



## Challenges of Clinical Practice Guidelines Adaptation in Iran: Lesson learned for Low and Middle-Income Countries

Azadeh Sayarifard<sup>1</sup>, Maryam Nazari<sup>2</sup>, Najmeh Bahmanziari<sup>2</sup>, Neda Mehrdad<sup>3,4</sup>, Laleh Ghadirian<sup>1\*</sup>

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### Abstract

**Background:** Developing a clinical practice guideline (CPG) is very time-consuming, expensive, and requires specialized knowledge; therefore, when an up-to-date and quality CPG is available, it is logical to adapt it according to local conditions. So this study aimed to identify the challenges of CPGs adaptation in Iran to help improve it and provide lessons for low and middle-income countries (LMICs).

**Methods:** This was a qualitative study that was conducted in 2019. Semi-structured interviews were conducted with 17 participants from two levels, groups involved in the CPGs adaptation process, from research centers and specialized medical associations and policymakers and planners in CPG development and adaptation from the Ministry of Health and Medical Education (MoHME).

**Results:** The identified challenges were classified into two basic and operational categories. Basic challenges include believing the need for CPGs adaptation, attention to CPGs adaptation in evaluation and reward systems, access to financial resources, and supervision of the adaptation process. Also, operational challenges were adaptation methodology, forming an adaptation team, consensus on interdisciplinary issues, changing programs and priorities, and external barriers in the work progress path.

**Conclusion:** The main challenges of CPGs adaptation in Iran, as one of the LMICs, are related to education, financing, and supervision of adaptation process steps. The most significant proposed interventions to overcome the current obstacles in countries with similar contexts are holding new training courses and programs for these CPG users at different headquarters' and environmental levels, establishing an appropriate motivating system, designing an integrated adaptation system focusing on organizing related supervision affairs like planning, policy-making, and supervision at the MoHME and universities level.

**Keywords:** Clinical Practice Guidelines, Adaptation, Evidence-Based Practice

**Conflicts of Interest:** None declared

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### Introduction

The application of clinical practice guidelines (CPGs) increases the effectiveness of patient care (1) because they translate strong evidence into practical measures. So in recent decades, in High-Income Countries (HICs) and Low

and Middle-Income Countries (LMICs), using CPG has been brought into the spotlight to improve healthcare delivery (2). Developing a CPG is very time-consuming, expensive, and requires specialized knowledge (3). Therefore,

**Corresponding author:** Dr Laleh Ghadirian, [lghadirianm@tums.ac.ir](mailto:lghadirianm@tums.ac.ir)

<sup>1</sup> Knowledge Utilization Research Center, Center for Academic and Health Policy, Tehran University of Medical Sciences, Tehran, Iran

<sup>2</sup> Department of Health Management and Economics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

<sup>3</sup> Endocrinology and Metabolism Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran

<sup>4</sup> Knowledge Utilization Research Center, Center for Academic and Health Policy, Tehran University of Medical Sciences, Tehran, Iran

#### ↑What is “already known” in this topic:

Developing a CPG is very time-consuming, expensive, and requires specialized knowledge. Therefore, when an up-to-date and quality CPG is already available, it is logical to adapt instead of developing a new one. In adaptation, recommendations of the qualified CPGs are transformed, considering local evidence for addressing local issues.

#### →What this article adds:

The main challenges of CPGs adaptation in Iran, as one of the LMICs, are related to education, financing, and supervision of adaptation process steps.

The most significant solutions are holding new training courses and programs for CPGs users, establishing an appropriate motivating system, designing an integrated adaptation system.

when an up-to-date and quality CPG is already available, it is logical to adapt instead of developing a new one (3-6). In adaptation, recommendations of the qualified CPGs are transformed, considering local evidence for addressing local issues (3). HICs and LMICs have different conditions considering economic status, service delivery model, payment method, insurance coverage, regulations, access to services by various groups, the burden of diseases, risk factors, and cultural components. Countries with similar background conditions expect to experience the same challenges during CPGs adaptation (7, 8). There is no fixed, particular process for adaptation, but search for available CPGs, CPGs quality evaluation, analysis of coherence between evidence and recommendations in CPGs, and adaptation of recommendations according to local evidence are taken in this process (9). Adapting a CPG to the context that is intended to use can be a fundamental step in the implementation process. Regardless of the local context, some of the recommended interventions in the evidence-based CPGs are inapplicable (10). Freus in his study in 2011, focused on ways to increase the effectiveness of CPGs adaptation, warned researchers and policymakers on the lack of high-quality CPGs; restrictions of their use in other environments, lack of adaptation process acceptability in target groups, the potential complexity of the adaptation process and difficulty of choosing a CPG among the various CPGs (11). According to Harrison, the adaptation of CPGs requires advanced methodological knowledge and proper foresight (12).

