Int J Nutr Sci 2025;10(2):305-313

International Journal of Nutrition Sciences

Journal Home Page: ijns.sums.ac.ir

ORIGINAL ARTICLE

Development and Validation of a Comprehensive Model for Diabetes Management in Iran

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ARTICLE INFO

Keywords:
Diabetes
Validation
Management
Iran

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Received: March 1, 2025
Revised: May 25, 2025
Accepted: June 1, 2025

ABSTRACT

Background: Diabetes is still a significant global health challenge and it is estimated that 9.2 million Iranians by 2030 to suffer from the disease. Effective management is critical to reduce complications, costs, and improve quality of life, yet Iran's care delivery system lags behind international standards. This study aimed to develop and validate a comprehensive model for diabetes management in Iran, tailored to its socio-economic context.

Methods: A mixed-method approach was employed in four stages of (i) literature review to identify factors affecting diabetes management, (ii) qualitative interviews with 20 experts to extract key components, (iii) Delphi method to prioritize factors and (iv) the exploratory factor analysis (EFA) with 400 specialists to validate the model. Content validity (CVI≥0.79, CVR≥0.42) and reliability (Cronbach's alpha=0.898) were assessed, with EFA confirming model fit (KMO=0.885, p<0.001).

Results: Five key components were identified including leadership, management information, financial resources, human resources, and medical technologies. These were validated as critical ones for effective diabetes management, emphasizing team-based leadership, staff empowerment, sustainable financing, and robust training systems.

Conclusion: The validated model offers a practical framework to enhance diabetes care in Iran that aligns with international standards and addresses local challenges. The strengthening leadership, investing in human resources, securing financial support, and leveraging technology are recommended in this relation. Future researches should be undertaken to validate the model across diverse regions and incorporate patient perspectives too.

Please cite this article as: Falahati F, Alimohammadzadeh K, Hosseini SM, Maher A, Jafari M. Development and Validation of a Comprehensive Model for Diabetes Management in Iran. Int J Nutr Sci. 2025;10(2):305-313. doi: 10.30476/ijns.2025.106935.1471.

Introduction

The prevalence of diabetes in 2010 was estimated 6.4 percent affecting about 285 million people, and is expected to reach 7.7 percent that will include 439 million people by 2030 (1). The International Diabetes Federation has also estimated 9.2 million Iranians to suffer from diabetes by 2030 (2). It was shown that if diabetes is left untreated, it can cause serious complications and affect several organs (3). Diabetes can cause direct and indirect costs to the

patient's health system and family too and can affect the patient's quality of life and negatively impact their ability to self-care (4, 5). This disease imposes a high cost on the health system. It was estimated that up to 12% of different countries' health budgets are spent on treating people with diabetes (6).

Proper treatment, management, strategy, innovation, and integration of health systems are needed to reduce the complications and mortality due to diabetes (7-10). Due to the difference between diabetes care conditions in Iran and international standards, the care delivery system in Iran needs to be improved and developed. These changes should be based on the socio-economic conditions of patients and the needs of specialists with an integrated care approach. In all countries with different economic conditions, diabetes management is a severe challenge for health systems. Therefore, this study aimed to identify the essential and practical variables that can contribute to successful diabetes management in Iran to improve the diabetes care delivery system and to align more closely with international standards.

Materials and Methods

The present study is a qualitative and quantitative study using a practical research method in four stages. In the first stage, by reviewing the literature, the factors and components affecting the management of patients with diabetes were identified. In the second stage, the effective ingredients of patient management and basic sub-components were recognized by interviewing experts, policymakers, planners, and health managers of non-communicable and chronic diseases. In the third stage, the Delphi method was used to prioritize and finalize the factors affecting the management of diabetic patients. The factor analysis method was used in the fourth step to test the best model.

In step 1, appropriate items of the model with related structures including Persian databases such as SID, Iranmedex, and MagIran, and reputable international databases such as PubMed, Web of Science, and Scopus were reviewed and searched. In step 2, a qualitative study was undertaken. In line with the specific objectives of the research and to document patient management, review and extract factors affecting patient management were conducted from the perspective of those involved in process coordination by semi-structured interviews and group discussion sessions. Totally, 20 subjects were selected by purposive sampling method. In this regard, we made this number a complete representation of the target community with a high diversity. Inclusion criteria were 20 professionals with more than five years of experience in health system management at Shiraz University of Medical Sciences, Shiraz, Iran.

