Quality assessment of clinical practice guidelines for management of type 2 diabetes mellitus Assessment of type 2 diabetes mellitus guidelines

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ABSTRACT

Aims: Diabetes mellitus is one of the most significant global health emergencies of the 21st century. Every year, an increasing number of people succumb to the condition and therefore suffer life-changing complications. So management of this disease has an important role to prevent complications. In this study, our objective is to assess the quality of guidelines related to the significant public health problem diabetes that have been developed by international and national organizations using the AGREE II tool.
Methods: This observational study assesses the quality of clinical practice guidelines used in the management of diabetes with AGREE II tool. Statistical analysis was performed using the SPSS 20 program package.
Results: The overall quality score of the guidelines ranges between 3 and 6.25. While NICE's guidelines scored the highest, the guidelines of the National Diabetes Foundation scored the lowest.
Conclusion: More comprehensive studies are needed for assessing the quality of guidelines in every subject.

1. Introduction

Diabetes mellitus is one of the most significant global health emergencies of the 21st century. Every year, an increasing number of people succumb to the condition and therefore suffer life-changing complications. At the end of 2015, there were 415 million adult diabetes patients, and this number is expected to reach 642 million by 2040 [1]. Diabetes accounts for 12% of the global health expenditure.

According to the International Diabetes Federation (IDF) Diabetes Atlas, the prevalence of diabetes in the Turkish adult population (20–79 years of age) was 12.5% in 2015. The standardized diabetes prevalence based on the global population distribution was calculated as 12.8% [1]. The results of the

Turkish Diabetes Prevalence Study-II (TURDEP II) show that the prevalence of diabetes reaches 13.7% among the Turkish adult population. The prevalence of DM in Turkey, its co-morbidities and accompanying diseases, and its adverse effects on life quality and financial costs make DM a significant public health problem [2].

Clinical practice guidelines are statements of recommendations to optimize patient care derived from research based evidence and the assessment of the benefits and harms of alternative care options [3]. As substantial differences have appeared in the quality of clinical practice guidelines [4,5] many assessment scales were developed to distinguish high-quality guidelines from low-quality guidelines [6]. The Institute for Quality and Efficiency in Health Care and the Institute for Research in Operative Medicine published a systematic review with the aim to present the developments and changes in guideline assessment scales and to compare the tools [7]. In this review, 5164 references; 446 of which were full-text articles were accessed through multiple databases. As a result of the implementation of the exclusion and inclusion criteria, it was identified that 40 different Guideline Assessment Scales were developed between 1995 and 2011. The result of the analysis performed emphasized that if a comprehensive guideline assessment is to be conducted, the most suitable choice is either using the AGREE II or DELBI scale. The Appraisal of Guidelines for Research & Evaluation (AGREE) II instrument is a tool that assesses the quality of a guideline [8].

In this study, our objective is to assess the quality of guidelines related to the significant public health problem diabetes that have been developed by international and national organizations using the AGREE II tool.

2. Methods

2.1. Ethics

The ethical approval for the study was granted by the Ethical Board of the Ankara Numune Training and Research Hospital (625/2015).

2.2. Design

This observational study assesses the quality of clinical practice guidelines used in the management of diabetes.

2.3. Selection of guidelines

The diabetes mellitus guidelines of SIGN (Scottish Intercollegiate Guidelines Network) and NICE (National Institute for Health and Clinical Excellence) which are pioneering organizations in guideline development, the IDF which is one of the prominent organizations in the diagnosis and treatment of diabetes, the TEMD (Turkish Endocrinology and Metabolism Association) which is a non-governmental organization with substantial experience on guidelines in Turkey, the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE), the Malaysian Ministry of Health, and the Turkish Diabetes Foundation were used (see Table 1). Four appraisers, who were trained in the assessment of guideline quality and had not participated in the development of these guidelines assessed the selected guidelines separately.

2.4. The AGREE II instrument

The AGREE II contains 23 key items classified within six domains and two global rating items ("Overall Assessment"). Each domain assesses unique aspects of guideline quality.

Domain 1. Scope and Purpose covers the guideline's general purpose, its specific health questions, and its target population (items 1–3).

Domain 2. Stakeholder Involvement relates to the extent of the involvement of appropriate stakeholders in the development of the guideline and presents the opinions of its intended users (items 4–6).

Domain 3. Rigor of Development addresses the process of evidence gathering and synthesis and the methods used to draw up and update the recommendations (items 7–14).

Domain 4. Clarity of Presentation concerns the language, structure, and format of the guideline (items 15–17).

Domain 5. Applicability covers possible barriers and facilitators to implementation, uptake improvement strategies, and resource implications of utilizing the guideline (items 18–21).

Domain 6. Editorial Independence addresses the generation of recommendations that are not biased in favor of the competing interests (items 22–23).

Overall assessment includes rating the overall quality of the guideline and evaluates whether the guideline would be recommended for use in practice [8].

Every one of the six AGREE II domains obtains a quality score, these scores are independent and therefore should not be combined into a single score.

