

Barriers of Clinical Practice Guidelines Development and Implementation in Developing Countries: A Case Study in Iran

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ABSTRACT

Background: Knowledge products such as clinical practice guidelines (CPG) are vitally required for evidence-based medicine (EBM). Although the EBM, to some extent, has been attended during recent years, no result has achieved thus far. The current qualitative study is to identify the barriers to establishing development system and implementation of CPGs in Iran.

Methods: Twelve semi-structured, in-depth interviews were conducted with a purposive sample of health policy and decision makers, the experts of development and or adaptation of CPGs, and the experts of EBM education and development. In addition, 11 policy-makers, decision-makers, and managers of the health system participated in a focus group discussion. The analysis of the study data was undertaken by thematic framework approach.

Result: Six themes emerged in order of their frequency include practice environment, evidence-based health care system, individual professional, politician and political context, innovation (CPG) and patients. Most of the indications in the treatment environment focused on such sub-themes as regulations and rules, economical factors, organizational context, and social context.

While the barriers related to the conditions of treatment environment, service provider and the features of innovation and patients had been identified before in other studies, very little attention has been paid to the evidence-based health care system and politician and political context.

Conclusion: The lack of an evidence-based healthcare system and a political macro support are mentioned as the key barriers in Iran as a developing country. The establishment of a system of development and implementation of CPGs as the evidence-based practice tools will not be possible, unless the barriers are removed.

Keywords: Barriers, clinical practice guideline, development, health care system, implementation, qualitative study

INTRODUCTION

In the countries such as the USA and Netherland, around

30-40% of patients do not receive evidence-based health care.^[1] Around 20% or more of the patients receive the treatments, which are not required or even they are sometimes harmful. In fact, there is a gap between what currently exists and the best evidence-based medical treatment.^[1] Evidence-based practice (EBP) is in need of evidence-based knowledge products, such as Clinical Practice Guideline (CPG).^[2] CPGs are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”^[3,4] The focus of this definition is on the fact that CPGs are supportive tools that not only are helpful for healthcare providers but also for patients. They can help patients by cooperating with them in the decision-making process.^[5] Field and Lohr state that the guidelines are not implemented by themselves.^[4] In fact, the implementation is a part of the guideline life cycle that must lead to a change in the clinicians’ behavior through following its mandates.^[6] There are some barriers in the implementation, which could be conceived in two sections; the first internal barriers, which are related to the features of guidelines and the second, external barriers, including structural factors (e.g., financial barriers), organizational (e.g., lack of equipment and facilities), peers group (e.g., the conditions in which the environmental standards of care are far from the favorite treatment), individual (knowledge, attitude, skills, etc.) and finally, the interaction of patient and physician (e.g., the problems related to information processing).^[7,8]

In Iran, the authorities already have thought of producing and localizing the knowledge products such as clinical evidence-based practice guidelines. For example, they have done such efforts as the planning for of developing clinical guidelines based on the burden of diseases in the country’s fourth and fifth Social, Cultural, and Economical Developmental Plans and the local evidence-based decision-making in the “Healthcare Reform Plan” and generating evidence-based guidelines in the “long-term plan of health sciences and technology.”^[9-12] In addition to legislation, a number of clinical guidelines are also produced and localized.^[13]

A study in Tehran illustrated that only 31.8% of clinicians involved in service delivery in Tehran were aware of clinical guidelines.^[14] The barriers to implementation of these guidelines from the perspective of these people included; ‘the physicians’ unawareness

of the way of developing clinical guidelines and their evidence-based nature (37%), long length of clinical guidelines (70%), inaccessibility (60%), the physicians’ lack of skill to use the guidelines (31%), and finally, the lack of necessary conditions and facilities to apply them (65%).^[14]

While the number of developed and localized clinical guidelines in Iran does not exceed from a dozen, their distribution is also limited, discontinued and or canceled. In order to encourage the authorities to select the policies of development and utilization of clinical guidelines, this study was conducted to identify the barriers for establishing production system and applying the guidelines.