On the other hand, despite the increasing number of CPGs, their use at the patient's bedside is often reported as unpredictable, slow, and complex. It is estimated that 30-40% of treatments are not based on scientific findings, and 20-25% of patients receive potentially unnecessary or harmful treatments (13).

Cavada considers the adaptation process to meet the needs of various user groups, including CPG developers, health care providers, and policymakers locally, nationally, and internationally. He also acknowledged that a clear, unequivocal report guarantees the quality and credibility of the adapted CPGs (14). To improve the quality of services and clinical effectiveness in Iran, the MoHME performed some activities such as compiling the Evidence-Based National Health Care System Document in 2013 (15). Also, measures have been taken to adapt CPGs in a non-coherent manner. However, most of the prepared CPGs have been stopped at the adaptation stage or have not been implemented yet. In terms of financial, human resources, time spent, and Iranian experts' historical background in the adaptation of CPGs, this inefficiency is not ignorable.

On the other hand, internal studies indicate that few studies have specifically addressed the barriers to the adaptation process. The main focus has been on topics such as the approach of adapting CPGs and the steps of preparing specific CPGs (16-18). Due to the complexity of the CPGs production process and the limited financial, human, and technical resources governing LMICs, the present study aimed to identify the challenges of CPGs adaptation to address promoting solutions and measures in Iran.

## Methods

This study was qualitative in terms of the nature of the subject and its purpose, approved by the Ethics Committee of Tehran University of Medical Sciences and Health Services (IR.TUMS.VCR.REC.1396.3166). The study was conducted in 2019. Given the purposeful sampling, efforts were made to interview with a wide range of experts in the field of research from two levels, first, the groups involved in the CPGs adaptation process, from research centers and specialized medical associations, and second, policymakers and planners in CPG development and adaptation from the MoHME. Inclusion criteria were having experience of participating in the CPGs adaptation process or experience in the policy-making or planning in this area. In a semi-structured, face-to-face manner, interviews were performed by two researchers (NB and LGh) that had a background in conducting qualitative studies and interviews. The 17 interviews took about 30-45 minutes and were conducted at the workplace.

The main interview questions were adjusted to focus on the participants' experiences about the CPGs adaptation process and the challenges and modifiable issues in the process. To observe the ethical principles of the interviews and obtain verbal informed consent from the interviewees, in each interview, the interviewers performed a protocol as follows; mentioning the title of the plan and the necessity of its implementation, obtaining permission to audio record the interview with emphasis on confidentiality, explaining the freedom to withdraw from participating in the study at all stages and sending final results to participants if they wish. For considering reflexivity, researchers tried not to interfere with their previous beliefs and personal perceptions into interpretations, avoid directed and judgmental talking (bracketing) when at the same time have a dynamic interaction with the participants. The interviews were continued until the saturation of findings based on the researchers' decisions. Data analysis was performed by the qualitative content analysis method using MAXQDA software. For this purpose, the interviews were transcribed carefully, then the participants' phrases that indicated a semantic unit (code), were extracted. After that, these phrases were reviewed to access subcategories, and based on these subcategories, the data were classified into different categories. To diversify, the collection of data was performed through interviews with participants selected from different levels. To ensure the validity, reliability, acceptability of the data and the coherence of the codes with participants' experiences, the member check method was used. Finally, the interviews and codes were rechecked by colleagues and faculty (Peer debriefing), and transcribed text of each interview was adapted to the notes made during the interview so that the verbal and non-verbal words were fit.

## Results

A total of 17 participants were interviewed about the challenges of guidelines adaptation. Among them, 13 individuals were from CPGs adaptation groups of research centers and scientific medical associations and four from the MoHME. Participants' education levels varied, including the master, general practitioner, clinical specialty, clinical

subspecialty, and Ph.D., and were six men and 11 women. Participants' comments were classified into two categories; basic and operational challenges, which had five and six subcategories, respectively (Table 1).

