

## Original Article

## A Stakeholder Perspective on Diabetes Mellitus and Diabetic Retinopathy Care in Iran; A Qualitative Study

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### Abstract

**Objective:** To assess the national health system for management of diabetes mellitus (DM) in Iran, with particular focus on diabetic retinopathy (DR).

**Materials and Methods:** In this qualitative study, the national stakeholders related to DR and DM management system were invited to participate. Two researchers performed interview using a semi-structured questionnaire recommended by the World Health Organization titled "Tool for Assessment of Diabetic Retinopathy and DM Management Systems". The questionnaire contains seven different sections, each consisting of closed and open-ended questions, and a final Likert-type score, ranging from 1 indicating the worst to 4 indicating the best status. Inconsistencies were resolved through a collective decision of the research team, followed by a focus group discussion with stakeholders at the Ministry of Health.

**Results:** Fourteen stakeholders out of 15 total invitees were interviewed (response rate: 93.3%). There were national priorities, defined policies, and running programs (score = 3), but the care system should be strengthened in terms of implementation of clinical guidelines, with specific reference to the availability of regular screenings for DR (score = 2). The network of care providers, health information systems, and promotional programs were insufficient (score = 2). The health workforce and technology for DR and DM were acceptable (scores 4 and 3, respectively); however, there were concerns about the appropriate distribution and utilization of resources and out-of-pocket costs paid by patients.

**Conclusion:** The existence of national policies, programs, a qualified workforce, and modern technology is promising. Nevertheless, other aspects of the health system need to be improved to ensure access to health and eye care for people with DM and achieve universal health coverage.

**Keywords:** Diabetes mellitus, diabetic retinopathy, Iran, management system

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### Introduction

Diabetes mellitus (DM) is one of the leading causes of death in developed and developing countries.<sup>1</sup> On the global scale, the number of people affected with DM is estimated to rise by more than double between 2000 and 2030 (171 million vs. 366 million).<sup>2</sup> The prevalence of DM in the Eastern Mediterranean region (EMR) is considerably high, and some of the countries in this region are listed among those with the highest prevalence of DM worldwide.<sup>3</sup> In Iran, the prevalence of DM among people above 20 years of age is approximately 7.7%, while

it is reported to be around 14% among people over 40 years of age.<sup>4,5</sup> The global prevalence of diabetic retinopathy (DR), the most frequent cause of blindness in patients with DM,<sup>6-10</sup> has been estimated at 34.6% among these patients.<sup>11</sup> Studies in the EMR and Iran reported nearly 24% – 30% of adults with DM have some degree of DR.<sup>12-14</sup>

The World Health Organization (WHO) recommended a framework for assessing DM and DR care systems on a national scale. This evaluation enables health authorities to obtain an estimate of available resources and their accessibility by patients in need and to plan improvements in health services related to DM and DR. In addition, it corresponds to the health system building blocks and allows WHO member states to generate evidence and conduct advocacy to improve eye health and prevent avoidable blindness.<sup>15</sup>

This study was performed to assess the existence, accessibility, and effectiveness of health care services, and the coordinated management of DM and DR in Iran as part of the above-mentioned framework of the WHO. In addition, we have attempted to identify the challenges faced at different levels, by the national health system providing eye care for patients with DM, and inform the government and stakeholders about priorities and challenges in this field.

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## Materials and Methods

This qualitative study assessed the condition of DM and DR management systems at a national level in Iran in 2015.

The Ethics Committee at the Shahid Beheshti University of Medical Sciences, Tehran, Iran, approved the study protocol. Written consent form was obtained from all participants before interview. The study involved identification of national stakeholders and key informants for DR and DM services, interviews with the stakeholders, data analysis and interpretation, sharing of the results with participants, conducting a focus group meeting in the Ministry of Health (MOH) to establish a consensus on the collective results, and ultimately dissemination of the final report to the government and the WHO.

### Assessment components and tools

For data collection, we used a semi-structured questionnaire developed by the WHO with advice from the University of Melbourne and the University of Sydney, with the support of the Development Cooperation of Italy and the Lions Clubs International Foundation, called "Tool for Assessment of Diabetic Retinopathy and DM Management Systems" (WHO-TADDS). The tool consists of seven general section themes, including priorities, policies and programs, service delivery, health workforce, health technology, health information management systems, health promotion, and health financing, in accordance with the WHO framework for analyzing health systems.<sup>16</sup> Each section consists of open and close-ended questions. In addition, at the end of each section, a total Likert-type score is provided, ranging from 1 indicating the worst to 4 indicating the best status, along with guidance, and each participant was asked to independently choose the most appropriate score from 1 to 4 that best represents the status.

