

Development of Iranian clinical practice guidelines: An experience in cardiovascular diseases-A policy brief

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In the wake of the dominance of evidence-based thinking, clinical practice guidelines (CPGs) within the country's health system have gained a key position in recent years and playing an important role in enhancing all functions of this system. However, the absence of a standard model, the inadequacy of existing documentation for designing clinical guidelines, data obtained from the national self-care project (IMPROVE-CARE), the Persian Registry of Cardiovascular Disease, the national priorities declared by the Iranian Network of Cardiovascular Research, and most importantly, the order from the Ministry of Health, all highlight the necessity of establishing a structure followed by the creating of a standard model for the development of guidelines, and subsequently, the creation of Iranian clinical guidelines. This policy brief article discusses the process of establishing the structure and the produced content and presents the necessary policies for the development of national clinical guidelines.

Key words: Clinical practice guideline, development, policy brief

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INTRODUCTION

The development of societies and the expansion of health systems, especially in the last two decades, along with the advancement of medical sciences globally, has led nearly all countries to develop clinical guidelines, strategies, policies, standards, and clinical protocols to meet their health-oriented needs. They have taken steps to improve the qualitative and quantitative level of service delivery, as well as to formulate macro policies within the framework of establishing evidence-based medicine. Designing and developing appropriate guidelines for health services is considered one of the most important aspects of modern management in the health sector.^[1]

Clinical practice guidelines (CPGs) in Iran's health system have gained their key position in recent years, following the dominance of evidence-based thinking, and have played a significant role in enhancing the overall functions of this system.^[2] The Standardization and Clinical Guidelines Development Office was established in the Ministry of Health in 2010 with the mission of developing, finalizing, and declaration of health guidelines and standards in order to plan and achieve desired outcomes in response to the existing and expert needs of the target population.^[3]

There were scientific and practical products, such as the proposal for the compilation of clinical guidelines and the national model of adapting guidelines,^[2] in the Ministry of Health, which primarily relied on the

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adapting guidelines. However, the available documents for the design of clinical guidelines are not sufficient, with the existing ones being very brief without mentioning details and not covering all types of guidelines (development, adapting, and updating) and the differences in their design. Moreover, these documents were not in line with the scientific sources of designing guidelines provided by authoritative organizations in developing guidelines, such as the World Health Organization and the National Institute for Health and Care Excellence.^[2]

Therefore, considering the importance of having standard criteria and a standard model for the developing of clinical guidelines, and in order to unify the process of developing guidelines and improve quality, the Office of Technology Assessment, Health Standards, and Tariffs of the Ministry of Health declared the development of a methodology for designing national clinical practice guidelines a necessity and ordered the preparation of a proposal and instructions for designing national guidelines (separately for developing, updating, and adaption) from the initial design stage to the preparation of the report, to the cardiovascular research institute.

In addition, the priorities announced by the Iranian Network of Cardiovascular Research^[4] and the data obtained from the Persian Registry of Cardiovascular Disease (PROVE) program^[5] further highlighted the existing gap in the field of planning for the development of guidelines. For this purpose, an organizational structure was needed, so the Guidelines Development and Update Unit was established for planning and management in this field at the Isfahan Cardiovascular Research Institute.

Based on the request of the Ministry of Health on the one hand, and information obtained from the national IMPROVE-CARE project,^[6] the PROVE program and the priorities of the National Cardiovascular Research Network, as well as data from the exchange of views at the hyperlipidemia and hypertension seminars,^[7] this unit first prepared documents to facilitate guideline design and then developed and updated several guidelines. The advocacy policy brief contained in this article is the result of this experience and a review of the relevant scientific evidence.

