Health Tech Asmnt Act. 9(2).

Research Article

Developing a National Accreditation Model for Medication Management in the Iranian Primary Health Care System

Esmaeil Moshiri[1], Masoumeh Ebrahimi Tavani[2], Farid Gharibi[1*]

[1]Social Determinants of Health Research Center, Semnan University of Medical Sciences, Semnan, Iran.
[2]Quality Improvement, Monitoring and Evaluation Department, Center of Health Network Management, Deputy of Public Health, Ministry of Health and Medical Education, Tehran, Iran.

* *Corresponding Author:* Farid Gharibi, Social Determinants of Health Research Center, Semnan University of Medical Sciences, Semnan, Iran. Email: gharibihsa@gmail.com.

Received 2024 December 10; Accepted 2025 February 21.

Abstract

Background: Medication management plays a critical role in the quality of delivered treatments and patient safety.

Objectives: The present study aimed to develop a national accreditation model for medication management within the Iranian primary health care (PHC) system.

Methods: The primary standards were developed by considering existing accreditation models worldwide, reviewing available medication management documentation in Iran's PHC system, and obtaining expert opinions in this field. The developed standards and measures were incorporated into a Delphi Questionnaire and evaluated by experts based on two criteria: Importance and feasibility, using a 9-point scale. The Delphi panel consisted of 20 experts, and the technique was implemented over two rounds. Of the 20 experts, 18 completed the questionnaire, with response rates of 90% and 100% in the first and second rounds, respectively.

Results: The study was conducted in 2021 - 2022. In the first round of the Delphi process, 55 out of 65 primary measures reached a quorum and were accepted. The remaining ten measures were approved by experts in the second round. The model developed in this study comprises five main standards: "Provision of resources for activities in the field of medication management", "development and consideration of the list of authorized medications for prescribing in the form of a pharmacopoeia", "safety in prescription and medication use", "ordering, storing, and dispensing systems of medications" and "educating the community about the correct use of medications". The total mean scores for all measures in terms of importance and feasibility were 8.32 and 7.68, respectively.

Conclusions: Given the high consensus among experts on the importance and feasibility of the developed standards, there is optimism that utilizing this model can lead to continuous improvement in the quality and safety of medication management in the Iranian PHC system.

Keywords: Accreditation; Model; Primary Health Care; Medication Management

1. Background

Medical errors are among the leading causes of death and injury to patients and are considered a primary challenge to the health system (1). Medication errors (MEs), the most common type of medical errors, represent a global issue (2). Currently, approximately 20,000 different medications are used worldwide, which can lead to side effects in addition to positive therapeutic effects (3). The MEs are defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is managed by a healthcare professional, patient, or consumer" (4). Studies have shown that over 85% of patients experience MEs, with a rate of approximately 3.5 errors per patient and 0.18 per prescription (5).

A significant safety challenge, particularly in developing countries, is the lack of reliable and adequate studies on medical errors, especially MEs (6). As one of these countries, Iran faces notable challenges in producing and utilizing information related to this area (7). However, the few existing studies indicate a higher prevalence of MEs in Iran compared to other countries (4). The adverse effects of MEs are considerable, with approximately 22% resulting in patient injuries (5). Medical errors account for 44,000 to 98,000 deaths annually in the United States (8), with 7,000 of these deaths attributed to MEs (9, 10). The MEs often lead to severe consequences, resulting in millions of patients experiencing prolonged hospitalization or physical and mental harm daily (11, 12).

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Adverse drug events (ADEs), which refer to any injuries resulting from medication use (13), occur in 5% to 20% of hospitalized patients and 12% to 17% of discharged patients (14-16). The MEs are costly, with adverse economic consequences affecting the community (4). The ADEs lead to prolonged treatment processes and extended hospitalization periods, necessitating additional treatments and medication interventions. The total cost of morbidity and mortality resulting from MEs in U.S. outpatient departments is $177 billion (16). The MEs also negatively impact the quality of treatment and the performance of healthcare staff (17, 18). However, the most serious consequences of medical errors, particularly MEs, include a decline in public trust in the health system and increased dissatisfaction rates (18, 19).

