally, the results showed that most people in the academic field of healthcare management with the frequency of 86 (21.5%) were respondent (Table 1).

Variables		No. (%)
SEX	Male	230(42.5)
	Female	170(57.5)
Age	<30	46(11.5)
	30-35	43(10.8)
	35-40	77(19.3)
	40-45	90(22.5)
	>45	144(36)
Education Level	Master's Degree	69(17.3)
	PhD	76(19)
	Public Doctorate	56(14)
	Medical expertise	64(16)
	Super specialist doctor	118(29.9)
	Fellowship	17(4.3)

Job Experience	<5	38(9.5)
	5-10	65(16.3)
	10-15	94(23.5)
	15-20	105(26.3)
	20>	98(24.5)
Management Experience	<5	76(19)
	5-10	128(32)
	11-20	121(30.3)
	>20	75(18.8)
Field of Study	Healthcare service management	86(21.5)
	Medical	76(19)
	Nursing	40(10)
	Urologist	20(5)
	Internist	42(10.5)
	Specialist of infectious diseases	2(/.5)
	Pediatrician	24(6)
	Medical files	1(/.3)
	Cardiologist	14(3.5)
	Traditional medicine	1(/.3)
	Policymaking	2(/.5)
	Emergency specialist	13(3.3)
	Neurologist	7(1.8)
	General surgeon	5(1.3)
	Health economics	8(2)
	Midwifery	9(2.3)
	Medical nutrition	3(/.8)
	Gynecologist	8(2)
	ENT specialist	5(1.3)
	Orthopedist	4(1)
Endocrinologist	19(4.8)	
ocular surgeon	7(1.8)	
Medical education	4(1)	

Table 1: Demographic characteristics of the Study.

To investigate data fitness, for exploratory factor analysis, KMO test as well as Bartlett test was used. Since KMO was 0.911 and the significance number of Bartlett test was sig<0.05, the data were fit for conducting exploratory factor analysis (Table 2).

KMO test	Bartlett's Test of Sphericity	Degree of freedom (df)	Significance level (p-value)
0.911	8073.36	1081	0.00

Table 2: KMO and Bartlett's Test.

To identify the most important and effective influential components on implementing clinical guidelines and detect the loading value of each variable on the principal components, exploratory factor analysis via principal components analysis with rotation was used. By performing exploratory factor analysis with vertical rotation, six factors were identified. Overall these six factors accounted for 52.35% of the variance (Table 3).

Component	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
Economic	12.521	26.639	26.639	12.521	26.639	26.639	4.652	18.796	18.796
Organizational	3.901	8.300	34.940	3.901	8.300	34.940	4.458	8.508	27.304
Insurance	1.975	4.203	39.142	1.975	4.203	39.142	3.752	7.486	34.793
Stewards	1.920	4.086	43.228	1.920	4.086	43.228	3.684	6.695	41.488
Clinical	1.564	3.328	46.556	1.564	3.328	46.556	3.469	5.963	47.451
Organizational Culture	1.336	2.843	49.400	1.336	2.843	49.400	3.204	4.903	52.354

Table 3: Total explained variance of the Studied Components.

Question	The features of clinical guidelines	Organizational culture	Insurance	Healthcare system trusteeship	Organizational factors	Economic factors
B1	Correcting the payment system		.585			
B2	Aggregating the resources of insurer organizations		.464			
B3	Optimal and strategic purchase of services		.490			
B4	Insurance tariffs		.668			
B5	Supplying financial resources		.647			
B6	Preparing, designing and developing incentive packages by insurers		.513			
B7	Integrated function of insurer organizations		.487			
T1	The necessity of integrated healthcare system			.414		
T2	Improving the structure and resolving the methodological problems of guidelines			.404		
T3	Developing regulations and bylaws and supervising the implementation			.476		
T4	Existence of a practical evidence-based system			.637		
T5	Paying attention to professional features and the strategy of implementing instructions			.444		
T6	Support of managers and decision-makers institutions			.705		
T7	Time and personnel management			.417		
T8	Resolving simulation in clinical setting			.430		
E1	The necessary investments for realizing implementation of guidelines					.413

E2	Financial profit in the using clinical guidelines						.448
E3	Developing the necessary infrastructures for implementing guidelines						.508
E4	Caring for the cost of access to evidence						.465
E5	Caring for clinical uncertainty						.459
E6	Availability of budget and resolving budget constraints						.644
E7	Multidimensionality of health phenomenon						.469
S1	Proper structure of the organization and development of the organization					.487	
S2	Interaction and cooperation in development sectors to implement the clinical guidelines					.430	
S3	Holding training courses in the academic education and constant training					.426	
S4	Caring for clinical guidelines in policymaking under macro conditions					.481	
S5	developing behavior adaptation and approving guidelines in case of availability of evidence and the alternative to the best method					.538	
S6	Ability, skill, and experience employing the research findings in the healthcare					.425	
S7	Familiarity, developing motivation, and attempts for teamwork					.412	
S8	changing the attitude of employees to reliability, importance, and usefulness of instructions					.463	
S9	Attracting the cooperation and contribution of beneficiaries					.417	
L1	The potential of localizing the guidelines in the country	.453					
L2	Implementability of guidelines across all patients	.676					
L3	Practicalizing guidelines	.485					
L4	Convenience in implementing clinical guidelines	.672					
L5	Access to higher-quality evidence	.698					