Calculating Domain Scores

The domain score is obtained by adding up the scores of the individual items and then scaling the sum as a percentage of the maximum possible score for that domain.

$$\text{Maximum possible score} = 7(\text{strongly agree}) \times 3(\text{items}) \times 4(\text{appraisers}) = 84$$

$$\text{Minimum possible score} = 1(\text{strongly disagree}) \times 3(\text{items}) \times 4(\text{appraisers}) = 12$$

The scaled domain score will be:

$$(\text{Obtained score} - \text{Minimum possible score}) / (\text{Maximum possible score} - \text{Minimum possible score})$$

2.5. Statistical analysis

The total AGREE scores are presented for each guideline by each reviewer and the score per domain. The data yielded

Table 1 – Guidelines included in the study.

Guidelines	Professional society	Purpose	Access link for the guideline
SIGN	Scottish Intercollegiate Guidelines Network	This guideline was developed by the Scottish Intercollegiate Guidelines Network and provides recommendations for healthcare professionals on management of diabetes	http://www.sign.ac.uk/pdf/sign116.pdf
NICE	National Institute of Health and Care Excellence	This guideline was developed by the National Institute of Health and Care Excellence and provides recommendations about care and management of type 2 diabetes. It is for healthcare professionals, commissioners and providers of diabetes services, adults with type 2 diabetes, and their families and carers	https://www.nice.org.uk/guidance/ng28/resources/type-2-diabetes-in-adults-management-1837338615493
TEMA	Turkish Endocrinology and Metabolism Association	This guideline was developed by the Turkish Endocrinology and Metabolism Association and provides recommendations for healthcare professionals. The guideline developed in 2005 and updated in 2015	http://www.turkendokrin.org/files/DIYABET_web.pdf
IDF	International Diabetes Federation	This guideline was developed by the International Diabetes Federation in 2005, updated in 2011 and provides recommendations for extensive evidence on the optimal management of diabetes, offering the opportunity of improving the immediate and long-term quality of life of those with diabetes	http://www.idf.org/guideline-type-2-diabetes
UDK	Turkish Diabetes Foundation	This guideline was developed by Turkish Diabetes Foundation in 2011. The seventh updated edition was published in 2017	https://www.turkdiab.org/admin/PICS/webfiles/Diyabet_tani_ve_tedavi__kitabi.pdf
AACE	American Association of Clinical Endocrinologists and American College of Endocrinology	Clinical practice guidelines (CPGs) for developing a diabetes mellitus (DM) comprehensive care plan are an update of the 2011 American Association of Clinical Endocrinologists (AACE) Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan	https://www.aace.com/files/dm-guidelines-ccp.pdf
MOH	Malaysian Ministry of Health	The fifth edition (2015) CPG supersedes the previous Clinical Practice Guidelines on Management of Type 2 Diabetes Mellitus (4th ed.) 2009	file:///C:/Users/hilal.aksoy/Downloads/CPG%20Management%20of%20Type%202%20Diabetes%20Mellitus%20(5th%20Edition)%20Special%20AFES%20Congress%20Edition.pdf

by the assessment of the guidelines after applying the AGREE II tool. Statistical analysis was performed using the SPSS 20 program package.

3. Results

3.1. Quality assessments of the clinical practice guidelines

3.1.1. Scope-purpose
The score obtained in this domain reflects the extent of the definition of the guideline's goals, general purpose, the health questions or problems it covers and the population (patient, the public, etc.) intended to use it. In this domain, the average score of the guidelines we evaluated was 69.57%.

3.1.2. Stakeholder involvement
This domain examines whether the guideline includes individuals from all relevant professional groups, whether the opinions and preferences of the target population were investigated, and whether the intended users of the guideline are specified. In this domain, the average score of the guidelines we assessed was 56.70%.

3.1.3. Rigor of development
This domain is the guideline assessment domain that examines the use of systematic methods when researching evidence, the knowledge provided about the strengths and limitations of the evidence, the association between the recommendations and the evidence, the appraisal of the guideline by external appraisers, and the updating processes. In

Table 2 – Scores achieved by guidelines in each AGREE II domain.

	Scope and purpose (%)	Stakeholder involvement (%)	Rigour of development (%)	Clarity of presentation (%)	Applicability (%)	Editorial independence (%)
SIGN	83.3	83.3	80.20	**93.0**	65.6	50.0
NICE	**91.6**	**87.5**	**87.5**	88.8	**81.3**	**88.3**
TEMD	62.5	43.0	38.5	68.0	42.7	87.5
IDF	58.0	54.0	43.0	68.0	53.0	75.0
UDK	47.2	36.1	22.4	54.1	15.6	8.3
AACE	58.3	33.3	51.5	52.7	22.9	41.8
MOH	86.1	59.7	65.1	72.2	31.5	39.5

Table 3 – Overall assessment of the reviewers regarding recommendation of guidelines and average overall quality score.