### Participants

We started with a list of participants suggested by the TADDS protocol, from formal organizations involved in the management and/or in providing care for DM and DR at a national level. Next, using a snowballing method, we asked all participants on the original list whether they could introduce more relevant stakeholders, and the list was expanded accordingly. The final list included the heads or representatives of the following organizations: Center of Non-Communicable Disease Control (CNCDC) at the MOH, the WHO representative office in Iran, Iranian Diabetes Society, Ministry of Labor and Social Welfare, Iranian Society of Ophthalmology, Iran Endocrine Society, medical services affairs and public health affairs departments of a medical university, a sample of medical recording systems from public and private hospitals, and insurance companies. In total, 15 people were invited to take part in this study.

### Interviews

Fourteen key stakeholders participated in the study; we could not arrange a meeting with one of the invitees (response rate: 93.3%). Two experienced researchers (MK and SR) conducted the interviews. All interviewees contributed adequately and the duration of each interview was about one hour, on the average.

The interviews focused on the participant's field of expertise, and all interviews took place at the work place of each stakeholder. A transcript was created from the recorded conversation and field

notes, and the transcript was sent to the respondent for verification. The interview process lasted from September to November 2015.

### Data Analysis

Two researchers evaluated and integrated the interviews' transcripts independently and entered the information provided in the TADDS forms. Then, the research team reviewed the independent results and any disagreement between the researchers was resolved through team discussion. To identify the final score for each section, the research team determined the most frequent score among all transcripts. The final transcript and chosen scores were shared with all participants. Then, a focus group discussion was organized at the MOH to achieve agreement on inconsistencies. All stakeholders were in agreement with the final TADDS results and endorsed the document.

## Results

In general, the stakeholders chose similar scores but there were inconsistencies between stakeholders in two cases; human resources and availability of guidelines. In relation to "human resources", two participants initially chose the score 4. The score given to this item by the rest of relevant participants was 3. In terms of "availability of guidelines", two participants initially scored it as 1. The score given to this item by the rest of relevant participants was 2. Nevertheless, after focus group meeting, the participants agreed on the given scores, as shown in Table 1. In addition, collective results of 43 questions and subsidiaries of are summarized in the following seven sections.

### Section 1: Priorities, policies and programs

DM is listed as a national health priority by the MOH, and there is a national plan and program for prevention and control of type 2 DM in the country. The national program covers the following items: primary prevention, complications including DR, community awareness, patient education, clinical care, services, and supplies.

The lead organization responsible for conducting the national program is the Office of Endocrine and Metabolic Control and Prevention, affiliated to the CNCDC, and deputy of Medical Services of MOH. In addition, a national program on food and nutrition is available.

The Iranian Diabetes Association, which serves as a non-governmental organization (NGO), conducts several activities: establishment of networks between service providers and patients with DM, arrangement of awareness raising campaigns and educational classes, translation and adaptation of key international messages and learning material, adaptation of the guidelines of the International Diabetes Association (IDF), and publication and distribution of educational material.

There are guideline available for DM management; however, these are mainly applicable to secondary or higher levels of the health care workforce.

There is a guideline for management of DR issued by the MOH that covers prevention of vision loss caused by DR, treatment and follow-up of patients. It has been developed for ophthalmologists and retina specialists who work in the tertiary level of the health care system.