L6	sufficient production and publication in the number and distribution of clinical guidelines	.656					
L7	availability of a clear protocol for production and adaptation	.747					
L8	resolving the ambiguity of clinical guidelines	.594					
F1	corresponding to patient needs		.535				
F2	interaction between physician and patient		.624				
F3	adequate notification to the patient		.819				
F4	developing collaboration and commitment for following up the course of treatment by the patient		.587				
F5	taking the patient preferences into account		.554				
F6	correspondence with previous experiences of using guidelines		.451				
F7	understanding the patient need to guidelines and patient adaptation		.438				
F8	physician understanding, generalizing the research findings to the patient population		.439				
Mean ± SD		4.630±.41	4.59±.43	4.59±.42	4.66±.34	4.62±.34	4.54±.46

Table 4: Rotated factor matrices.

Extraction Method

Principal Component Analysis

To obtain a meaningful structure from factorial loads, based on conventional methods and using orthogonal rotation, the extracted factors were transferred to new axes which have non-right angle. Therefore, in exploratory factor analysis, 47 variables were categorized into six main principal components including the factors of insurance, organizational culture, the feature of clinical guidelines, economic factors, organizational factors, and trusteeship of the healthcare system. The insurance tariffs (0.668) (insurance factors), support of managers and decision-makers institutions (0.705) (out of healthcare system trusteeship factors), availability of budget and resolving budget constraints (0.644) (out of economic factors), developing adaptation of behaviour and approving guidelines with the factorial load of 0.538 (among organizational factors), adequate notification to the patient (0.819) (out of control factors), and existence of a clear protocol for production and adaptation (0.747) (out of the feature of clinical guidelines) are the most important influential factors on implementing clinical guidelines (Table 4).

Furthermore, to analyse the confirmed factor, the data and the studied responses were used according to the proposed structure. The results of fitness indices for the model are presented.

Suggesting approval of the studied index. Therefore, in general and considering the calculated indices, goodness of fit of the model can be concluded (Figure 1).

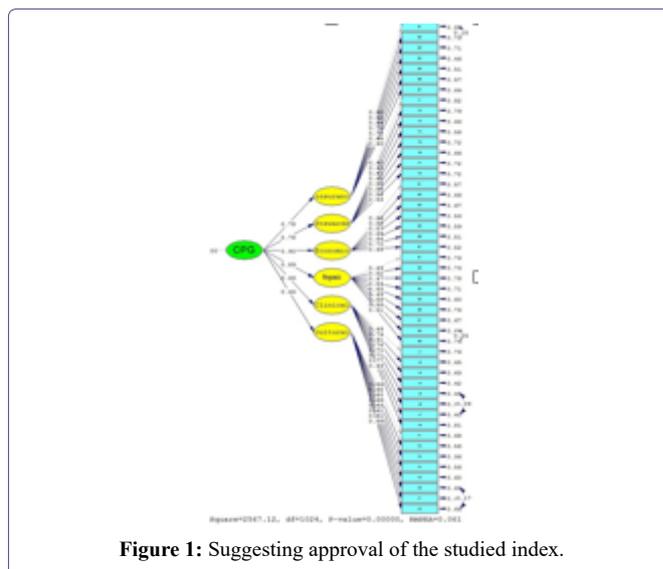


Figure 1: Suggesting approval of the studied index.

Discussion

The present research has been conducted with the aim of identifying the most important effective factors on creating a system for developing and implementing clinical guidelines and the loading value of each factor on the principal components in the context of Iran.

Clinical Performance Guidelines (CPGs) are considered as one of the knowledge products with the aim of improving clinical services, helping in decision-making for physicians and patients, a means for insurance with the aim of controlling the costs, and helping governments in policymaking or prioritizing healthcare [24].

In this study, based on exploratory factor analysis 47 effective variables on implementing clinical guidelines were investigated in the form of six principal components including organizational culture, organizational factors, healthcare system trusteeship, feature of clinical guidelines, insurance, and economic factors. In the present study using a questionnaire, the extent of the impact of 47 variables was measured on implementing clinical guidelines for designing the model for implementing the guidelines.