**Basic challenges:** The basic challenges are the factors that are considered as necessary platform requirements for starting the process of CPGs adaptation, so the absence of any of them prevents its flowing.

These challenges have four subcategories, including believing in the necessity of CPGs adaptation, experts' motivation to participate in the adaptation process, access to financial resources, and the supervision of the adaptation process.

• **Believing in the necessity of CPGs adaptation**

This part points to the belief in usefulness and the necessity to review and update of CPGs. Some participants believed that managers are supportive only if they believe in the usefulness of CPGs contents: "If a senior manager doesn't believe in the need to compile a CPG, goes hard. Some believe that doctors know what to do and don't need guidance" (Member of Adaptation Groups-2).

Another participant stated although health decision-makers believe in evidence-based decision making, they do not have a sense of need to adapt the CPGs of the other countries: "Some experts believe that we have a lot of good foreign CPGs and there is no need to adapt" (Member of Adaptation Groups-1).

• **Attention to CPGs adaptation in evaluation and reward systems**

Failure to use appropriate incentives will discourage some experts from participating in the adaptation process. Low valuation for participation in the adaptation process in

performance evaluation and promotion systems in the country, for faculties or researchers, have repeatedly been raised by the participants: "Unfortunately, the faculties' evaluation systems in our country do not value the noteworthy activities such as adaptation or development of CPGs, so they have no motives to participate in CPGs adaptation" (Member of Adaptation Groups-9).

• **Access to financial resources**

The prevailing economic condition (especially dealing with sanctions) has removed CPGs adaptation from the health system research priorities. Consequently, it leads to insufficient funding allocation: "The university did not give us enough budget to adapt CPGs. The cooperation of most professionals was achieved by the request and pressure of the head of the research centers, so when they don't value work, don't allocate the appropriate budget" (Member of Adaptation Groups-5).

• **Supervision of CPGs adaptation process**

Based on this study, the process of CPGs adaptation lacks a systematic structure in all three stages include ordering, confirmation, and implementation: "The process of ordering to adapt CPGs, confirmation of adapted guidelines and implementation of CPGs are not systematic." (Member of Adaptation Groups-12).

"We do not have a specific proctor to approve the adapted CPGs. There is no proper structure in MoHME. It is unknown who finally reviews the CPGs to confirm" (Member of Adaptation Groups-8).

Establishing a supervisory-advisory committee seems essential in organizing this process: "There is no an office or central committee to produce and implement CPGs at the university that has both; teaching and consulting in addition to a supervisory role" (Member of Adaptation Groups-6).

Table 1. Categories and subcategories of CPGs adaptation challenges

Category	Subcategory	Code
Basic challenges	Believing in the necessity of CPGs adaptation	Utility of CPGs content
		Necessity to review guidelines
	Attention to CPGs adaptation in evaluation and reward systems	Strengthening supervision
		Restriction of authority
Access to financial resources	Value of adaptation in reward systems	
	Value of adaptation in performance evaluation systems	
Operational Challenges	Supervision of adaptation process	Preparation of financial resources
		Allocation of adequate budget
	Adaptation methodology	Systematization of order, confirmation and implementation process
		Scope of CPG application
		parallel works
		Principled adaptation method
	Adaptation team	Usability of CPG evaluation tools
		Possibility of production of supportive evidence for alternative recommendations
	Consensus on interdisciplinary issues	Quality of comprehension from content and its transmission
		Composition of team members
Change of programs and topics with a need to adapt prioritized new CPGs	Competency of team members	
	Commitment of team members	
	Conflict of interest of team members	
External barriers in the work progress path	Variety of stakeholders in interdisciplinary issues	
	New interdisciplinary issues	
		Pressure due to change in priorities
		Sabotage of reviewers and external evaluators
		Managerial changes

Some of the participants believed that one of the neglected issues in selecting CPGs for adaptation is their scope of application: "Some issues have priority in local level, not nationally, so the scope is important for prioritizing issues."

Another point is that in choosing topics, we also noticed parallel actions: "Each university has prioritized issues by their own, so there is parallel work in the production of CPGs in the country" (Ministry expert-3)

**Operational challenges:** Operational challenges are factors that disrupt the adaptation process. These challenges were categorized into five subcategories: standard methodology, forming an adaptation team; consensus on interdisciplinary issues; the quality of the adaptation process, and external barriers in the progress path.