The prevalence of MEs is considered a key indicator of healthcare quality and safety. Therefore, reporting and analyzing related information is crucial (20). The MEs can occur at any of the five stages: Prescription, transcription, dispensing, administration, and monitoring (13, 21). More than 95% of MEs occur during the prescription stage. The most common prescription errors are related to omission (26.9%), unauthorized medications (18.3%), and incorrect medication dose or frequency (3.17%) (17). The MEs may occur in various aspects related to medications, such as professional activities, healthcare products, treatment procedures and prescribing systems, order-related communications, labeling, packaging, naming, combining, dispensing, management, training, monitoring, and use of medications (22-24). In theory, all MEs are preventable (25). The MEs are multifactorial problems; thus, eliminating them requires adopting multilateral solutions (26). Establishing a "reporting system" and creating a "no-blame culture" are two main approaches that can effectively manage medical errors (12). Utilizing scientific and purposeful research studies to select and implement interventions can be effective. These include the design, implementation, and evaluation of an effective reporting system for medical errors; evaluation of individual and system factors leading to MEs; assessment of involved individuals' viewpoints on MEs; evaluation of the effectiveness of preventive measures related to MEs; and assessment of the effectiveness of intervention approaches related to reporting and improving the status of MEs (27).

Strengthening the medication management system and all its aspects, especially quality and safety, can lead to improvements in this area. Studies have shown that accreditation is considered the primary approach to improving the quality and safety of healthcare. Accreditation leads to improved standardization of service provision processes, increased compliance between services and guidelines, development of organizational culture to enhance quality and safety, implementation of more activities related to continuous quality improvement, and strengthening of the leadership function in healthcare organizations (28). Few studies on the impact of accreditation on safety, particularly MEs, have demonstrated the appropriateness of using accreditation in this regard, as the level of safety culture and scientific attitude toward reporting MEs have significantly improved with the implementation of the accreditation system (29).

A review of the existing literature shows that all studies focus on managing MEs in hospital and outpatient settings, with no publications specifically addressing primary health care (PHC). This significant shortcoming may harm patient safety and decrease community health and health center performance (2, 16).

2. Objectives

Considering the necessity of improving the quality and safety of medications in the PHC system of Iran and the lack of an accreditation model for improving the situation in this field (5), this study was designed and implemented to develop a national accreditation model for medication management in the PHC system of Iran.

3. Methods

The study was conducted in 2021 - 2022. Since the positive effects of accreditation are often achieved through the development of effective and optimal standards (30), the first step in this study was to identify valid methods and resources for developing efficient standards (31, 32). A review of published data on medication management suggests that existing accreditation standards in this area, combined with various methods such as hospital accreditation models and valid PHC systems globally, reviewing available scientific documents related to medication management in Iran's PHC system, and obtaining expert opinions, will help develop evaluation indicators.

Accordingly, the research team developed primary accreditation standards using pioneering and effective accreditation models worldwide in hospital care, such as those from the USA, Canada, and Australia, as well as successful models in the eastern Mediterranean region (EMR), Egypt, Lebanon, and Jordan (32, 33). To obtain the primary standards, researchers also used PHC accreditation models from Egypt, Jordan, and Saudi Arabia (34-36), as these models considered medication management in their assessment standards. After holding specialized meetings with experts in medication management within PHC and obtaining their views on the development and content of assessment standards, all available scientific documents in the PHC field were carefully reviewed.

After developing the initial standards using the aforementioned methods, a Delphi Questionnaire was created to reach a consensus on standards and measures based on indicators of importance and feasibility on a 9-point scale (31). The standards and initially developed measures were included in the questionnaire for review based on these two indicators from the experts' viewpoints. Although the Delphi technique requires the participation of at least ten people (37, 38), this study selected 20 experts in medication management within Iran's PHC sys-

tem to compensate for potential loss during the Delphi process and to maximize expert input. The experts included individuals with PhDs in health services management or health policy with at least ten years of experience as faculty members, as well as MDs in pharmacology with at least five years of management experience in the "medication and laboratory" unit at the Ministry of Health and medical sciences universities. Experts were identified through mailings with national boards of health services management and the deputy of health affairs in the Ministry of Health and Medical Education.

The designed questionnaires were distributed in two ways: In person to available experts and by e-mail to specialists in other provinces. After analyzing the results of each stage, the next round's questionnaires were prepared and presented to the experts, continuing until final agreement and consensus on the standards were reached. The decision-making process in the questionnaire analysis section was based on the median index, which disregards unconventional and extreme responses. Standards with medians between 1 and 4 were excluded from the study, while those between 4 and 7 were considered for further analysis. A standard with a median score higher than 7 was accepted directly and included in the final model (39).