The criterion for excluding the participants' reluctance was the continuation of the study. Delphi could be a precise approach to control the suppositions of specialists on an issue and their agreement. To perform the Delphi technique for the present study, the opinions of experts and specialists were extracted from senior managers during group discussion sessions. We asked the participants to use a 5-point Likert scale from strongly agree to completely disagree. Expressing their opinion about the criteria and sub-criteria and also, in any case, if necessary, proposing the necessary amendments and adding new criteria or sub-criteria after the end of each round were determined including the average, frequency, and percentage of the agreement. Experts for each item of calculation, suggestions, and additions were reviewed. The results were redesigned and sent to the experts with the necessary information and were asked to be judged similarly to the previous stage. Cases in which the collective agreement rate was more than 75% were included in the template, and items that were less than 50% were removed. The cases in which the agreement was between 50 and 75%, in addition to the points suggested by the experts in the second stage of the Delphi test, were also enrolled.

In step 3, the content validity of the questions was determined. To determine the content validity ratio, a panel of 20 experts was asked to comment on each indicator according to the necessity of each question, and we employed the Lawshe method (11). In this method, each indicator was evaluated by four options of "necessary", "useful", "unnecessary", and "useless". The ratios obtained for each index were compared with the numbers provided in Lawshe method. When there were 20 experts, a CVR of 0.42 or more was approved based on Lawshe method. CVI above 0.79 was also acceptable. In step 4, validation of the model by using exploratory factor analysis was carried out. To design a management model for providing services to patients based on the identified frameworks and indicators, the final questionnaire was provided for 400 specialists in diabetes clinics, health care providers (family physicians, health information managers, quality improvement manager, medical records), and the head of the health network of the cities of Fars province, southern Iran.

A sample size of 400 participants in the fourth stage of the study, where exploratory factor analysis (EFA) was conducted to validate the proposed diabetes management model, was determined

based on established guidelines for EFA and practical considerations specific to the study context. Exploratory factor analysis typically required a sufficient sample size to ensure stable and reliable factor solutions. Common recommendations in the literature suggest a minimum sample size of 5-10 participants per item in the questionnaire or a total sample size of at least 200-300 participants for robust results (12, 13). In this study, the final questionnaire included a set of indicators derived from the Delphi process, with an estimated range of 30-50 items based on the identified frameworks and sub-components. To meet the conservative guideline of 10 participants per item, a sample size of 300-500 participants was deemed appropriate. Additionally, we considered the subject-to-variable ratio, aiming for a ratio of at least 10:1, which is widely accepted for EFA (14).

With an anticipated 40 items, a sample size of 400 was selected to satisfy this criterion. Furthermore, to ensure adequate representation of the target population, we included specialists from diabetes clinics, family physicians, health information managers, quality improvement managers, medical records staff, and heads of health networks across Fars province, which required a sufficiently large sample to capture diverse perspectives and ensure generalizability within the study context. Practical considerations, such as the availability of eligible participants and logistical feasibility, also informed the decision to set the sample size at 400 subjects. This number was considered sufficient to achieve statistical power for EFA; while remaining feasible within the study's resource constraints. In this section, the exploratory factor analysis method was used to determine the construct validity, and Cronbach's alpha was used to assess the reliability of the questionnaire.

In current research, EXCEL software (version 2016, developed by Microsoft, USA)) was used to measure CVI and CVR index, and SPSS version 20 (IBM corp., Chicago, IL, USA) software was used to perform exploratory factor analysis to determine the validity of the structure and Cronbach's alpha to assess the reliability of the research tool. The significance level of statistical tests was considered as $p<0.05$. The study received ethical approval from the Islamic Azad University North Tehran Branch Research Council (IR.IAU.TNB.REC.1399.020), Tehran, Iran.

Results

Based on a systematic review of previous studies and research, the results of group discussions, and interviews, five main components in managing diabetic patients were proposed. Leadership, management information, financial resources, human resources, and medical technologies were identified as effective indicators. Based on the final results and integration of expert opinions, the following components of each main indicator were obtained and shown in Figure 1. Content validity of the questionnaire items was done by CVI and CVR methods, and the results for each item were demonstrated in Table 1. According to the Lawshe method and based on 20 senior managers, the minimum amount of CVR accepted was 0.42 or more, and the minimum amount of CVI accepted