#### • **Adaptation Methodology**

Ignoring the principles of adaptation methodology leads to deviation from the correct path: "The ADAPTE method was used differently in different groups around the country. They did every part they could and overlooked every part of the instructions that they could not follow. It was possible that the missing part that they did not understand and did not perform, incidentally, was the most important part of the methodology. From the selected CPG recommendations, they choose only the recommendations that they can implement. The expert will be asked for an alternative for those recommendations they could not choose. It is not clear if this advice is evidence-based; there is no conflict of interest, or it is cost-effective or not" (Ministry expert-2).

In some cases, adherence to adaptation principles and standards is influenced by issues such as using non-functional tools like The Appraisal of Guidelines for Research and Evaluation (AGREE); lack of availability of evidence, and the cost of CPG production: "The AGREE tool is suitable for CPGs applicability evaluation not for adaptation because it's the most important item for CPGs evaluation is the existence of a link between recommendations and their supporting evidence and the appropriate review of the evidence" (Ministry experts-1).

"We needed local evidence for some recommendations, especially about cost, in which there was no or just local evidence or evidence was not available" (Member of Adaptation Groups-3).

Sometimes, individuals' understanding of the recommendations are not the same during translation so, this can make it hard to convey the concept: "We had a challenge to translate the scenarios from the main CPG. People's perception of the original scenario were different" (Member of Adaptation Groups-2).

#### • **Adaptation team**

The presence of some main groups and stakeholders in several adaptation sessions is not achieved due to personal reasons or carelessness. Also, in the absence of mentioned groups, no action is taken to obtain their views: "If important people don't attend to expert panel or consensus meetings, there is no creative way for getting their opinion. But, because these people can play a key role in CPGs implementation, their views must be taken into account through other methods" (Member of Adaptation Groups-2).

It is important because some experts seem reluctant to

implement the CPG if they have no participation in its adaptation process; "Getting the maximum participation of experts in providing CPGs is important very much because these people can prevent the CPG implementation" (Member of Adaptation Groups-6).

Also, some of the people present at the meetings do not have enough necessary, up to date technical knowledge and experience: "It's good that the involved people in consensus have executive power because it helps to implement CPG, but on the other hand, some of these people may not be academic or up to date" (Member of Adaptation Groups-1).

On the other hand, some of the adaptation team members do not have essential skills for participating in teamwork: "In multidisciplinary cases, it is even more important to have teamwork skills. Unfortunately, we don't know the teamwork well. We need training" (Member of Adaptation Groups-6).

The further important point is when teams are made up of volunteers, not skilled members, they may not be eligible: "We need more human resources. It is currently voluntary. Those who work voluntarily are not necessarily the most suitable" (Member of Adaptation Groups-4).

Also, when people in the adaptation team whose personal or group benefits conflict with their responsibility, decision-making becomes problematic. The power rate of people with a conflict of interest is effective on the bias of recommendations in favor of their profession: "The composition of members in consensus meeting is essential, and the stronger group can push CPG recommendation toward their benefit" (Member of Adaptation Groups-6).

Sometimes members' commitment is so low to the extent that they even refuse to attend meetings:

"Not all related stakeholders were present at the consensus meetings" (Member of Adaptation Groups-7)

#### • **Consensus on interdisciplinary issues**

Some participants pointed that achieving consensus on subjects common between several majors (interdisciplinary) is hardly possible—from choosing the appropriate CPGs to finalizing the recommendations: "In the case of multidisciplinary issues, all the steps become more difficult; for example, in pulmonary embolism, the heart group accepted their own CPGs, while lung group preferred their own CPG" (Member of Adaptation Groups-6).

Focusing on new topics also intensifies the difficulty of consensus: "When there are different disciplines, it's hard to reach a consensus, especially when it's a new issue" (Member of Adaptation Groups-6).

#### • **Change of programs and topics with a need to adapt prioritized new CPGs**

Prioritizing health topics and CPGs adaptation at the country level is determined by macro-decisions of the health system. Also, setting a deadline for providing CPGs has adverse effects on the quality of final outputs: "When it was supposed to urban family physician program performed for university-covered population, once we had a large number of orders for providing family doctor's CPGs because it hadn't been considered before. Time limitation could reduce the quality of produced CPGs" (Member of Adaptation Groups-12)

### • External barriers in the work progress path

The progress of affairs related to CPGs, in any stage, could be affected by managers in charge and even stopped by managerial changes: "Work depends on the individual, it is not systematic. If the senior director in the MoHME believes in CPGs, things are going well, but with the change of manager, things will stop" (Ministry experts-1).