Another noteworthy point in this process was providing feedback on the results obtained from previous rounds to all experts (the total median), as well as the specific score given by each expert to any standard. This feedback encouraged experts to reflect more on their scoring, modification, and adjustment of the points they assigned. The consensus process considered a standard agreed upon if the difference in points given by experts in two consecutive rounds was less than 15% of the total median score. In such cases, there was no need to include the standard in the next Delphi round (40). All analyses conducted in various phases of the Delphi process were performed using SPSS version 16.

4. Results

The primary standards of accreditation in this study were developed through a careful examination of relevant scientific data, including accreditation models from the hospital sector and valid PHC systems globally, available scientific documentation related to medication management in Iran's PHC system, and expert comments in this specialized area. The standards and measures related to medication management were extracted from the texts after thorough examination. Subsequently, the extracted scientific content was aligned with current activities and programs in the field of medication management within Iran's PHC system and ultimately classified according to a rational framework. The standards were then incorporated into a Delphi Questionnaire and presented to experts in this field for review and comment over two rounds.

The result of these studies was the development of five main standards: "Provision of resources for activities in the field of medication management", "development and consideration of the list of authorized medications for prescribing in the form of a pharmacopoeia", "safety in prescription and medication use", "ordering, storing, and dispensing systems of medications" and "educating the community about the correct use of medications", along with 65 measures related to these standards. In the first round of the Delphi process, a questionnaire containing 65 measures and five main standards was presented to 20 Iranian experts who were key figures in the health departments of Iranian medical universities in the field of medication management. Of the 20 experts, 18 completed and returned the questionnaires, resulting in a 90% response rate.

After performing the required analyses, 55 measures were approved by obtaining a minimum score of 7 in both importance and feasibility standards. Ten measures were considered in the second round due to receiving a score between 4 and 7 in one or both standards, and none of the measures scored less than 4, which would have led to exclusion from the study. In the second round of the Delphi process, the ten remaining standards were sent to the experts, and 18 experts provided their responses, achieving a 100% response rate. At this stage, the total median score and the score assigned by each expert to each measure in the first round were presented to the experts to allow them to modify their points. The experts then rescaled the measures, and all the standards achieved the required minimum for approval. Additionally, the qualitative feedback provided by the experts was incorporated into the written and content standards and measures to ensure their full quality.

The final approved standards and measures, their confirmation rounds, and the final median scores are presented in Table 1.

Table 1. The Selected Measures and Their Approval Process

Measures	First Round	Second Round	Importance	Feasibility
Standard 1: Provision of resources for activities in the field of medication management				
The required personnel are provided to carry out the activities related to medication management with a reasonable number.	√	-	8	8

Personnel in this field have received adequate and proper in-service training.	√	-	8	7
Personnel in this field have the skills and experience to carry out their duties.	√	-	7.5	8
The funds required for medication management are provided and used appropriately.	-	√	7.5	7.5
Health centers finance the field of medication management based on existing health priorities.	-	√	9	8
Health centers have sufficiently invested in developing and expanding information management infrastructure, such as computer systems, the internet, and medication management software.	√	-	8	7.5
Health centers have made viable investments, working with higher management levels to provide portals, websites, and databases related to medication management.	√	-	7	8
Health centers and higher levels of management, through the creation of the infrastructure, expand production capacity, storing and disseminating reliable information about the field of medication management.	√	-	7	7
The required physical spaces for carrying out activities in the field of medication management are provided appropriately.	√	-	7.5	7
Equipment needed to function correctly in medication management is provided and used appropriately.	√	-	7	8
Medications and other raw materials used in medication management are provided with sufficient and reliable sources.	√	-	9	8
Standard 2: Development of a list of authorized medications for prescribing in the form of a pharmacopoeia				
A multidisciplinary and experienced team developed the health center's pharmacopoeia, designed to reduce costs and increase the effectiveness of prescribed medications.	-	√	8	7
Effectiveness, safety, cost, and medication access are considered when developing pharmacopoeia.	√	-	8	7.5
The development of pharmacopoeia considers the comprehensive list of medications to address the community's needs and enhance the country's self-sufficiency in producing medications.	√	-	9	8
The pharmacopoeia is available to all medication prescribers.	√	-	8.5	8
All medications listed in the pharmacopoeia have been provided in good quality and quantity at the pharmacies of comprehensive health centers.	√	-	8.5	8
Prescribing medication in comprehensive health service centers is based solely on pharmacopoeia.	-	√	7.5	9
Health centers use written and rational criteria for adding or removing medications to/from the pharmacopeia.	-	√	8.5	8
Health centers have a clear framework for reviewing the pharmacopoeia and updating the information.	√	-	8	8
Developing and considering pharmacopoeia has led to an increase in people's access to the required medications.	√	-	8	8.5
Developing pharmacopoeia increased the efficacy of prescribed medications.	√	-	7	7.5
Developing pharmacopoeia increased the quality and safety of prescribed medications.	√	-	7.5	8
Developing pharmacopoeia has reduced the cost of prescribed medications for people and the health system.	√	-	7	7
Standard 3: Safety in prescription and medication use				