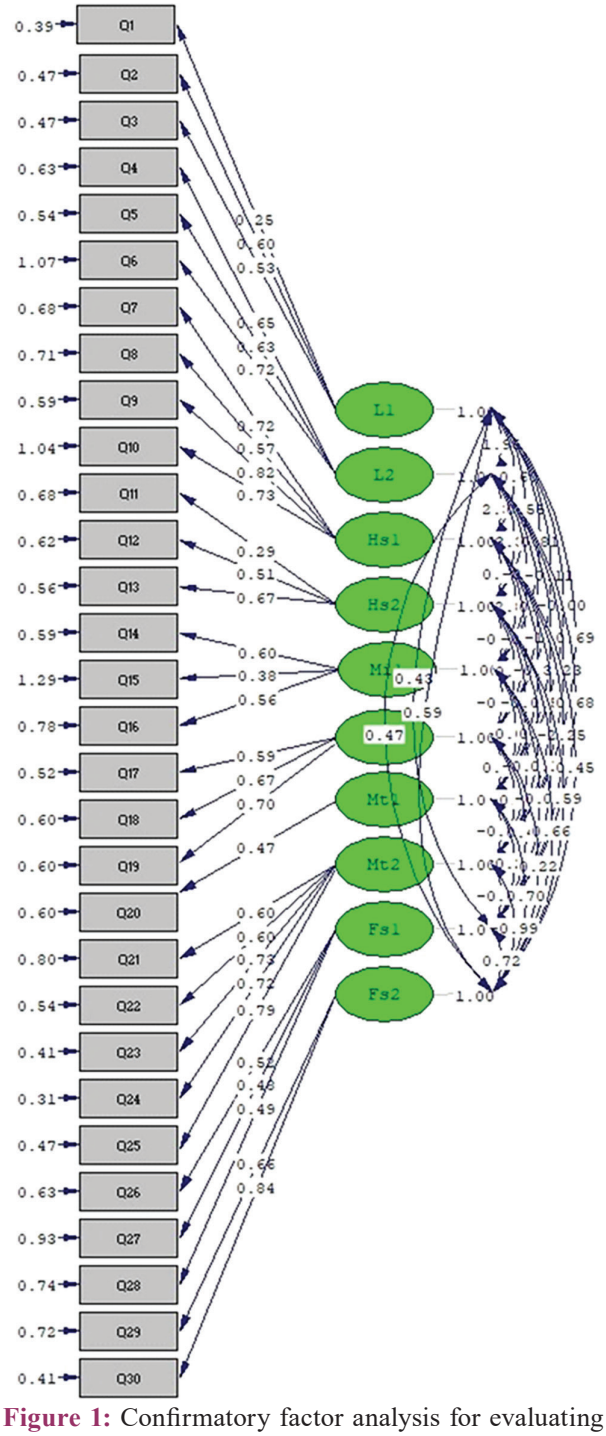

Figure 1: Confirmatory factor analysis for evaluating the questionnaires.

Table 1: Content validity of the questionnaire.

Leadership			
Questions	**CVR**	**CVI**	**Item status**
Establishing the necessary communication at all levels between managers and staff of diabetes centers and patients	0.86	0.81	Accepted
Ensuring a process for managing patients in crisis situations	0.60	0.86	Accepted
Motivating, encouraging and providing appropriate mechanisms for intra-organizational collaboration for better patient management	0.73	0.86	Accepted
Supervising the implementation of programs in the second and third levels of service delivery	0.73	0.93	Accepted
Organizing the health team in coordination with the city health center	0.86	0.86	Accepted
Preparing a monitoring program in accordance with the instructions and minimum standards of care	0.81	0.86	Accepted
Human resources			
Equipping and supplying the required manpower for the second and third levels of providing services in accordance with the standards of the instructions	1	1	Accepted
Cooperation and executive planning of screening and disease detection levels through executive meetings with city health centers	1	1	Accepted
Determining the minimum standard of health care for diabetes at specialized and sub-specialized care levels	0.86	0.86	Accepted
Designating partner program laboratories in cities for screening and care tests	0.73	0.81	Accepted
Following up approvals related to specialized care, preparation and distribution of medicine and care facilities	0.86	0.81	Accepted
Management of information			
Developing and implementing training programs in the field of diabetes management	0.86	0.81	Accepted
Identifying, categorizing and adapting staff knowledge in the field of diabetes management	0.86	0.81	Accepted
Providing information, instructions, supplies and advice for managing diabetes	1	1	Accepted
Planning to organize workshop meetings and trainings for patient management	0.73	0.83	Accepted
Content and educational information suitable for the use of hospitalized patients, their families, the general public and staff of health centers	0.73	0.81	Accepted
Managing the integration of the diabetes program in the family physician team	0.86	0.93	Accepted
Creating an integrated health information system at national, university and county levels	0.86	0.81	Accepted
Medical technology			
Managing and updating patients' electronic records (diabetes program software) and monitoring the sending of information by the university	0.73	0.93	Accepted
Providing adequate training to become familiar with new technologies, especially decision support systems to control blood sugar and regulate insulin dose	0.73	0.93	Accepted
Providing the infrastructure needed by the natives in providing services and updating new services	0.73	0.81	Accepted
Production of prototype and semi-industrial new diagnostic and therapeutic methods as leading technologies in the field of diabetes interventions	0.86	0.81	Accepted
Assessing health technologies in the field of diabetes	1	1	Accepted
Providing a comprehensive database of diabetes clinics and patients	1	1	Accepted
Financing			
Justifying and attracting financial support from government officials for the diabetes management program at the level of medicine and treatment	0.86	0.81	Accepted
Determining and providing the necessary funding for the implementation and integration of the diabetes program at the level of treatment and medicine	0.73	0.93	Accepted
Supporting research in line with set indicators and priorities	0.86	0.93	Accepted
Creating and providing the requirements for specialized services in hospitals and diabetes clinics	0.81	0.93	Accepted