Six groups of the influential factors were identified after analysis. In this regard, some of these factors have also been mentioned in other frameworks and models. For example, in “coordinated implementation model” the most important factors were organizational setting, education, economic factors, social, and administrative factors and eventually the personal environment of individuals and the role of information, motivation, existence of regulations, patient conditions [25]. Furthermore, Thrones mentioned factors including knowledge, attitude, and skills of patient and physician, organizational and economic factors as the obstacles against implementing guidelines. In this study, also the effect of support of managers, thought of leaders, professionalism of individuals, organizational efficiency, the characteristic of colleague groups, and other service providers have been mentioned [26]. In another model which also propounds the clinical performance setting, a combination of economic, organizational, cultural, and policymaking effects has been mentioned as influential factors. In addition, it emphasizes the effect of the ability of implementation, awareness, and attitude of physicians [16]. Financial interventions in the present study referred to disciplinary and motivational interventions. Generally, financial interventions focus on service providers or patients [27]. As long as financial incentives and the payment system are not corrected, adhering to clinical guidelines cannot be expected [11].

In other studies, the obstacles against implementing clinical guidelines have been mentioned as knowledge, attitude, and behaviour change of patients and physicians, features of clinical guidelines including clarity and simplicity [28], environmental factors such as lack of adequate time and resources and the payment system problems [16]. Furthermore, in other relevant studies, the most common obstacles against implementation of guidelines in the healthcare system have been mentioned as research obstacles, limited support of colleagues, and obstacles of change [29]. Poor communication, deficiency of technical abilities of policymakers, limited capacity for conducting clinical research, constraint of resources, legal processes, infrastructures, equipment, and the recognized market and resolving the budget constraints, lack of valid support for altering the leadership and diminished leadership power were also mentioned as the main obstacles against implementing guidelines [5,12, 30-33]. In addition, factors such as presence of contradictory instructions and environmental factors such as lack of time, refund system [5], organizational constraints, and the increased understanding of the need to implementing clinical guidelines have been mentioned as obstacles against implementing clinical guidelines [34].

Absence of an evidence-based healthcare system has been one of the main reasons behind the attempts of economic development of

Evidence-Based Practice (EBP) over the past decade in Iran [35]. Indeed, absence of an evidence-based healthcare system and improper political support on macro scale in Iran as a developing country have challenged the creation of a system for developing and implementing Clinical Performance Guidelines (CPG) [36]. Studies conducted in Iran on the awareness and attitude of physicians about CPG have suggested inadequate familiarity of physicians as the most important factor in not implementing clinical guidelines [20,37,38].

Inadequate production and publication of CPGs might be one of the reasons of the unfamiliarity with CPG by physicians. In a study, most physicians stated that they had access to a limited number of CPGs and used them in their clinical practice. The findings of a study in the US indicated that over half of physicians have changed their clinical methods based on CPG, while 3% had no belief in it and did not use it in their practice [39]. Successful implementation of the guidelines involves development, publication, and implementation [6]. The organizations involved in production of guidelines should:

1. Develop the strategies for publicizing guidelines for timely delivery of information.
2. Reduce the complexity of clinical guidelines for physicians.
3. Produce clinical guidelines which are simple and understandable [40].

In qualitative studies conducted on the influential factors on implementing clinical guidelines, the factors were:

1. Approving the subject and content.
2. Approving the references.
3. Organizational factors.
4. Patient characteristics.
5. The strategies of publication of journals [28].

A supportive organizational culture can act as a catalyst for EBP implementation with respective factors including available information, abundant sources for developing change, and skilful personnel to change the practice, having prerequisite skill and powerful leadership [41].

Therefore, the results of the present study and the similar results from other studies suggest that alongside the trend of Corresponding and Developing CPG, planning should also be done for their implementation. Evidently, imposing the mentioned interventions with the ultimate goal of sustainable behaviour change in healthcare service provision, contribution of all practitioners and presentation of suitable facilities for implementing clinical guidelines based on evidence, time and personnel management, training methodology and planning, developing the necessary infrastructures, existence of adequate supervision and leadership and developing professional and legal motivation are required.

Research limitations

Lack of awareness about clinical guidelines in some of the selected universities across the five chosen regions, no implementation of guidelines, and incompatibility with guidelines and uncooperativeness of some medical sciences universities.

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Author's Contribution

Seyed Mojtab Hosseini and Mohammadkarim Bahadori developed the study concepts and design. Farzaneh Kimiaimehr collected the data. Mohammadkarim Bahadori, Ali Maher and Farzaneh Kimiaimehr analyzed and interpreted the data. Farzaneh Kimiaimehr and Mohammadkarim Bahadori wrote the manuscript. Khalil Alimohammadzadeh revised and edited the manuscript. All authors read and approved the final manuscript.

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Conflict of Interest

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