Guidelines	Reviewer 1	Reviewer 2	Reviewer 3	Reviewer 4	Average overall quality score
SIGN	Yes	Yes	Yes with modification	Yes	4.75
NICE	Yes	Yes	yes	Yes	6.25
TEMD	Yes with modification	Yes with modification	Yes with modification	Yes	4.5
IDF	No	Yes with modification	Yes	Yes with modification	5.25
UDK	Yes with modification	Yes with modification	Yes with modification	No	3
AACE	No	Yes with modification	Yes with modification	Yes	3.75
MOH	Yes	Yes	Yes with modification	Yes with modification	5

this domain, the average score of the guidelines we assessed was identified as 55.48%.

3.1.4. Clarity of presentation

This domain examines the clarity of the recommendations and also whether the guideline offers different options for the condition or health problem. In this domain, the average score of the guidelines we assessed was identified as 70.97%. The average score of this domain is the highest among all domains.

3.1.5. Applicability

This domain examines the definition of facilitators and barriers to guideline application, the consideration of the potential outcomes of the implementation of the recommendations regarding resources and the monitoring and auditing criteria of the guideline. In this domain, the average score of the guidelines we assessed was 44.65%.

3.1.6. Editorial independence

This is the domain which examines the documentation and influence of the financing organization's opinions on the guideline and the conflicts of interest among the members of the development group. In this domain, the average score of the guidelines we assessed is 55.77%.

3.2. Findings on domain scores

The total AGREE II scores of each guideline in each domain are shown in Table 2. While the NICE guideline obtained the highest scope and purpose, stakeholder involvement, rigor of development, applicability and editorial independence scores, the SIGN guideline obtained the highest clarity of presentation score. It was noted that the UDK obtained the

lowest scope and purpose, rigor of development, applicability and editorial independence scores, and the AACE guideline obtained the lowest stakeholder involvement and clarity of presentation domain scores.

3.3. Findings on overall assessment and recommendations

The overall guideline assessment scores and comments of each appraiser are presented in Table 3. The overall quality score of the guidelines ranges between 3 and 6.25. While NICE's guidelines scored the highest, the guidelines of the National Diabetes Foundation scored the lowest.

4. Discussion

Assessing the quality of clinical guidelines has become popular in recent years. Also it is a new issue in Turkey. There are many studies that compared the quality and recommendations from different diabetes guidelines [9–14].

But this is the first study that compares diabetes guidelines in our country. The guidelines assessed in the study are very qualified. For example The Scottish Intercollegiate Guidelines Network (SIGN), NICE (National Institute for Health and Clinical Excellence), IDF (International Diabetes Federation), American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) are one of the leading organizations in the diagnosis and treatment of diabetes. The guidelines chosen from Turkey are also the publications of highly experienced civil society organizations.

But there are some limitations of the study. The appraisers did not receive a specific training course about the AGREE II

instrument, they only use the user guide to overcome shortcomings. Another limitation is the overall assessment in AGREE II is not clear. It is defined as CPG was recommended, recommended with modifications, or not recommended [15]. There is no guidance in the user guide how to make the assessment. Agree II needs to be revised for explaining how to make the overall assessment of the guideline.

To assess the methodological quality of a guideline, the guideline development process should be well documented [16]. But there is no sufficient information about development process in most of the guidelines.

In our study the overall quality score of the guidelines varies between 3 and 6.25. The scores were relatively low. It can be due to not using the AGREE II instrument in developing or updating the guideline.

In our study the lowest score was taken from "applicability "(44.67%). A meta-review evaluated 42 studies that 626 guidelines on different topics from 1980 to 2007. In this study the guidelines were assessed with the AGREE instrument and it was found that most guidelines achieved low scores for applicability compared to all other domains [17].

Not well-defining of implementation strategies for the organisational problems and cost implications during the guidelines development process can be related with the low scores of applicability [18].

The score from "Rigour of development" was low (55.47%) in the study. Low AGREE II scores in the "Rigour of development" domain means that the guidelines have not got available evidences [19].

In a systematic review conducted by Holmer and his friends, it was reported similar findings [13].

Another low score is the "Editorial Independence" (55.77%) which assess the effects of funding body and it can be assessed through the embedding of declaration statement by the appraisers [20].

Insufficient evidence can cause variations between management of the diabetes mellitus.

The low score of Stakeholder Involvement (56.70%) was also expected. Because during the guideline development process the scientific committee study alone. There is inadequate consideration of patients' views during guideline development and the description of the target users is also unclear. Inclusion of patients' views in a guideline development has important effects for the implementation of clinical guidelines [21].

Diabetes mellitus is one of the most significant disease seen in clinics. During clinical practice, using guideline is very important to follow current evidences and practices. Different guidelines were developed for management of the diseases. So it is difficult to decide the most appropriate one. Quality assessment of guidelines can be helpful through this issue. More comprehensive studies are needed for assessing the quality of guidelines in every subject.

Declaration of Competing Interest

The authors declare that there is no conflict of interest.

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