in this questionnaire was 0.79 according to the number of participants. Table 1 illustrated that the amount obtained for the available questions was more. This indicated that the questions in the questionnaire were acceptable. In the next step, Cronbach's alpha and test-retest methods were used to determine the validity of the questionnaire. In the next step, Cronbach's alpha and test-retest methods were used to determine the validity of the questionnaire. An alpha value of 0.898 was obtained for all questionnaire questions (Table 2).

Table 2: Validity and Cronbach's alpha questionnaire test results.

Disease Management Index	Descriptive variables	Reliability	
	Mean±standard deviation	Cronbach's alpha	Coefficient
Leadership	47/28±19.56	0.79	r=0.81 p<0.001
Human resources	26.28±10.02	0.83	r=0.78 p<0.001
Management information	22.00±6.39	0.75	r=0.80 p<0.001
Medical technology	32.28±4.07	0.81	r=0.81 p<0.001
Financing	41.35±8.026	0.80	r=0.86 p<0.001

Table 3: Correlation results between questionnaire variables.

Components of disease management	Leadership		Human resources		Management information		Medical technology		Financing	
	Coefficient	*P* value	Coefficient	*P* value	coefficient	*P* value	Coefficient	*P* value	Coefficient	*P* value
Leadership	-		0.87	0.001	0.92	0.002	0.537	0.002	0.42	0.04
Human resources	-	-	-	-	0.76	0.001	0.61	0.001	0.54	0.001
Management information	-	-	-	-	-	-	0.58	0.001	0.73	0.002
Medical technology	-	-	-	-	-	-	-	-	0.63	0.001

Findings revealed that diabetes management scales had a relatively high internal consistency coefficient. Also, the retest coefficient of all five scales was significant (p<0.05). The structural equation analysis approach was used to test the conceptual model in the next step. Structural equations provided a coherent framework for estimating the strength of relationships between all variables of a theoretical model. The purpose of assessing the fit of the whole model was to determine to what extent the whole model was consistent with the experimental data used. For this analysis, the correlation between the variables was first evaluated. Table 3 exhibits the findings of the correlation between the variables. The KMO index value was 0.885, indicating the sample size's adequacy. The Bartlett Sphericity test (5806.6) was also significant (p<0.001, Degree of freedom=561); which indicates that the correlation matrix was suitable for factor analysis of data.

Discussion

Diabetes is still the most common metabolic disease of the gland and is one of the most common non-communicable diseases in the world (15, 16). It is associated with various complications, such as hyperlipidemia, hypertension, hyperglycemia, hepatic dysfunction, and cardiovascular diseases in the long term (17, 18). Based on the importance of the disease, this study developed and validated a comprehensive model for diabetes management in Iran and identified five key components of leadership, management information, financial resources, human resources, and medical technologies for an effective service delivery. Through a mixed method approach, including systematic literature reviews, using expert interviews, the Delphi method, and exploratory factor analysis, a questionnaire was designed with high content validity (CVI≥0.79, CVR≥0.42) and reliability (Cronbach's alpha=0.898). Structural equation modeling confirmed the model's fit (KMO=0.885, p<0.001) and provided a robust framework for improving diabetes care in Iran's health system.