METHODS

This qualitative study was a thematic framework approach with a purpose of applied policy research.^[15] Purposive and snowball sampling were utilized and continued until theoretical saturation.^[16] Twelve in-depth interviews, lasted 62 minutes on average, were conducted in the semi-structured manner. The interviewees were chosen from healthcare policy-makers and decision-makers (three persons), the experts with previous experience in the production and adaptation of CPGs (four persons), and from EBM education and development experts (five persons). A focus group discussion (FGD) was also arranged including 11 participants from healthcare policy-makers, managers, and decision-makers to fulfill triangulation purposes. Data collection was undertaken after obtaining the participants’ verbal consent. In order to find a suitable framework for the analysis of the interviews, the EBP and Knowledge Translation and Exchange models were used in addition to the studies that had considered the barriers to development and implementation of CPGs.^[17,18] After repeatedly listening and studying the interview transcripts for familiarization and also reviewing the literature, the frameworks and the foregoing models, the main themes were extracted, and the thematic framework was specified. At the next stage, MAXQDA® (Version 10) software was used for indexing and charting stages.^[15]

RESULTS

The six main themes after the analysis of interviews, in order of their frequency, include

Practice Environment, Evidence-Based Health Care System, Individual Professional, Politician and Political Context, Innovation (CPG) and Patients. The practice environment contained a number of sub themes [Table 1].

In the following section, some of the indications of the participants have written *Italic* to approve the chosen themes (reflexivity). The indications of the different interviewees were coded. Code 1 was given to the indications of the policy makers and decision makers (in-depth interview and FGD), code 2 for the experienced production and adaptation experts of the guidelines, and finally, 3 for the EBM education and development.

PRACTICE ENVIRONMENT

In this section, the sub themes of regulations and rules, economic factors, organizational conditions, and finally social considerations were attended. The participants mentioned the first problem to be lack of supervision and regulations and bylaws both in development and implementation of the guidelines:

(2)... one of the problems is that in Iran, no one checks your work... so, the physician is really free, and there is no control over their work; not from their colleagues, their specialist associations and not from the Ministry of Health and not from insurance organizations! Accordingly, there could be a real chaos ...

In fact, as the judgment of supervisory organs in the event of medical errors is based on textbook

and not on clinical guidelines, they found the observation of the guidelines challenging:

(3)... if a legal problem emerges and or if sometimes an error surfaces or their patient dies or any side effect is seen, they will complain, and they apparently will not accept the guidelines in a board in the country's medical council...

The next problem concentrated on economic factors. The lack of third parties' support, financial warranty, and particularly that of comprehensive insurance, which makes a direct financial relationship and service providers and finally, the uncertain cost-benefit of adherence to the guidelines were mentioned:

(3)... currently 60-70 per cent of healthcare cost in Iran is out-of-pocket. When people want to receive a service, they directly pay the large amount of its cost. The direct relationship, which is created between physicians and patients, removes the possibility of supervision from the different supervisory organizations....

The organizational circumstances were the other group of factors. For example, the lack of utilization from the empowered staff in such organizations as third party organizations and or pharmacies which could exercise their supervision on the prescriptions:

(2)... the insurance organizations which have the main duty are short of scientific manpower for such tasks. They are not at a scientific level that could assess my prescriptions...

The workload of each physician and the lack of sufficient time such as the indications related to the organizational barriers which reduced the level of obedience from the guidelines. Another sub theme of this section was social conditions, especially cultural problems. The advocates of this idea knew the highest share at first the place related to culture of the providers:

(3)... as I said we have a couple of cultural problems. First, we normally do not pay attentions to details. Second, in response to any question, we respond: "I myself know that, and there is no need to any guideline"... and we think: "why should need a guideline for a simple work".

(3)... we essentially do not use any of guidelines, text books or papers. We use experiences. It seems experience is very important in our country.

Another social barrier is the interaction of the colleagues both in development and implementation sectors. The problem of emulating and eventually the issues of a group thought into the obedience of the guidelines were problematic:

Table 1: The barriers for development and implementation of clinical practice guidelines in Iran

Barriers	References [†]
Practice environment	[1, 17-25]
Regulations and rules	[17, 23, 25-26]
Economical factors	[1, 17-19, 21-23, 25]
Organizational context	[1, 17-23, 25, 27]
Social context	[1, 17-18, 21-23, 25, 27]
Evidence-based health care system	[23, 25, 28-32]
Individual professional	[1, 17-23, 25-26, 28]
Politicians and political context	[23, 25-26]
Innovation (clinical practice guideline)	[17, 19-27, 33]
Patients	[1, 17-21, 23-25, 27]

[†]The resources used for selection of thematic framework themes

(3)... another barrier stymieing the implementation of the guidelines is the culture of 'group thought.' For instance, when you work in a Health Network, the patients ask you to prescribe a specific medicine for them as the previous physicians were doing. If you resist their request, in fact, you are swimming against the tide....