APPROACH AND RESULTS

The studies related to the guidelines were designed and carried out after the formation of the structure and preparation of the strategic plan for the Development and Updating of Guidelines Unit at the Isfahan Cardiovascular Research Institute. Initially, a 1-year project was carried out to revise the methodology of compilation and adaption of CPGs in four stages: reviewing the literature and

preparing a draft, conducting a focused group discussion with six specialists in the field, summarizing and refining the points, and collecting feedback again through the Delphi method. An educational package was created for developing, updating, and adapting CPGs, which consisted of 13 knowledge products encompassing the definition of the guideline design process (along with its algorithm) and a checklist for determining the type and necessity of the guideline, pre-proposal forms, proposal forms for developing, updating, and adapting the CPG, instructions for completing each of them, and reporting forms for periodic and final reports. This package was approved by the Ministry of Health and communicated to all universities to be utilized by anyone interested in designing CPGs.^[2]

Cardiovascular disease and related risk factors (e.g., hyperlipidemia) are among the most significant health issues in many countries, including Iran, and are a research priority in the field of cardiology.^[4] In addition, proper management of this condition is essential, especially considering the health system structure in the country. There is also a notable absence of Iranian guidelines in this area. Ultimately, in response to the order from the Ministry of Health, it was determined that the guideline development unit takes responsibility for the development of Iranian guidelines for the management, diagnosis, and treatment of hyperlipidemia in adults and children.^[8]

To this end, using the aforementioned educational package and in the form of an action-research project, CPGs for the diagnosis and management of hyperlipidemia in adults and children were developed over 2 years through three phases: designing the scope and PICO Questions (Population, Intervention, Comparison, and Outcomes), conducting a systematic review to search for evidence, and preparing recommendations based on the evidence). These guidelines were approved by the Ministry of Health and communicated to all medical universities and relevant organizations in the country.^[8,9]

Hypertension is a leading cause of CVD globally and is the most common condition among CVDs in Iran. Despite significant efforts made in the diagnosis and treatment of hypertension, there are still many challenges regarding the management and treatment of this condition in Iran, including in Isfahan province.^[6,10]

According to some studies, only about 16% of affected people have their blood pressure under control. In a prioritization study of CVDs conducted by Isfahan Cardiovascular Research Institute in 2021, hypertension was selected by a panel of experts as the first cardiovascular research priority in Iran.^[4]

According to the mentioned issues and the planning and order of the Treatment Deputy of the Ministry of Health,^[8] the Iranian Hypertension Guideline was scientifically updated by the guideline unit through action research and following the standard educational package issued by the Ministry. The first edition of the guideline for the diagnosis, management, and treatment of hypertension in Iran was compiled in 2011 based on the most reliable evidence and considering the social status and healthcare needs of the country. This guideline was updated 3 years later; however, considering that more than 5 years have passed since the last update and the need to maintain the dynamics of CPGs, this important task was carried out and communicated to the medical universities and other relevant organizations in the country.^[9,11]

Ischemic heart diseases (IHDs), including acute coronary syndrome (ACS), account for almost half of the deaths related to CVDs.^[11] In Iran, CVD is the leading cause of death and disability-adjusted life year and is responsible for 46% of all deaths and 20%–23% of disease burden. Most CVD-related deaths are due to IHD. Despite remarkable advances in new diagnostic and treatment methods for IHD that are available in many parts of the country today, the burden of IHD is still high.^[12] ACS is the most common cause of hospitalization for both men and women in the United States, with more than 5 million people visiting the emergency department annually for chest pain and related symptoms. Of these, 10% are diagnosed with acute myocardial infarction, and 50% suffer from unstable angina.^[13]

Due to the absence of an Iranian guideline for ACS, most physicians in Iran rely on American or European guidelines. Nevertheless, the available guidelines, whether European or American, do not have optimal applicability within the healthcare structure of Iran. Therefore, it was necessary to develop a guideline and prepare recommendations for each level within the healthcare system.

Moreover, the existing guidelines mainly pertain to one of the three categories of ACS (ST-Elevation Myocardial Infarction, Non-ST Elevation ACS, and unstable angina). Considering that Iranian patients differ in terms of awareness and cultural (including misconceptions about heart pain), social, and economic conditions, as well as the structure and environment of health service delivery in Iran compared to other countries (with a well-established health system and the possibility for training and follow-up of patients), the planning and development of the first Iranian guideline for the management and treatment of ACS was initiated. This aims to address some of the challenges present in various aspects of disease management, from home care to hospitalization.