Also, the sabotage of reviewers and external evaluators can hinder the progress of the adaptation process: "External review process is very time-consuming. Those who consider themselves experts in this field, sometimes make barriers against beginners" (Member of Adaptation Groups - 2).

### Discussion

The governments' role and social accountability necessitate that the national health care system provides the highest quality services to the people. One of the main bases for health services quality attainment is clinical effectiveness, that to achieve, the context for the realization of the desired medicine must provide. Achieving this aim depends on using the best evidence in health care (15). Adaptation of high-quality CPGs is an effective way to improve evidence-based care (12); therefore, in the present article, common challenges that performers may encounter during the adaptation process are reviewed to convey Iran's experiences to other counterparts in LMICs. In this study, the challenges of CPGs adaptation were classified into two basic and operational categories.

**Basic challenges:** Basic challenges included believing in the necessity of CPGs adaptation, attention to CPGs adaptation in evaluation and reward systems, access to financial resources, and supervision of the adaptation process. Regarding the beliefs about the need for adaptation, Shayo, in 2014, in the article entitled "Challenges of Publishing Clinical Guidelines," pointed to lack of knowledge about the existence of the CPGs, disagreement on the supporting evidence, and non-acceptance of new practices by service providers (19). One of the most critical corrective strategies with this challenge is the introduction of content and benefits of the CPGs to the target users through letters, lectures, visits, workshops and Intellectual leaders. In addition, the use of new publishing methods, such as virtual paths including applications, QR codes, audio files, e-mail and networks will encourage target groups to use CPGs.

Lai and Hou, in 2013, introduced the payment system as a barrier against adhering CPGs similar to doctors' culture, beliefs, and habits (20) that was in line with findings of the present study about considering CPGs adaptation in evaluation and reward systems. Financial and non-financial incentives such as privilege for faculty members' promotion, festival awards, and engaging interested students can be considered incentive opportunities. In favor of findings on access to financial resources, Keiffer, Barth, and Vogel, in separate studies in 2015 and 2016, introduced limitations in resources, time, medicines, equipment, space, staff, and training as reasons for not adhering to the CPGs (21-23). In Kimiaeimehr's study in 2019, the budget was identified as most effective among the economic factors influencing

CPGs implementation (24). It is recommended that special attention be paid to international organizations, private sector assistance, and governmental sponsors to provide financial resources. For example, if insurance companies consider financial incentives, stakeholders will be more motivated to adhere CPGs (2).

Concerning supervision of the adaptation process, Baradaran, in 2013, in a study on barriers of development and implementation of CPGs in LMICs, pointed to the lack of supervision in Iran's health care system (15). Also, in separate studies, Jun, Alnaim, and McKee indicated the role of leader and their support on the use and implementation of CPGs (25-27).

Kimiaeimehr has mentioned the following characteristics in the definition of supervision in CPGs; Integration of the health system, the existence of an evidence-based approach, improving the structure and troubleshooting of methodology, developing regulations and monitoring implementation, considering professional characteristics and implementation strategy, supporting the managers and decision-making bodies, time and staff management and problem-solving in a clinical setting (24). Based on the findings of this study, the authors suggest that the authority for ordering, approving, and monitoring of CPGs implementation should determine at each stage of the adaptation process.

**Operational challenges:** Operational challenges included adaptation methodology, forming an adaptation team, consensus on multidisciplinary issues, changes in prioritized programs and topics, and external barriers in the work progress path.

The result of Harrison's study in 2013 in Canada on assessing the experiences of five guidelines adaptation, the need for advanced methodological skills was declared as one of the challenges (12) that confirms the findings of this study about the methodology of adaptation.

McGowan also has pointed to the limited expertise of clinical epidemiologists and biostatisticians, who should have a clear clinical view of recommendations supporting evidence (28).

In addition to the role of knowledge and expertise in accomplishing correct methodology, several researchers have pointed to the importance of CPG translation quality, content interpretation, and reflection (19, 28-30). Training how to develop and adapt CPGs is one of the strategies to overcome this challenge (31). Training related to CPGs can include clinical knowledge, awareness of others' experiences, patients' preferences, policy and implementation, development and critical evaluation methodology, retrieval of supporting evidence, project management, and implementation (19).