The highest concentration in this section was on the effect of obedience from opinion leaders:

(3)... in the current circumstances, our treatment is still at a level that the experts' views are more valuable than incomplete evidence for us.... Key knowledge leaders are more effective than other... most of them are old experts who are somehow known. Some of them are not quite familiar with or do not accept the EBM. But, from their own perspective, the leaders were considered as acceptable.

Inactivity of the national associations as the foundation that can affect the members was mentioned as another barrier.

EVIDENCE-BASED HEALTH CARE SYSTEM (EBHCS)

The lack of an evidence-based stewardship for healthcare system was echoed many times:

(1)...we believe until the stewardship for healthcare system is not founded on an evidence-based decision-making, there will be no chance for the operationalization of its decisions at lower levels. It means we should consider all cases together...

(2)...if you now ask me what is the biggest barrier for using guidelines? I'll say it is the lack of the evidence-based practice system...or why is not the guideline generated in the country so far? It is "because we have not had a system." And why not used? I'll answer: "because we have not had a system"...

On the other hand, the loss of serious concern to utilization of clinical guidelines was also seen as barriers:

(1)...the reality is that in our country, except for few limited, unsystematic, and unplanned works, we have not done any other thing...in our healthcare system, the topic of clinical guidelines, has never been a serious concern...

As such, given the integrated nature of country's health care and medical system, the lack of evidence-based education was also mentioned as an influential issue. From the interviewees' viewpoint, the weakness of education from two perspectives could cause problems; first, because

of not using the guidelines in the education process and curriculums and the second, the lack of an education system, which is responsive to local needs:

(3)... we have never been taught in the form of guidelines during the all our education period...the clinicians whom are trained under this system, think: "we have lived and worked so far without the guidelines, why must we use the guidelines to treat our patients now?"...

In addition, they criticized the lack of integrity in the health system in practice:

(3)... education is not aware of treatment... a responsive education system should receive the national and local data, does that obtain?"

As such, a large amount of healthcare system problems were mentioned to be related to not utilizing knowledge on one hand and the lack of studies aiming to solve problems on the other:

(1)... and given the volume of experience and specialized knowledge we have, it seems we have not used this owning of us so far...

(1)... it means our research is saturated with the topics that are not really helpful... this won't go anywhere, writing papers, and papers... what is the point... this cannot be a guideline for us, but a research topic... three research centers in the country are swallowing up lots of money,... but where are they? Where do they go? If these links are formed, beneficial science will emerge...

Finally, concurring with the lack of evidence-based healthcare system; some indications focused on criticizing the efforts conducted in relation with evidence-based practice so far:

(1)... what is the benefit of holding evidence-base courses? For example, if a center wants to be evidence-based, what role should play in this...?

INDIVIDUAL PROFESSIONAL

The level of knowledge, attitude, and the abilities of the practitioner were mentioned in this regard. The weakness of English language, inability for searching evidence, critiquing articles, the lack of responsibility commitment for promoting the knowledge level, not using the information data bases, low professional commitment and individual characteristics such as old age or being a general practitioner or specialist were raised as the problems affecting disuse of the guidelines:

(2)... the first problem of our physicians is that they

'don't know' and the second, 'they are not aware of their negligence!' accordingly, they are very happy... meanwhile changing the way of practice is very difficult for them, because they must study every day and keep themselves up-to-date... even many have a problem for reading English texts...

(3)... firstly, if they want to go in line with EBM, I think, the most important part is the access to information i.e. the skills for searching and finding articles and appraising. They are incompetent in information mastery....

However, the other attitude was that the system should lead its manpower carefully and does not require those with specific abilities and exceptional professional commitment. For example, they pointed to the circumstances of health service's providers in the Canadian healthcare system:

(2)... Every physician that works over is a member of the system. You are not supposed to be a genius. If you eagerly want to be a genius, you should go somewhere and conduct molecular researches and so on, instead of practicing medicine and do not see patients at all, and go to the trial sector. An ordinary doctor in his area is considered a member who should move on the guidelines....

POLITICIAN AND POLITICAL CONTEXT

From the interviewees' perspective, not only the conditions of policy-making in the Ministry of Health and Medical Education (MOHME), but also at the macro level will be influential in establishing such a system. Instability, political and policy-makers changes, the lack of political support, and commitment were the perceived barriers:

(1)...one of our problems is that the conducted policies and planning lacking information support from the operational perspective. Some work and planning might be done, but when a new government comes to the power, because of their new views start to do new things and previous findings are filed ...the political support for the recommended works should be at a higher position than Ministry of Health.