### Section 2: Service delivery

Service delivery starts at the primary health care (PHC) units by

Table 1. Summarized incorporated score

Section	score	Key for selecting the best score
<b>Governance</b>		
Plan/ Program	3	1) DM is not a priority; there is no national plan and no national program. 2) DM is listed as a priority; there is a national plan but no program has been implemented. 3) DM is listed as a priority; a national plan has been formulated and a program is in place but does not cover the whole country. 4) DM is listed as a priority; both a plan and a program are in place and there is national coverage.
Guidelines	2	1) There are no MOH-recommended guidelines. 2) MOH guidelines have been formulated but health professionals are unaware of their availability and thus they are not widely used. 3) MOH guidelines are available and known to the appropriate audience but they are not widely followed. 4) MOH guidelines have been formulated and are commonly followed.
<b>Service delivery</b>		
DM screening	3	1) Services are available in few places and for few people/Services are not available everywhere; they can be found only in large hospitals and are accessible only to those who can pay. 2) Some services are available to part of the population/Services are available in regional hospitals or health centers and are partly paid by the patients. Populations in rural areas cannot reach services easily; transport to the health facilities and the cost of service are the main barriers. 3) Services are available everywhere but do not reach some of the population/Services are available in most rural and urban areas providing care at district, regional, provincial and tertiary levels; however, costs, transport or unawareness are barriers for some patients.
DR screening	2	4) Services are available everywhere for the whole population/Services are available in all locations and costs are paid by insurance schemes, are subsidized by the state, or are available free of charge.
Networks	2	1) There is no known collaboration between separate providers of care for DM and DR. 2) Few centers provide patient-centered care. 3) Some centers provide patient-centered care by means of collaboration between DM and DR services. 4) Most centers provide patient-centered care based on collaboration between DM and DR services.
Workforce	4	1) Largely inadequate. 2) Few training opportunities; consequently, fewer human resources than needed. 3) Training available only in large cities and hospitals. 4) Training for DM and DR is appropriate and of good quality.
Technology	3	1) Modern examination technology not available to the majority of patients. 2) Modern examination technology available only in major hospitals and private clinics. 3) Modern examination technology available in most provincial hospitals and clinics. 4) Modern examination technology available to all patients.
Information	2	1) Prevalence of DM and DR is neither known nor estimated; information about patients is inadequate. 2) Prevalence of DM and DR is known or estimated but patients' records are not utilized. 3) Prevalence of both DM and DR is known or has been estimated; patients' records are used to analyze data at national level. 4) Prevalence of both DM and DR is known or has been estimated; patients' records are collated, analyzed and regularly published.
Promotion	2	1) Little information is provided to the community and little education to patients. 2) Information to the community is provided occasionally and only through national-level media; not all patients receive education. 3) Information is provided at national and provincial level; most patients receive education. 4) Information is provided to the community at all levels; all patients receive education and patients' organizations are actively involved.
DM: diabetes mellitus; DR: diabetic retinopathy; MOH: ministry of health		

PHC workers. They provide assessment and management of risk factors (hypertension, obesity and dyslipidemia), diet programs, and patients and families education and they are responsible for evaluating individuals over 30 years of age and pregnant women, referring those at risk of diabetes to general practitioners (GPs) or family physicians for further assessment. Diagnosis is based on two fasting blood glucose tests. Patients are referred, as required, to the secondary health care system for evaluation of DM complications, and services are provided by integrated DM

clinics that deliver several services as one stop service. Those in need of further consultation are referred to the tertiary health care system. These facilities provide diabetic and eye care services but at present, they can cover less than 25% of patients and are mainly located in large cities. In addition, the referral pathway is usually one-way, and patients are often responsible for arranging their own eye care referral visits. As the referral arrangements are not routinely documented and audited, there is lack of data on the effectiveness and coverage of these services.

**Table 2.** Financial sources of interventions for people with diabetes mellitus

Activity	Government	Social security insurance	Private insurances	NGOs	Patient (out of pocket)
Out-patient costs	20%–25%	25%–30%	0–5%	0–5%	40%–50%
In-patient costs	35%–40%	35%–40%	5%–10%	0–5%	15%–20%
Medications	25%–30%	30%–35%	0–5%	0–5%	20%–25%
Laboratory tests	30%–35%	30%–35%	0–5%	0–5%	20%–25%
Other *	---	---	---	---	100%

\*Self-control by glucometer test strips and pay for non-generic medications. NGOs: non-governmental organizations

**Table 3.** Financial sources of interventions for people with diabetic retinopathy

Activity	Government	Social security insurance	Private insurances	NGOs	Patient (out of pocket)
Prevention (retinal screening)	10%–20%	20%–30%	0–5%	0–5%	50%–60%
Laser photocoagulation	20%–30%	30%–40%	5%–10%	-----	20%–30%
Vitreoretinal surgery	20%–30%	30%–40%	5%–10%	-----	20%–30%
Intravitreal injection	20%–30%	30%–40%	5%–10%	-----	20%–30%

NGOs: non-governmental organizations

There are different types of facilities for diagnosis and treatment of DM, including government-supported clinics, academic hospitals, private clinics, and NGOs. Individuals with DM who are registered by professional organizations such as Iran Diabetes Society, PHC units, DM clinics, and those who receive services at private clinics are referred for retinal examination; therefore, it is mainly a clinic-based recommendation/referral system. Adherence to a regular DR screening program usually depends on patients' health awareness and having access to an affordable retinal examination service.

Ophthalmologists or retina subspecialists, who usually work at regional (provincial) and tertiary levels, perform comprehensive eye and retinal examinations. Almost 60% of individuals have potential access to DR services, but the utilization of these services is around 20% – 30%. Costs, lack of awareness, and lack of facilities and human workforce in some remote districts are the main barriers that prevent access to services.