Pharmaceutical personnel actively work with doctors and health personnel to manage medications safely and effectively.	-	√	8	8
Doctors and prescribing personnel have access to accurate and up-to-date information on indications, contraindications, intake amounts and doses, and undesired effects of medications.	√	-	8	9
Doctors and health and medical personnel provide training on how the patients use the medications.	√	-	8	7.5
Doctors and health and medical personnel acquire the necessary training and skills to prevent adverse medication events and appropriately apply them.	√	-	9	8
Health centers have an effective mechanism for reporting medication errors (MEs).	√	-	8	8
Health centers have an effective mechanism for rooting out MEs.	√	-	9	8
Health centers have designed and implemented a list of effective interventions to correct potential and actual MEs.	√	-	8	8
Health centers have an effective mechanism for recording and reporting undesired side effects of the prescribed medications.	√	-	8	7.5
Health centers define a list of high-risk medications and make it available to the public.	√	-	8.5	7
Health centers label the medications clearly and legibly.	√		7	7
Doctors and prescribers of medicines in health centers follow the principles of correct and legible prescriptions.	√	-	8	7
Doctors and prescribers of medicines in health care centers consider contraindications, especially for pregnant and lactating women, children, the elderly, and people with specific diseases when prescribing medications.	√	-	9	9
A pharmacist or experienced medical personnel supervises proper medication prescriptions by matching medications and medication orders with the patient's disease condition.	√	-	8.5	8
Health centers establish a medication audit system and ensure good prescription and medication use.	-	√	9	8
Implementing the medication safety program has led to an increase in the quality of prescriptions and a reduction in insurance deductions for medicinal drugs.	√	-	9	8
Implementing medication safety at health centers has led to continuous reductions in MEs.	-	√	9	7.5
Implementing the medication safety program in health care centers has continuously reduced the undesired effects.	-	√	8	8
Implementing the medication safety program has continuously increased the efficacy of prescribed medications and improved patient satisfaction.	√	-	8	8.5
Implementing the medication safety program has led to a continuous increase in community satisfaction and reduced medication-related complaints.	√	-	9	8
Standard 4: Ordering, storing, and dispensing systems of the medications				
There is a mechanism for registering medication orders in a rational and need-based manner so that adequate medications of good quality are provided.	√	-	9	8
All medication storage areas in the comprehensive health services centers are monitored periodically to ensure proper medication preservation.	√	-	9	8