In addition, the features and individual attitudes of the politicians were also found to be important:

(3)... briefly, there is no necessary belief to develop clinical guidelines among the high-up authorities. Therefore, this work is abortive...the biggest barrier in terms of support is that those in the highest and most important positions must have a belief in the approach towards this issue, otherwise nothing will happen...

Of course, the interviewees believed that unlike the pluralistic and capitalistic structure of the countries, which are unsuccessful in establishment of a system for implementation of the guidelines, Iran's healthcare system is somewhat similar to that of successful countries, and they had a better prognosis for the country:

(2)... the USA has a pluralistic system... in such countries, the guild associations are very strong and, by contrast, the public sector is fragile... conversely, the UK has a socialist healthcare system... therefore, the guilds are feeble, and the government is strong; regulations are more dominant, and you can do whatever you want... I think the ideology behind our health services delivery system is akin to the socialist system. Therefore, we must certainly pursue this planning...

INNOVATION (CPG)

In this section, the following reasons were raised for disusing the current adapted and generated guidelines in the country: No clear protocol for generation and adaptation, unfamiliarity with and the production team's disobedience from international and known protocols of guideline development, the lack of implementation program, ambiguity of evidence and recommendations, no utilization of national evidence, and the lack of participation from stakeholders:

(1)... when I went into its detail... I realized that neither its compilation, nor its development has been based on established methodology! More interestingly, they had no model for its implementation ...some time, it is left at development, other times, they have used primary research, and it is not clear at all, what have they done... there is no guideline around the world, which lacks grade of recommendation... you can't show a guideline in Iran, which it has the level of evidence and grade of recommendation...

(3)... such cases are more similar to the translations compiled only under the view of very few experts and are not based on a clear methodology...

(3)... I ... read the first line of that for you: "in the USA and Europe..." where is an Iranian over there? Such a guideline in three pages could be found in many places. Which part of that is adapted? If you read it until the end, nowhere you can see 'to be written Iran'...

PATIENTS

Among the other influential elements, both in

establishing the system and in obeying guidelines, the characteristics, conditions, culture, and the expectations level of the patients were mentioned, which could lead to an interference in compliance the guidelines:

(1)... for example, the guideline says that, when you measured patients' blood pressure, do not tell them immediately that they are suffering from high blood-pressure. Let them to rest for five days...is this applicable in our country? The patient is even reluctant to visit a physician once let alone he/she is required to visit a couple of times!"...

(1)..... some patients do not accept and say "we ourselves have seen in the internet." They have more trust in the internet than physicians...

(3)... If he comes and I do not prescribe anything for him and tell him that he is fully healthy, will not return to me any more...

(2)... Sometimes a patient even does not know that he is suffering from cancer, and you as the physician can't tell him the truth, while this is against medical ethics. Most of the time, we treat patients based on the views of his relatives, and their beliefs are preferred to that of the patient. We also do not know their financial issues...

DISCUSSION

The current study aimed to identify the barriers to establish the development and to implementation system of clinical guidelines in Iran's context. Despite the legal mandates for generating CPG in Iran, the local clinical guidelines are rarely used to provide clinical services.^[9-12, 14] The qualitative study was fruitful in gaining an in-depth identification of barriers in the country's context. As such, using thematic framework approach for analyzing the interviews and an extensive literature review aiming to identify the barriers and influential factors both have boosted the quality of the results analysis.^[15]

Six groups of establishment barriers were generated following the analysis of the interviews: As in Table 1, the other frameworks and models somehow pointed to some of these barriers. For instance, "Coordinated Implementation Model" associates the transference of studies' results to clinical practice to educational, economic, community, administrative, and ultimately personal environment and considers the role of information, incentives, regulation, public pressure, and patients vital for this purpose.^[17,23] Similarly, Thorsen relates