Our previous study laid the groundwork for this research to qualitatively identify the same five components through semi-structured interviews and focus groups with experts from Shiraz University of Medical Sciences, Shiraz, Iran. That study emphasized responsible leadership, particularly through monitoring and organizing, as a central theme in diabetes management, to highlight the need for stable management, continuous training, and resource allocation. However, it relied solely on qualitative methods and managerial perspectives, limiting its generalizability and empirical validation (19).

The current study advanced this work in several key ways. First, we adopted a mixed-methods approach, integrating qualitative insights with quantitative validation through exploratory factor analysis and structural equation modeling. This allowed us to not only confirm the five components; but also quantified the relationships between them and provided a more robust and evidence-based model. Second, while the earlier study was confined to Shiraz University of Medical Sciences, the present research aimed for broader applicability across Iran's health system, addressing socio-economic challenges and aligning with national health priorities. Third, the development and validation of a reliable questionnaire (Cronbach's alpha=0.898) represented a significant methodological improvement and offered a practical tool for policymakers to assess and monitor diabetes management programs.

These advancements are significant for several reasons. The mixed method approach enhanced the scientific rigor of the model and addressed the qualitative limitations of our prior work and provided a statistically validated framework that can guide policy and practice. The broader scope ensured relevance to diverse regions in Iran, where resource constraints and regional disparities posed ongoing challenges, as noted in our earlier findings (19). Moreover, the validated questionnaire offers a standardized tool in evaluation of the management practices and enabled continuous improvement in service delivery. It is in line with recommendations to analyze expert opinions and managerial cooperation before implementing management programs to ensure an evidence-based decision-making (19).

To achieve service goals for patients and their management, Iran Ministry of Health had essential tasks such as identifying and providing the resources needed to strengthen management, developing incentive mechanisms to improve managerial performance at the provincial and city levels, and using the views of experts. In this relation, local experts were responsible for making decisions and providing the feedback. It was suggested that before implementing any management plan in any situation, the opinions of experts and the cooperation of managers should be analyzed, and essential factors should be identified and plans should be made accordingly (11-14). In the present study, effective indicators were designed based on the views of managers. In supplementary analyses, the weaknesses of managers in current systems were identified, and the proposed model was used to remove obstacles. Based on the results and views of experts at Shiraz University of Medical Sciences and based on experiences gained in this field, preparing a monitoring program, organizing and establishing the necessary communications at all levels of leadership in health system can lead to appropriate services to patients.

Accordingly, the leadership approach was based on team performance. Using leadership in the service delivery model could improve the quality of organizational decisions more effectively. This effect will pave the way for effective executive planning. In our previous study, leadership development was influenced by organizational structure, culture, and strategy and leadership was demonstrated as the interface between various service factors and organizational effectiveness and the health system was based on leadership principles. Competency development, a continuous evaluation as one of the fundamental characteristics of leadership could provide a unified perspective on health challenges, thus creating cooperation within the organization and was known as the functional area of leadership in service delivery (19).

Therefore, the leadership power of senior organizational managers is an essential factor in the success of organizations and disease management. Based on the results of this study, human resources were essential in patient management from two dimensions. The first is the participation and empowerment of active human resources in the provision of services. This index plays an important role in employee recruitment, development and motivation, and finally the retention. In a study, subjects related to employee maintenance and care, were considered as necessary and important measures in high-performance work systems (6).

It was shown that communication and rewards were important factors in empowering human health in the health system and participation and empowerment were directly and positively related to service effectiveness (11). Based on the findings of this study and the views of experts, it seems that the participation and empowerment of human resources in the pattern of services to patients acted as internal customer-oriented strategies in the sense that employees made more efforts to meet the needs of patients. In the study of Shirazi *et al.* in 2017, they achieved the important point that managers and leaders of the health system can increase patient services through participation and empowerment (20).

Therefore, it can be acknowledged that updating the knowledge of employees and improving their capabilities is the main factor to improve the organization's performance. The second dimension of the workforce component was demonstrated to be the functional skills of the personnel. In this area, the human resources of each organization were known as a treasure trove of talents. In our study,

this component was considered one of the critical cases in providing services to diabetic patients. Based on the fitted model, it was determined that it is an efficient and vital component in patient's management. Mohammadi *et al.* reported that functional skills can systematically ensure the optimization of human resources in the health system and these organizations must discover their inner talents to achieve the goals that align with the study (6).