The medications are stored appropriately, following the manufacturer's instructions.	√	-	8	7.5
Medications are available to patients in health centers based on their needs and services.	√	-	8	7
Emergency medications are protected against being lost or stolen.	√	-	9	7
Emergency medications are replaced promptly and adequately after use, deterioration, or expiration.	√	-	7.5	9
There are no unlabeled medications in the pharmacies.	√	-	8	8
All information on the medications is fully legible.	√	-	8	8
Medications are prepared and dispensed in a safe and clean environment using appropriate equipment.	√	-	8	8.5
Dispensing medications in different parts of the health centers is done according to needs and in a timely and safe manner.	√	-	9	7.5
Accurate preservation and dispensing of medications and their raw materials prevents their deterioration and the associated extra costs.	√	-	8	8
There is a mechanism for registering medication orders in a rational and need-based manner so that adequate medications of good quality are provided.	√	-	9	8
Standard 5: Educating the community about the correct use of the medications				
Continuous and accurate evaluations are done regarding the behavioral problems of the community in medication use and the roots of these behaviors.	√	-	8	8
The educational needs of the community are determined based on the needs.	√	-	8	9
Appropriate training packages are taught based on the needs of the experts.	√	-	9	8
Valid scientific evidence and experts' views are used to develop educational packages.	√	-	7.5	7
The educational contents emphasize the adverse health and economic effects of unusual medication use.	√	-	8	7.5
In the educational content, the use of the medication following the physician's instructions is emphasized.	√	-	8	9
Doctors and medical personnel train the patients on how the medications are used.	√	-	9	8
Training is provided to the community by qualified people and through different educational methods.	√	-	8	9
Other administrative and management interventions, such as limiting the sale of medications without prescription or prescribing a reasonable amount of medicines to patients, are designed and implemented to enhance the impact of training.	√	-	8	8
Training and the associated interventions have led to continuous reductions in the use of medications, especially antibiotics.	-	√	8.5	7.5
Training and the associated interventions have led to continuous reductions in medication resistance cases.	√	-	9	7
Training and the associated interventions have led to a continuous decline in the costs of medication use.	√	-	8	7

Among the various standards, "safety in prescription and medication use" achieved the highest score in terms of importance, with an average of 8.62 for its measures. Conversely, "development and consideration of the list of authorized medications for prescribing in the form of a pharmacopoeia" received the lowest score, with an average of 7.34 for its measures. Additionally, within the final model, "ordering, storing, and dispensing systems of medications" scored the highest in terms of feasibility, with an average of 8.40, while "development and consid-

eration of the list of authorized medications for prescribing in the form of a pharmacopoeia" scored the lowest, with an average of 7.25 for its measures. The total mean scores for all measures based on the criteria of importance and feasibility were 8.32 and 7.68, respectively.

5. Discussion

This study was implemented to develop a national accreditation model for medication management in the PHC system of Iran. The main objective was to develop a comprehensive, acceptable, and effective model in this field. The final model developed in this study consisted of five main standards: "Provision of resources for activities in the field of medication management", "development and consideration of the list of authorized medications for prescribing in the form of a pharmacopoeia", "safety in prescription and medication use", "ordering, storing, and dispensing systems of medications" and "educating the community about the correct use of medications".

The first standard of the model addresses providing the resources needed for activities in medication management, aiming to supply the required quantitative and qualitative inputs such as human resources, funds, information infrastructure, physical space, equipment, and materials. The second standard focuses on developing and considering the list of authorized medications for prescription as a pharmacopoeia, emphasizing its role in increasing efficiency, effectiveness, and access to required medications in a systematic and rationalized manner.

The third standard emphasizes the importance of safety in prescribing and using medicines due to the high volume and widespread effects of MEs worldwide. This standard includes several important issues, such as improving the health team's collaboration to provide effective and safe treatment, establishing a comprehensive risk management mechanism in medication management, identifying safety and medication problems, designing and implementing effective interventions, focusing on medication audits by experienced individuals, and considering the expected short-term and long-term effects of these processes and activities. These activities might include improving treatments, reducing undesired medication effects, and increasing community satisfaction with the services provided.

The fourth standard addresses the necessity of establishing a system for ordering, storing, and dispensing medications. This part focuses on creating and observing a logical ordering mechanism based on health centers' needs, considering quantity and quality in medication orders, providing healthy and safe storage conditions, and timely and on-demand dispensation of medications. The ultimate goal is to reduce medication waste costs and, consequently, the costs imposed on health centers and the health system.

The fifth and final standard emphasizes providing correct community education regarding medication use. This standard was included due to the importance of proper medication use, stressing issues such as identifying community education needs, providing proper education about appropriate medication use and avoiding nonprescription medication, training physicians and health personnel on prescription norms, designing and implementing social interventions to promote proper medication use, and the expected implications of these activities, such as cost reductions and minimizing medication misuse effects, especially medication resistance.