Development of the ACS guideline was conducted according to the standard model issued by the Ministry of Health and through a scientific approach over 2 years through action research method.^[8]

All the aforementioned plans were carried out through the action research method, and during the execution, it became evident that awareness regarding the methods of developing, updating, and adapting guidelines was very limited. Therefore, while developing the CPG, two national webinars, two provincial webinars, and two national continuous education webinars for physicians were organized on the topic of how to develop guidelines. In addition, this topic was presented at four national and international congresses through lectures and symposiums.

Regarding the implementation and evaluation of guidelines, various measures were adopted, including coordinating with the vice-chancellors of education, treatment, and health; correspondence regarding the necessity of implementing and educating about national guidelines through the aforementioned vice-chancellors; executing educational programs; coordinating with the insurance organization; and preparing a research proposal for evaluating the implementation of the guidelines.

Figure 1 provides all the aforementioned steps in the form of a diagram.

POLICY RECOMMENDATIONS

This article aims to provide policy recommendations based on the actions taken in the development of national clinical guidelines. As mentioned, the actions began through a scientific process initiated by a request from the relevant ministry and a needs assessment and were carried out through scientific stages. The requested documentation was prepared and disseminated nationwide. Therefore, the recommendations provided are entirely based on scientific evidence.^[8] These documents not only facilitate the design of various clinical guidelines but also expedite the production of guidelines that are suitable for the structure. Researchers believe that CPGs developed systematically and based on up-to-date and credible research evidence can enhance the effectiveness and efficiency of health interventions and promote equity in access to services.^[14]

Planning and developing the use of the proposed model for designing (developing, updating, and adapting) guidelines

For years, health policymakers, physicians, healthcare providers, and even patients have utilized clinical guidelines for informed decision-making and improving health care.^[1] When guidelines are developed correctly,