Establishing and enforcing adherence to a standardized method for evaluating and adapting CPGs can also be beneficial (32). CPGs should also be as short, concise, and user-friendly as possible, like pocket cards, applications for smartphones and tablets, and checklists (2, 33). Finally, translation review by professional people in the field of translation and editing will be effective.

To form the adaptation team, Brown, in his study that assessed the obstacles against evidence-based practice among

nurses, pointed to establishing a panel team from all groups of stakeholders and involvement and commitment of members (19). Khodyakov et al. In 2019, with emphases on the role of stakeholders participation in preparing CPGs, stated that involving these people can increase CPGs credibility, meet the patients' needs and expectations, facilitate CPGs implementation, improve the chance of following the recommendations and ultimately improve the quality of care (34). Being in the process of development or adaptation of CPGs leads to a sense of ownership, and in this way, it promotes the acceptance of CPGs and adherence to them (2, 12). After identifying the CPGs stakeholders, it is necessary to use a combined model of traditional (face-to-face) and non-traditional (virtual) methods tailored considering the preferences of the active groups for acquiring their point of view. In addition, special attention should be paid to selecting team members to control the power and influence of individuals and pressure groups. Consensus on interdisciplinary issues was another challenge in this study; choosing capable individuals in group decision-making, explaining the conflict of interest examples, and determining how to consult and make decisions in the panel will be the adaptation team facilitators' actions.

McGowan pointed to challenges of interacting with the MoHME, including being under pressure to provide a vast number of CPGs in a limited period or bureaucratic problems (28). It confirms the findings of this study about changes in prioritized programs and subjects and external barriers in the work progress path. The work pressure and hardship of facing deadlines increase stress and mistakes that lead to decreased output quality and reduced chance of using CPGs in the clinical setting.

Baradaran et al. have also referred to instability, political changes, and lack of support as obstacles to health system policy-making regarding CPGs (15). While the use of CPGs is effective in quality improvement, satisfying the community, evaluating performance, and providing and managing resources. It will help policymakers to develop and monitor services and achieve significant goals systematically. Therefore, the development and implementation of appropriate CPGs are among the most critical aspects of modern management in the health sector (35). On the other hand, in addition to the serious efforts of managers and policymakers in designing and using CPGs, if the measures are defined considering up-to-date policies and significant goals of the health system and are finished at the right time, they are less likely to stop. It is noteworthy that different groups state the challenges of this study, and it doesn't mean that all groups are encountered all the challenges, rather each participant according to available facilities and the perceived situation, has shared their experiences. As if, in addition to mentioned issues, some researchers have identified challenges that have not been addressed during the present study; for example, patient's preferences and non-acceptance of recommendations by them, patients with multiple problems, multiple recommendations, and lack of up-to-date CPGs, limitations due to social norms, ethics and regulations and lack of study culture (19, 28, 33). Instead, in the present study, challenges such as the im-

portance of adaptation valuation in reward systems and academic professionals' performance evaluation were addressed that were not pointed in other studies. Funding, training, a particular authority for ordering, approving, and monitoring the adaptation of CPGs were the main issues in common among the studies.

### Conclusion

Having a comprehensive and reliable list of obstacles and problems in the process of CPGs adaptation will result in the identification and implementation of corrective strategies by managers and policymakers of the health system. The main challenges of CPGs adaptation in Iran, as one of the LMICs, are related to education, financing, and supervision of adaptation process steps. Some of the most significant proposed solutions to overcome the current obstacles in countries with similar contexts are holding new training courses and programs for CPGs users at different headquarters' and environmental levels, establishing an appropriate motivating system, designing an integrated adaptation system focusing on organizing related supervision affairs like planning, policy-making, and supervision at the MoHME and universities level. The prerequisite for moving on the way to these reforms is understanding the necessity and importance of adapting CPGs to improve the quality of provided clinical services and governing Evidence-Based Practice.

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### Ethics approval and consent to participate

The Ethics Committee of Tehran University of Medical Sciences and Health Services approved the study (IR.TUMS.VCR.REC.1396.3166). Verbal informed consent was given from participants. On the other hand, cooperation in answering the interview questions showed their satisfaction in participating in the study.

### Conflict of Interests

The authors declare that they have no competing interests.

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