the obstructing factors and application barriers to knowledge, attitude, and the skills of practitioner and patient, on one hand, and also to environmental determinants such as social, organizational, and economic factors, on the other. As to the social factors, the effects of managers, opinion leaders, professional organizations, peers, and other service providers are important. As such, as a part of social barriers, the interaction of patients and their organizations and associations are considered, whilst the effect of patients' knowledge, attitude, and skills of obeying orders was separately seen.^[20] By the same token, Grol and Wensing attributed the difficulties and incentives for changing health care to innovation, practitioner, patient, and social, organizational, economic, and political conditions. As to economic and political context, not only the policies, but also the regulations were mentioned, while the organizational conditions included such factors as structure, staff, resources, and capacities. In abovementioned classification, the social effects are not contingent upon the patients' effect.^[26] This is while; another study by Grol and Grimshaw knows the patient experience as the organizational effects of practice environment. Similarly, they considered the effect of routine methods of practice and current standards such as medical education and pharmaceutical companies' advocacy as social context.^[1] As current study, Ottawa model also considers the practice environment is a mixture of economic, structural, cultural and social effects, apart from that it knows patients' effects as part of environmental effects. In addition, it emphasizes on the effect of innovation and ability characteristics and the potential adopters' awareness and attitude.^[22] To the contrary, Dobbins' model distinguishes between organizational and environmental features and points to individual and innovation characteristics.^[20] Consistently as regards the barriers for obeying clinical guidelines, Cabana speaks not only about the internal factors of service providers (e.g. knowledge, attitude, and change of behavior), but mentions the external ones such as patients, the characteristics of clinical guidelines, and environmental factors like lack of enough time and resources and the problems of the payment system.^[19] Finally, following a systematic meta-review, the features of clinical guidelines, implementation strategies, professionals, patients and environmental characteristics found to be the influential factors in CPGs utilization.^[24]

With a quick glance at the foregoing studies, models, and frameworks, an obvious difference could be seen in the structure and classification. Notwithstanding these differences, all influential barriers and factors were mentioned by the interviewees in the current study [Table 1]. It appeared that the applied framework, developed based on literature review and after familiarization with transcribed interviews, appropriately organize the interviewees' indications for identifying the barriers related to Iranian context from various aspects. Another strength of current study was separately weighting the "evidence-based health care system" and "politician and political context." In fact, the majority of previous studies, models, and frameworks have been conducted in the high-income countries, with a long experience in the evidence-based practice implementation.^[24] Nowadays, in those countries, the disuse of an evidence-based health care system is not a big concern anymore, as no attention is paid to the lack of politics and high-up authorities' commitment in establishing that system. In this regard, the previous studies about political context, however, which considered the context in the same line with regulation, are attended.^[26] Nevertheless, the establishment of the given system in Iran cannot be seen yet, in spite of utilizing the production regulations of CPG. As mentioned in the results, the shortage of political commitment and a need for a political support from the authorities even higher than MOHME, on one hand, and the lack of a system that tries to systematically produce and apply the knowledge products, on the other hand, were the important examples of barriers in this section. In fact, the given finding is essential in Iran's conditions, as a developing and middle-income country; as also indicated before about the necessity of evidence-based stewardship for healthcare system.^[34] In addition, the absence of an evidence-based health care system said to be one of the key reasons for abortive EBP development efforts during last decade in Iran.^[35]

In this regard, two models can be mentioned, which have attended to the necessity of EBHCS and known its shortage as the barrier to EBP implementation.^[28-30] The ARCC (Advancing Research and Clinical Practice through Close Collaboration) model recognizes the absence of EBP mentors and champions in line with the

lack of sufficient EBP knowledge as the potential barriers. It not only knows the barriers and facilitators of EBP at individual level but inside health care system and sees the organizational changes required similar to individual changes.^[28,29] Moreover, the Joanna Briggs Institute's Model of Evidence-Based Health Care attaches same importance to the attention to organizational level as practitioner level. The main focus of this model is systematically on various stages of EBHC implementation, including evidence production, synthesis, knowledge transfer, and evidence utilization.^[18,30] As such, we should mention the special emphasis of participators on non-genuine integration in the structure of MOHME. Indeed, from their perspective, there are numerous problems for not utilizing the research findings in education, health and clinical sectors. This is whilst, the needs of health care sector and also policy-making are not considered as research priorities. These debates all somehow accentuate a need for serious consideration of knowledge translation and transference and overall on utilization of health knowledge, as also indicated earlier.^[36,37]

As the final word, the diversity in people selected for the study (i.e., maximum variation sampling), could elaborate on the barriers for establishing a development and implementation system of CPG in the country's current context. Finally, it worth noting that it will be overly difficult to operationalize the EBM, without an established evidence-based system and clinical guidelines, whose application is seriously supervised.

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