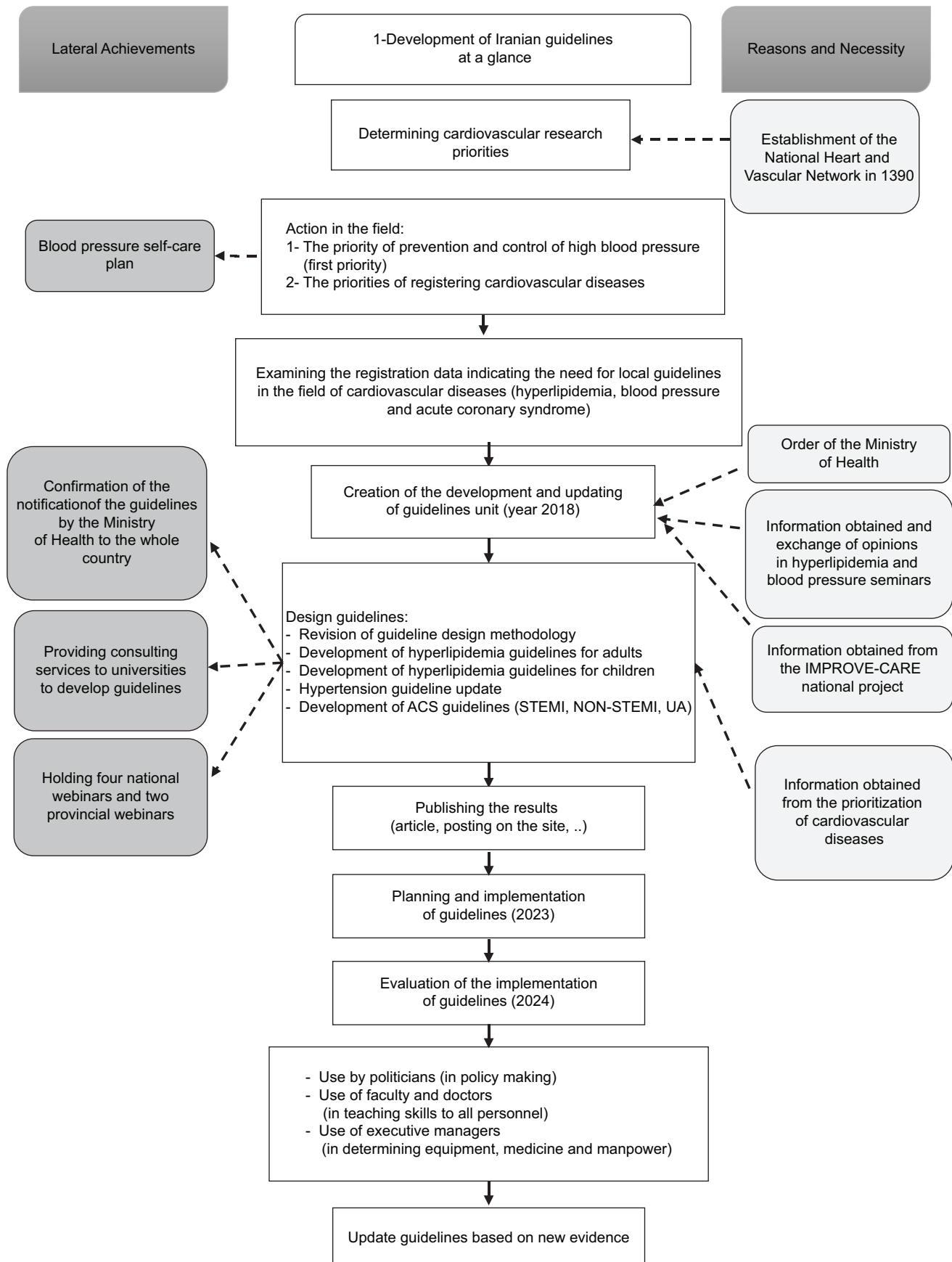


Figure 1: Development of Iranian guidelines at a glance

scientifically, and in accordance with the target community, they lead to an improvement in both the quality and even the quantity of health services, while also preventing the imposition of additional costs and serving as a resource for training staff.^[2] Therefore, designing strategies to enhance the use of the national standard model mentioned above for the design of clinical guidelines by policymakers and executive managers is of great importance. This will assist them in systematically developing and monitoring services, thereby enabling them to achieve their goals regarding the provision of health services and care and to respond effectively to the needs of the people and the community.

Planning and development of the use of standard national clinical guidelines

The preparation and updating of four Iranian clinical guidelines using standard methods assist physicians in managing and treating related diseases scientifically and based on the latest evidence, considering the national health structure and existing conditions. Designing strategies to encourage healthcare providers to utilize national clinical guidelines, which are prepared using standard methods and based on existing infrastructure, can enhance patient satisfaction and improve the quality and efficiency of the healthcare delivery system.

Planning for monitoring services based on national clinical guidelines

Incorporating the content of national guidelines into the monitoring and evaluation programs of healthcare units is another useful strategy. This approach aids in the implementation and application of national guidelines by clinical specialists during practice. National guidelines can also be utilized in reviewing medical malpractice and medical errors in relevant committees and organizations.

Training faculty members and specialists in designing national guidelines based on the established national model

Among the proposed strategies for this purpose, education plays a key role. Training on the developed content and national guidelines for medical professors and educating medical students on national clinical guidelines are fundamental strategies for systematically and evidence-based disease control.

Community education

Since graduates and the general public should not be overlooked in the educational process, preparing various educational materials for distinct target groups in different electronic and printed formats can be a thoughtful proposed policy. Producing simplified versions of necessary recommendations for the general public can help them adhere more closely to physicians' advice and support individuals with illnesses.

Continuous re-education of physicians and other health team members regarding national guidelines

Employee performance impacts the outcomes of an organization's activities, and training and development of employees assist both the organization and the employees in achieving various goals. It is the responsibility of organizational leaders to plan for the training and retraining of employees and to use systematic approaches for evaluating staff.^[15] For this reason, the continuous retraining of physicians and other members of the healthcare team should also be considered by policymakers.

CONCLUSION

In our country, given the unique structure of the healthcare system and specific socioeconomic conditions, policymakers need to develop national standard clinical guidelines and make decisions to implement them as effectively as possible. Considering the resources prepared, which were mentioned in the article, and the favorable scientific potential in universities, it seems that this can be achieved through the application of the proposed policy recommendations.

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Conflicts of interest

There are no conflicts of interest.

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