



Developing a Clinical Diabetes Guideline in Diabetes Research Network in Iran

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Abstract

Development of evidence-based clinical guidelines to raising standards of medical care in diabetes is a core element of coping with the global diabetes epidemic. The purpose of this study was to develop a systematic clinical diabetes guideline from the latest scientific evidences and also to localize its recommendations according to regional and cultural needs of our society. Searches were conducted using NICE, SIGN, WDPCP, IDF, JDC, ADA, AACE, ICSI, CDA, AMDA, IDC, NyDoH guidelines which were examined and criticized and scored using Agree method. Guidelines which got higher score in some important areas of Agree scale including: rigor of development, clarity and comprehensiveness of the recommendations and applicability, especially in the climatic conditions of our country were selected. The existing recommendations were extracted by committee members and supporting evidences of each recommendation were determined based on the sources listed in the clinical guideline. Recommendations grading were classified from grade A to D based on the quality of their supporting evidences (BEL1-5). This guideline covered all areas related to diabetes including screening and diagnosis, lifestyle modification and patient education, management, complications and hypoglycemia. Regarding capacities of this guideline and lack of comprehensive and updated guidelines in our country and region, it is suggested that designing a pilot study to implement this Learner-centered guideline and finding its weaknesses can lead to patient care improvement and also propel us towards our goal to design a comprehensive guideline in compliance with regional and national needs in Middle East.

Keywords: Diabetes, Clinical guidelines, Diabetes network, Iran

Introduction

Noncommunicable diseases have become one of the major reasons of deaths and increasing burden of disease index all over the world (1). Diabetes is one of these diseases that has affected approximately 6% of the world's population and it is predicted that its global prevalence will reach from 285 million people in 2011 to 439 million people by 2015 (2). About 3% of deaths in the world are

attributed to diabetes, more than 80% of which occur in developing countries with low and middle income. In Iran, about 2 % of deaths are due to diabetes (3).

The prevalence of type 2 diabetes (T2D) ranges from 1.2 to 14.6 % in Asia, 4.6 to 40% in the Middle East and 1.3 to 14.5% in Iran (4). In Iran, the overall prevalence of diabetes in the popu-

lation between 25-64 years has been reported 7.7%, which is estimated higher, about 8.6% in urban population and 5.7% in rural population, however over half of these patients are not diagnosed (5,6).

Global cost of diabetes was estimated at nearly 232 billion dollars in 2007 and this figure will reach 302 billion dollars by 2025. The average annual cost of treatment for each diabetic patient is two-thirds more than non-diabetic person; much of this cost is related to complications of diabetes (7, 8). In Iran, direct costs, indirect costs, and total annual costs of diabetic patients have been reported respectively 590.676 ± 65.985 , 153.506 ± 10.370 and 744.183 ± 69.595 million dollars. Direct costs, indirect costs, and total costs related to diabetes complications have been estimated respectively 207.001, 56.295 and 263.357 million dollars (9).

High rate of morbidity, mortality and costs of diabetes is mainly related to long-term complications of diabetes (10-12).

T2D is a major reason of cardiovascular disease, blindness, chronic kidney failure, amputation and high rates of hospitalization (13). Moreover, it is associated with the increased risk of cancer, serious psychological diseases, cognitive decline, chronic liver disease, accelerated arthritis and other debilitating or fatal diseases (14,15). The medical annual costs of diabetic patients with chronic complications, is two times more than the costs of diabetic patients without complications. In other words, most of the economic costs of T2D are attributed to the treatment of its micro and macrovascular complications. As a result, the control and appropriate treatment of diabetes and prevention of its complications plays an important role in reducing the economic costs of diabetes and improving the quality of patient life (16).

Despite the high prevalence of diabetes in Iran, current researches examining quality of care and control of T2D in our country show that the care status was not in satisfactory level (17) and only 6.4% of the patients underwent HgA1c test at least once during the last year (18). This figure is so far from the results reported (72%) from the study of Diabetes Care Quality Improvement in America (19). Furthermore, according to the

results of this study, only 20.5% of patients had a foot examination in their medical care visits, which was almost half the rate reported in the study of Diabetes Care Quality Improvement in America, while diabetic foot examination is a simple intervention that does not require special equipment and only is related to the awareness level of diabetic patients and physician adherence to standards of clinical guidelines (17,18).

In our country, it seems that the lack of clear standards in the field of prevention and control of risk factors of diabetes, diagnosis of it and its complications, timely referral of patients, control methods, care and management and patient education has led to inconsistency in care services and failure in control of diabetes, which show the need for an identical and specific plan for different target groups (20).