Section 3: Health workforce

Several health professionals including endocrinologists, ophthalmologists, GPs, general, DM or ophthalmic-trained nurses, and internal medicine specialists provide care to patients with DM. The ratios of providers to the population for vitreoretinal surgeons, ophthalmologists, optometrists, general and family physicians, endocrinologists, general nurses, and internal medicine specialists are 1/380,000, 1/45,000, 1/40,000, 1/1000, 1/300,000, 1.3/1000, and 1/23,500, respectively. Continued and compulsory medical education is also available for health professionals at different levels.

Section 4: Health technology

Biochemical laboratory tests for diagnosis and control of DM, including HbA1c (glycated hemoglobin), lipids, creatinine, urinary proteins, and blood glucose are available. Slit lamp biomicroscopy, direct ophthalmoscopy, and mydriatic and non-mydriatic fundus cameras are used to perform retinal examinations for DR, but retinal imaging technology is mainly available at

regional and tertiary levels. Some DM clinics are also equipped with fundus cameras.

Section 5: Health information management systems

The prevalence of DM is monitored via a national survey conducted by the CNCDC approximately every 3 years. In addition, academic research centers conduct population-based surveys and publish their results in peer-reviewed journals.

At the national level, DR is not monitored routinely; however, research centers conduct sub-national population-based surveys.

Hospital records of patients with DM contain information regarding risk factors, complications, previous eye examinations, treatment and follow-up, but they are not systematically shared and managed at national or sub-national levels.

Section 6: Health promotion

Community education regarding DM is delivered via printed material and the national/regional media. The provided information includes details regarding the symptoms, signs, risk factors, complications, management, and information about care facilities.

Communication methods at the individual level, such as personal record books, information cards, and mHealth using mobile phones are also available, but these are only provided locally by some NGOs or clinics to remind people with DM to have follow-up eye examinations. A systematic and comprehensive recall system is not in place. It is estimated that only less than 30% of people with DM are registered in the health system or NGOs, and receive informative messages regarding DM.

World Sight Day and the World Diabetes Day are celebrated annually in Iran. During these occasions, different events with media coverage are organized to increase public awareness.

Section 7: Health financing

Estimates for financial support to patients with DM and DR are summarized in Tables 2 and 3, respectively.

There are uncertainties in these estimates, because the levels of insurance coverage are different, and coverage depends on



the type of insurance as well as the type of provider. Therefore, identifying actual costs is rather complicated. Almost all Iranians have access to partial or complete medical insurance schemes; nevertheless, stakeholders claim that the level of out-of-pocket costs is still high, especially for certain outpatient critical diagnostic and curative services. In addition, the insurers do not cover non-generic medications that are prescribed for patients. Many outpatient visits including fundus examinations for DR screening are performed at private hospitals and clinics, where insurance coverage is not sufficient.

## Discussion

Several studies have reported different aspects of DM and DR management systems in Iran focusing on a particular province, district, or institution.<sup>4,5,9,10,14,17,18-22</sup> The current study delineates the status of DM and DR management systems at the national level, based on a tool recommended by the WHO.

The participants agreed that DM is one of the main priorities of health system in Iran. Iran, as well as 10 out of 22 countries in the EMR, and 127 out of 156 countries in all WHO regions reported having an operational policy/strategy/action plan for DM.<sup>23-24</sup>

Almost 70% of the countries worldwide and 60% of the countries in the EMR have guidelines for prevention and management of DM.<sup>24</sup> Iran is one of the countries with national DM and DR guidelines approved by the MOH;<sup>25-26</sup> however, most of the health professionals are not informed about these guidelines. It is recommended that the MOH advise professional organizations to encourage their members to implement the guidelines. Furthermore, monitoring and regulating care providers should be considered as priorities for planning the future course of action.

The results indicate that there are integrated DM clinics affiliated to medical universities in Iran. In addition, the Iranian Diabetes Society and other NGOs provide integrated care for registered members. However, the geographical and societal coverage of the mentioned services and the referral links are not sufficient. The importance of integrated care has been shown in previous studies.<sup>27-30</sup> In the study of more than 100 PHC centers in Australia, factors related to health centers, including longer participation in quality improvement programs, and geographically distant location of PHC centers were found to account for 37% of the differences in the level of service delivery, in comparison to patient-related factors like age, co-morbidities, and complications associated with the disease, which only accounted for a further 1% of inutility.<sup>30</sup>

We realized that DR diagnostic services are mainly available in regional eye clinics and hospitals. High cost and transportation are the main barriers to the coverage of screening services in rural areas. One of the possible solutions to overcome these barriers is establishing and implementing a national screening program. The DR screening programs have been successfully implemented in some countries to increase the accessibility and cost-effectiveness for patients with diabetes.<sup>31-33</sup> Therefore, this program may be implemented as an operational program if it is funded and involved mid-level health personnel as tele-medical screening networks for DR.