The experts in this study believed that "safety in prescription and medication use" and "developing a list of authorized medications for prescription in the form of a pharmacopoeia" were the most and least important standards, respectively. This indicates that while experts emphasize the importance of MEs and promoting medication safety, they consider the positive health and economic consequences of developing and using a pharmacopoeia as less important. Additionally, "ordering, storing, and dispensing systems of medications" and "developing and considering the list of authorized medications for prescription in the form of a pharmacopoeia" had the highest and lowest feasibility, respectively. This can be attributed to the ease of intervention in ordering, storing, and dispensing medications, the pharmacopoeia's implausibility, and the health centers' lack of technical power to participate in this standard.

The implementation of the final developed accreditation model in Iran's health system may encounter challenges such as insufficient procurement of required resources, a lack of an independent organization with highly competent staff for conducting external evaluations, low knowledge and experience among healthcare center managers and staff regarding accreditation, and a lack of defined motivations for successful individuals and organizations that comply with accreditation standards. To overcome these challenges, measures such as formal acceptance of accreditation and its organization by the Ministry of Health, providing sufficient resources for healthcare organizations, training health managers and staff about accreditation, defining an effective motivation system, and using the experiences of pioneers and successful health systems in accreditations could be proposed.

Medication management is always considered one of the main areas of hospital accreditation. Studies show that all hospital accreditation models worldwide, especially pioneering models in the United States, Canada, and France, as well as successful programs in the EMR such as Jordan, Egypt, and Lebanon, emphasize proper medication management. The standards and measures defined in these accreditation models are based on factors such as the existence of a drug pharmacopoeia and compliance with it in medication preparation and prescription, timely and sufficient production or ordering of medications, correct and safe storage according to

manufacturer instructions, correct prescription based on patient condition and needs, and evaluation and management of medication side effects. Iran's hospital functional accreditation model includes all these items with full accuracy and detail (33).

Even though "preparation of essential medications" has been mentioned as one of the eight primary functional areas since the beginning of the primary healthcare movement, accreditation models developed in public health have not paid particular attention to it. Surveys show that leading PHC accreditation models in the United States, Canada, and Australia, or leading models in the EMR such as Jordan and Egypt, have focused very little on developing standards and measures for this important area, making only general and limited references. Based on this, the accreditation model developed in the present study aims to address this significant shortcoming by ensuring appropriate quantity and quality of drug provision, maintaining and delivering medications correctly and safely, monitoring correct prescription, and educating society on proper medication use (41).

One of the strengths of this study is the use of existing effective accreditation models worldwide and the documentation available in Iran's PHC system in medication management to develop accreditation measures. The high response rate of experts to the questionnaires was another notable strength. Although experts were selected based on purpose, the main limitation was the right choice of participants and their expertise and representativeness. Experts' geographical situation was another limitation resolved by using internet platforms. The possibility of insufficient expert response was addressed by repeated follow-ups by the research team to obtain opinions.

5.1. Conclusions

The present study was conducted to provide an appropriate framework for improving medication management in Iran's PHC system through valid scientific sources, the most credible and successful accreditation models worldwide, and a strong research approach in developing standards and accreditation measures. Given the importance of medication management in the quality and safety of services provided to patients, implementing this developed model could improve community health and satisfaction. The researchers hope that applying the present model can provide a consistent and efficient structure, leading to continuous quality and safety improvements in medication management in Iran's PHC system. Implementing all recommended suggestions would maximize this model's benefits.

Acknowledgments

The researchers of the present study appreciate the sincere collaboration of all the colleagues and experts involved in the different stages of the study. They also appreciate Tabriz Health Services Management Research Center's financial support.

Authors' Contribution

Design: Esmaeil Moshiri & Farid Gharibi

Literature Review: Masumeh Ebrahimi Tavani & Farid Gharibi

Primary Model Development: Esmaeil Moshiri & Farid Gharibi

Conducting Delphi Technique: Masumeh Ebrahimi Tavani & Farid Gharibi

Finalizing Developed Model: Esmaeil Moshiri & Farid Gharibi

Writing Manuscript: Esmaeil Moshiri, Masumeh Ebrahimi Tavani & Farid Gharibi

All authors read and approved the final manuscript.

Clinical Trial Registration: Not applicable

Conflict of Interests:

The authors declare no conflict of interest.

Data Reproducibility: All study information is given in the manuscript and the data will available according to the request of the editor f the journal.

Ethical Approval: IR.TBZMED.REC.1393.259

Funding/Support: The study was funded from Tabriz University of Medical Sciences.

Informed Consent: Not applicable.

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