Due to the growing clinical knowledge, the role of evidence-based clinical guidelines in standardization of medical care is highlighted more. Using these guidelines has led to care quality level improvement and patient safety (21-24). Studies show that in controlling diabetes, clinical guidelines can help the physician in choosing the appropriate treatment option from the existing treatments and medications and preventing questionable therapeutic measures and can also lead to reduced costs (25-28). On the other hand, the production and distribution of updated clinical guidelines cause the health system make sure that the medical team is familiar with the latest evidence-based treatment methods in order to provide the best service to all diabetic patients (29-30). A study conducted in 2013 which is a comparative study about the national-regional diabetes guidelines in non-western countries (countries other than North America, Western Europe and Australia). This study covered 75 countries in four categories including: -Middle East and North Africa -countries in East and South Asia-Central and South American and -other countries. The results showed that the very limited existing national and regional guidelines in Middle East countries, in fact, were made to source the same recommendations only from one of the international diabetes guidelines including the

World Health Organization, or the American Diabetes Association, or the International Diabetes Federation or European association for the study of diabetes, which could not fully meet the local populations and region needs (31). Studies also show that the last update of these regional guidelines was in 2008(32). Furthermore, in most cases, existing regional guidelines have not covered all areas related to diabetes such as screening and diagnosis, management, complications and prevention, or have not considered specific groups of patients such as children or women with gestational diabetes (33).

In this regard, the Diabetes Research Network in collaboration with the Ministry of Health and the Institute of Endocrinology and Metabolism of Tehran University of Medical Science, formed a committee of endocrinologist, general practitioner, trained nurse, pharmacist, dietitian and diabetes educator. The purpose of the committee was to: develop a systematic clinical guideline from the latest and most reliable scientific evidences which determine clinical approaches in dealing with diabetic patient in a classified manner with regard to priorities, effectiveness, cost-effectiveness in the prevention, control and treatment of diabetes and its complications, for the target group including general practitioner. Moreover, this committee in line with the standardization and localization of recommendations tried to combine the latest scientific evidences with the condition and needs of the region, cultural requirements of society and the countries' Health Care System facilities. Regarding capacities of this guideline and lack of comprehensive and updated guidelines in the Middle East (34), it is trying to use this guideline as a pilot in countries of our region after implementation, and fixing its shortcomings in the country.

Methods

This project was aimed to develop user-friendly and evidence-based clinical guideline which could provide the best clinical recommendations in diabetes management. A number of reference books and clinical guidelines available in the field of diabetes including NICE, SIGN, WDPCP,

IDF, JDC, ADA, AACE, ICSI, CDA, AMDA, IDC, NyDoH guidelines were examined (Table 1), and were criticized and scored using Agree method (Appraisal of Guidelines for Research and Evaluation) (Table 2). Agree instrument for the quality assessment of clinical practice guidelines consists of 23 items grouped into six domains: 1) Scope and purpose 2) Stakeholders involvement 3) rigor of development 4) Clarity and Presentation 5) Applicability and 6) Editorial independence. The committee members scored each guideline using this scale and then compared their individual scores for each item and came to consensus on discrepant scores. For example, scope and purpose domain was included 3 items as follows:

- The overall objectives of the guideline are specifically described.
- The health questions covered by the guideline are specifically described.
- The population to whom the guideline is meant to apply is specifically described.

Each item was rated on a seven-point Likert scale that measured the extent to which an item was fulfilled: 1-strongly disagree to 7-strongly agree. Scores were standardized within domains by dividing the difference between the consensus score and the minimum possible score by the difference between the maximum and minimum possible scores.

Guidelines which got higher score in some important areas of Agree scale including: rigor of development, clarity and comprehensiveness of the recommendations and finally, applicability of the guideline, especially in the climatic conditions of our country were selected. The existing recommendations were extracted by committee members and supporting evidences of each recommendation were determined based on the sources listed in the clinical guideline. Recommendations grading were classified from grade A to D based on the quality of their supporting evidences [Best Evidence Level (BEL) 1-5] (Table 3,4).

If there was more than one recommendation for a clinical question or recommendations were not consistent with each other and if the cause of inconsistency in recommendations were due to the

difference in the level of evidences, those recommendations that had a lower level of supporting evidences were removed. Furthermore, if the level of evidences relating to some of the recommendations was low, higher level of evidences including systematic review studies or clinical randomized

trials (interventional), the standard cross-sectional studies (diagnostic), and cohort studies were considered. Evidence level for each recommendation is mentioned at the end of that recommendation.