The stakeholders agree that the number of high-level DM and DR care providers is appropriate. The ratio of endocrinologists to people is 1/300,000 in Iran, which is almost similar to the observed DM specialist physicians in New Zealand, which has

a national mean of 0.35 full-time equivalent (FTE) per 100,000 people. However, the recommended ratio in the UK is 0.8 FTE per 100,000 people.<sup>34</sup> In addition, considering the role of DM nurse specialists, it seems necessary to enroll a number of nurses to become specialized in DM. Recruitment of mid- and primary-level staff who can be involved in screening of DR at the national level should be also enhanced.

The results reveal that the availability of health technology for DM and DR is appropriate. However, modern technologies are mostly concentrated in provincial hospitals and clinics.

Prevalence is an approved indicator in Iran, and information regarding the prevalence of diseases is collected through intermittent surveys. Approximately 10% of the Iranian population have DM.<sup>35</sup> Nevertheless, patients' records are not collected and monitored routinely at a national level. Modifying the health information system in terms of reporting and monitoring DM/DR indicators, and sharing information among different care providers and upstream organizations are the actions recommended.<sup>36</sup> Deep vitrectomy rate per diabetic individual can be probably considered as a proxy for evaluating the effectiveness of DR control.

People who actively seek care are the ones mostly informed of care provider organizations. Meanwhile, the current study estimates that around 30% of the people with DM are registered at NGOs and academic DM centers. Information to the rest of the community is provided occasionally through national and sub-national media; therefore, not all patients may receive proper education regarding DM. The education level of people at the post-secondary level and beyond can have considerable impact on the level of awareness regarding eye examinations.<sup>37</sup> In addition, patient education and support, the changing role of providers, and availability of telemedicine are related to better control of glycemic and vascular risk factors among patients.<sup>38</sup>

Continuation of promotional and educational activities is necessary, especially among disadvantaged groups, including those of low socioeconomic status, people who live in slums and remote areas, and uneducated and disabled people. Therefore, education regarding DM and DR, and using digital and smartphone-based follow-up and reminders are proposed.<sup>39</sup> These programs can be delivered through the current PHC network and the local media.

Despite high medical insurance coverage, the level of out-of-pocket costs is still considerable. This implies that patients are covered, but the providers are not reimbursed. Increasing insurance coverage in government and university-affiliated centers, with referrals that are reimbursed appropriately might be an effective way to diminish patient costs. Reimbursement of the private sector through complementary insurance schemes is also recommended.

A limitation of our study is lack of complete data for health financing. Stakeholders suggest the percentages in Table 2 and 3 subjectively. Further research should be performed to evaluate the accurate data on health financing. In addition, as it is a qualitative study and the given scores are ranking of each section of health system based on stakeholders' opinion, those numbers and their intervals do not have the same value as a numerical/quantitative data and caution is required when comparing the scores with each other and with scores from other similar studies.

In conclusion, the current study evaluated the service provisions available and the barriers to access to DM care, and recommend efficient prevention and management strategies for timely

detection and control of DM and DR at the national level. Hence, this study can assist policy-makers to achieve the objectives of the Global Action Plan for the Eye Health (2014–2019), including prevention of DR as an avoidable cause of visual impairment.

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## Conflict of interest

*None of the authors has any conflict of interest.*

## Novelty statement

*The current study assessed diabetes mellitus (DM) and diabetic retinopathy (DR) management systems in Iran from the perspective of the stakeholders who are engaged in DM and DR care at the national level. The results represents the availability of service provisions and barriers to access to proper care, and recommend efficient prevention and management strategies for timely detection and control of DM and DR at the national level. Hence, this study can assist policy-makers to fulfil the objectives of the Global Action Plan for the Eye Health 2014–2019 including prevention of DR, which is an avoidable cause of visual impairment.*

## Authors' contribution

*MK contributed to study design, analyzing the results, and critical reviewing of the manuscript; Mas.K and SR contributed to data collection and analysis; SPM contributed to developing the methodology of the study, and critical reviewing of the manuscript; SS contributed to literature review and analysis, and drafting the manuscript; S.SH, HA and PK advised on data analysis and contributed to critical reviewing of the manuscript; SFM and AM contributed to data control and verification, and critical reviewing of the manuscript.*

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