One of the main components from the participants' perspective in our study was financial resources as one of the factors affecting the service delivery model. Also, two sub-components of instrumental and contextual factors were each involved separately in this model. So the identified factors in financing system of the diabetic patient's management were identified as the dimensions of the budgeting system, health-oriented services, and the central tax system. A research has presented dimensions related to the budgeting system and instructions on how to implement the financing system (11). In the study of Eichler *et al.*, one of the poor management cases in providing services to diabetic patients was the lack of financial support, which was recognized as one of the main components of violation of management programs (21).

The lack of financial support and its adverse effects on implementing health policies for chronic diseases was mentioned in the report of Busse *et al.* The report revealed no solution other than the continuous support of the government and insurance companies for absence of financial resources (22). The results of this study and the views of experts showed that management information is a significant factor in the management of diabetic patients. It was shown that inadequate caregiver competence is a major concern in diabetes management (23). Al-Adsani *et al.* discussed the evaluation of the diabetes program and continuing medical education activities for staff and healthcare providers. The findings of this study indicated an educational system based on identifying educational needs and planning and monitoring the coverage and provision of these needs. Inadequate monitoring did not allow physicians to determine the actual state of education, problems diagnosis, making appropriate decisions, and overshadowing of the patient's care and treatment (23).

Therefore, based on the experiences of our study, health system managers need to be empowered by participating in training courses and creating consensus to deal with management barriers. As the analysis of this study showed, the two effective components in managerial information included policy, strategy, and training. According to the experts in this study, the items included in this component were following clinical standards, evaluating the diabetes care program and its quality, identifying and categorizing them, and adapting staff knowledge to provide content and training information appropriate for patient use. Our findings were similar to those of other studies (24, 25). The diversity and variety of therapeutic interventions to prevent and control diabetes and the need to pay attention to issues such as harmful drug interactions and constant care are important in adjusting and balancing treatment options according to their risks and benefits and to manage diabetes in patients. Therefore, it is important for physicians caring of these patients to have sufficient knowledge and skills to manage diabetes (26, 27).

The World Health Organization (WHO) stated that all countries should invest heavily in strengthening and improving staff training strategies and policies as healthcare providers are among the most important drivers of change and maintenance. In other words, since the ultimate goal of the specialized workforce in health systems is to provide high-quality care for service recipients, human resource management must be seen more than providing the number and composition of the workforce; even it is necessary for future training and educational plans. The training of these forces can also make policies and plans to promote the knowledge, skills, and competence of these forces. Therefore, in our study, when the training of physicians and health care providers was not sufficiently sufficient for any reason, the concern of diabetes planners and managers in not achieving the goals of service delivery seems to be appropriate and reasonable (26).

While the study provided a robust model, it has limitations too. The sample was drawn from Fars province, southern Iran which may limit generalizability to other regions of the country with different socio-economic conditions. Additionally, the study focused on health system perspectives and did not directly incorporate patient or community viewpoints. Future research should validate the model in diverse Iranian contexts and include patient feedback to ensure a holistic approach. Supplementary analyses could also explore weaknesses in current management systems to refine the model further and address implementation barriers.

Conclusion

Our validated model offers a practical framework to enhance diabetes care in Iran to align with international standards and addresses local challenges too. The strengthening leadership, investing in human resources, securing

financial support, and leveraging technology are recommended in this relation. Based on the validated model, we recommend strengthening of the leadership structures by implementing team-based leadership programs and continuous competency evaluations to enhance decision-making and service quality at provincial and city levels. Enhancing human resource capacity is also suggested by investing in staff training, empowerment programs, and retention strategies to improve participation and functional skills and ensuring a high-quality patient care. A secure financial support should also be considered by developing sustainable budgeting systems and advocating government and insurance-backed financing to address resource gaps in diabetes management. An improvement in management information systems seems necessary by establishing policies to conduct staff training, adherence to clinical standards, and quality monitoring to address caregiver competency and to improve patient outcomes. Finally, leverage medical technologies are essential to integrate advanced technologies into diabetes care to support innovative and efficient management practices. It seems that future researches should validate the model across diverse regions of the country and to incorporate patient perspectives too.

Acknowledgement

We would like to thank the experts and participants who engaged in the research.

Funding

Nil.

Authors' Contribution

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work. FF: formal analysis; investigation; methodology; writing–original draft. KA: conceptualization; project administration; supervision; validation. SMH: conceptualization; supervision. AM: writing–review and editing. MJ: methodology; validation.

Conflict of Interest

The authors declare no conflict of interest.

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