Table 1: Source of guidelines

Source of guideline	Internet address
National Institute for Clinical Excellence (NICE)	http://www.nice.org.uk/page.aspx?o=ourguidance
Scottish Intercollegiate Guidelines Network (SIGN)	http://www.sign.ac.uk/guideline/index.html
International Diabetic federation (IDF)	http://www.idf.org
Canadian Diabetes Association (CDA)	http://www.diabetes.ca
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org
American Diabetes Association (ADA)	http://www.diabetes.org
American Association of Clinical Endocrinologists (AACE)	http://www.aace.com
American Medical Directors Association (AMDA)	http://www.amda.com
International Diabetes Center (IDC)	www.parknicollet.com
Joslin Diabetes Center (JDC)	www.joslin.org
New York state Department of Health (NyDoH)	https://www.health.ny.gov
Wisconsin Diabetes Prevention and Control Program (WDPCP)	www.dhs.wisconsin.gov/diabetes
Andreoli and Carpenter's Cecil essential of medicine, 8 th .ed, 2010	
Harrison's principles of internal medicine SANUNDERS, ELSEVIER, 18 th .ed, 2012	
SholmoMelmed, Kenneth S. Polonsky MD, P. Reed MD Larsen and Henry M. Kronenberg MD, Williams Textbook of Endocrinology, SANUNDERS, ELSEVIER, 12 th .ed, 2012	

Table 2: Appraisal of guidelines for research and evaluation

Reviewed clinical guidelines	Different areas of AGREE					
	Scope and purpose	Stakeholders involvement	Rigor of development	Clarity and comprehensiveness of recommendation	Applicability	Editorial independence
*AACE	83	39	48	83	29	33
*ADA	56	50	38	67	58	33
AMDA	44	50	17	94	38	0
*CDA	78	78	58	94	42	33
*ICSI	72	44	60	78	83	42
IDC	22	22	6	72	46	0
*IDF	83	44	63	89	38	42
JDC	61	50	10	72	38	0
NyDoH	17	6	0	78	8	0
*NICE	6	28	56	72	54	8
*SIGN	94	94	81	83	83	25
WDPCP	56	50	17	83	46	8
Mean**;	56	46	38	81	47	19
range	6-94	6-94	6-81	67-94	8-83	0-42

All values are in percent. /*Guidelines NICE, SIGN ,IDF, ADA,AACE, ICSI, CDA were selected as sources of study.

/**Domain scores were averaged across guidelines

Table 3: Evidence level

Numerical measures of recommendation evidences	
Semantic description on the basis of research methodology	Numerical description on the basis of evidences level
Randomized clinical trials or their meta-analysis	1
Meta-analysis of case-control or non-randomized prospective studies, non-randomized clinical trials, case-controls and prospective cohort studies	2
Cross-sectional studies, epidemiology, case series and case report	3
Consensus on the basis of citing guidelines	4
Consensus on the basis of country's experts opinion	5

1 strong evidences, 2 moderate evidences, 3weak evidences, 4and 5 there is no evidence.

Table 4: Criteria for grading recommendations

Criteria for grading recommendations	
Level 1 evidences show profit is over the loss	A
At least one study from level 1 and most studies of level 2 show profit is over the loss	B
There are no conclusive evidences of whether profit is greater than the loss or equal to it and recommendation is on the basis of experts opinion	C
There are no conclusive evidences of whether profit is greater than the loss	D

Owing to the limited number of local and valid evidences, the decisions were made based on consensus in order to localize guidelines and referral cases. Since general practitioners are the user of this guideline, the recommendations have listed with respect to the referral levels (first level care providers include general practitioners, and higher levels include specialists or subspecialists). Moreover, indications of patient referral were determined from the first level (general practitioner) to higher level (specialists or subspecialists). Due to the problems that diabetes can cause to patients, referral time of patients was adapted to the existing local conditions based on referral advice segmentation from NICE guideline and was considered as follows:

- Immediately (at the time of the visit)RI
- Urgently (within 24 hours)RU
- Soon (within 2 weeks) RS
- Routinely (normally) RR

To illustrate this point, it is noteworthy that for example, RI means primary care physicians are

asked to refer patients for a specialist consultation at the time of the visit and this point is marked by RI on that recommendation (Likewise also in other cases).RS means after completing patient's record by general practitioners in that occasion, they should be referred to a specialist for consultation soon (within 2 weeks). And again this point is determined by RS on that recommendation.

In order to facilitate access to contents, each section of the guideline has been presented with a specific color which has been identified in the table of content and between sectors.

All the articles that have been cited as a reference in the passage are citing studies of practical guidelines for determining the levels of recommendations' evidences and are listed in order to facilitate access for enthusiasts of these resources. The evidences levels of recommendations which are contained in the charts have been also inserted into the guideline passage.

Results

The guideline is divided into fifteen separate sections which can be read consecutively or referred to the sections separately as the need arises: -diabetes diagnosis guide -diabetes prevention guide -diabetes care guide –diabetes nutrition guide -diabetes patient education guide -diabetes management guide (oral agent and insulin therapy) -dyslipidemia control guide -hypertension control guide –hypoglycemia treatment guide –prevention and management of diabetes acute complications guide (DKA, HHS) - prevention and management of diabetes chronic

complications guide (micro and macro vascular complications) -diagnosis and management of gestational diabetes mellitus guide –Ramadan fasting guide-antiplatelet in diabetes and, - vaccination and diabetes.

The following table (Table 5) is planning flowchart for organizing interventions required in each visit which also shows time frequency of these actions and interventions in adult patients with diabetes. Moreover, there is a rather similar table for children and adolescents with diabetes in our guideline as well.

Table 5: A summary of interventions should be performed in each visit, and time frequency of these actions in adult patients with diabetes

	First visit	Annually	Other cases	Each visit
Components of the initial visit				
Medical history and complete physical examination	X			
Medical history and brief physical examination				X
Weight and Height	X			X
Blood pressure	X			X
Eye exam	X ¹	X*		
Dental examination	X		X(2times per year)	
Foot examination	X			X
Electrocardiogram	X	X* (age above 50 years)		
Laboratory evaluation				
CBC, HbA1c	X		X(4times per year)	
Fasting lipid profile	X	X ²		
Test for microalbumin/ creatinine in urine	X ¹	X		
TSH	X	X		
Liver blood tests	X	X		
Prevention/ Intervention				
Anti-platelet	X ³			
ACE/ARB drugs	X ⁴			X*
Smoking cession	X*			X*
Other diseases that may affect blood glucose levels	X	X		
Nutrition				
Nutritional status& Eating patterns	X	X		X (if needed)
Patient education				
Diabetes self-management education	X	X*		
Vaccination				
Vaccination	If needed			
Treatment				
Current medications	X			X
Blood glucose monitoring				
Self-monitoring of blood glucose	X*			X
Symptoms of hypoglycemia	X			X

* Refer patient to a specialist consultation if needed.¹Screening should be done 3-5 years after diabetes diagnosis (in type1 diabetes). ²Should be checked once a year if it is under control. ³Refer to guide if required.⁴If blood pressure is high, or if there is nephropathy.

Discussion

In current guideline, it has been trying to cover all areas related to diabetes including screening and diagnosis, lifestyle modification and patient education, appropriate management pathways (line therapy), starting insulin therapy, diagnosis and management of acute and chronic complications of diabetes, hypoglycemia and all the things that general practitioners need to know in order to control a diabetic patient. On the other hand, in this guideline, different groups of diabetic patients including women with gestational diabetes, children, adolescents and elderly have been considered (31-34). Another distinguishing feature of this guideline is using learner-centered approach. Under this approach, the recommendations of the guideline are set based on the training needs of the target group namely general practitioners' society. Despite all the strengths mentioned above, due to the lack of designing and implementing internal research studies in our country, formulating the recommendations of this guideline has been done based on overseas researches. It seems that the implementation of this guideline can greatly assist in determining priorities and research requirements in order to design studies, so that this guideline will be developed and updated according to local studies in the future (35). In other words, guidelines can be set based on local studies and conditions of our region. In addition to what mentioned above, the guideline evaluation is also an undeniable and important part in updating process in order to eliminate deficiencies.

Therefore, designing a pilot study to implement this Learner-centered guideline and finding its weaknesses can lead to patient care improvement and elimination of ineffective interventions, as well as propel us towards our goal to design a comprehensive guideline in compliance with regional and national needs (36). Although it is not possible to run the guideline without spending money, the use of comprehensive and effective executive strategies for the implementation of guideline, could result in appropriate disease

management while significantly reducing the costs (37).

Hereupon, it is suggested that with proper planning to eliminate existing uncertainties in developed guideline and through holding inclusive educational workshops on the state level for all general practitioners partners at all universities in Iran, the way of using the guidelines, recognizing priorities as well as clinical and administrative instructions contained in it, the way of using the recommendations based on levels and grade of evidence and necessity and ways of patient's referrals to higher levels should be taught in order to achieve optimal results in diabetic patients care.

The main limitation of this article is due to the fact that it is not evaluated by health professionals and policy makers in terms of feasibility, practicality, efficiency, effectiveness, being time-saving and cost-effective because the project has not yet been implemented in a national scale. The next stride will be carrying out these evaluations after the project is implemented nationally.

Conclusion

This guideline tried to combine the latest scientific evidences with the condition and needs of the region, cultural requirements of society and the countries' Health Care System facilities.

Ethical considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/ or falsification, double publication and/ or submission, redundancy, etc) have been completely observed by the authors.

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