

Quality Evaluation of Chinese Diabetes Management Guidelines based on AGREE II and AGREE-China

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Abstract: The purpose of this study is to verify the applicability of the Chinese clinical practice guideline evaluation tool (AGREE-China) by evaluating the diabetes mellitus (DM) guidelines, and to compare its characteristics with the clinical guideline research and evaluation tool II (AGREE II), in order to provide reference for clinical practice and subsequent revision of guidelines.

Keywords: Guide quality evaluation; AGREE II; AGREE-China; Diabetes.

1. Introduction

Diabetes mellitus (DM) is a group of metabolic diseases characterized by hyperglycemia caused by insulin secretion deficiency or its biological dysfunction. Epidemiological survey shows that by 2020, the prevalence of diabetes in adults in China is 12.8 %, the total number of diabetic patients is about 129.8 million, the treatment rate is 49.0 %, and the control rate is 49.4 %. A considerable proportion of patients are older and accompanied by multiple risk factors [1]. Drug therapy is the preferred method to control blood glucose, reduce complications and improve prognosis in diabetic patients. However, existing studies have shown that there are irrational drug use in clinical practice, affecting the treatment and health of patients [2].

Clinical practice guidelines (CPGs) are a bridge to bridge the gap between the latest research evidence and clinical practice [3]. High-quality clinical practice guidelines can effectively guide clinicians' medical behavior, but the quality of guidelines developed by different medical organizations is uneven [4]. Low-quality guidelines not only hinder the selection and use of clinical staff, but also may cause potential or direct damage to patients. Therefore, the quality evaluation of guidelines is particularly important for clinical practice.

At present, the Appraisal of Guidelines for Research and Evaluation (AGREE II) is the 'gold standard' of internationally recognized evaluation guidelines. Although it is widely used in the world and has been widely recognized, the application of AGREE II evaluation guidelines still faces the following difficulties [5]: some domestic guidelines cannot be achieved, the score difference is large, the importance of the items is not reflected, and the evaluation takes a long time. In order to meet the needs of the current evaluation of Chinese clinical guidelines, a more practical evaluation system of Chinese clinical practice guidelines (AGREE-China, 2017 edition) has been established, which is more in line with the actual situation in China. However, the practical application of this evaluation tool is less, and its application and universality to domestic guidelines need to be tested in practice. Therefore, this study intends to use AGREE II and AGREE-China to evaluate the quality of the selected guidelines, analyze the current situation of the development of clinical practice guidelines for diabetes in China, and provide reference for the standardized development and

formulation of clinical guidelines for diabetes in China. At the same time, understand the characteristics and practicality of the two evaluation tools, and explore the applicability of the two evaluation tools to domestic clinical guidelines.

2. Materials and Methods

2.1. Retrieval Strategy

The guidelines for diabetes management published in domestic journals included in China National Knowledge Infrastructure (CNKI), Wanfang Database, and VIP Chinese Science and Technology Journal Database (VIP) were searched. At the same time, the guidelines for diabetes management published in monographs or other forms were obtained by searching Medlive Guideline Network, MedSci, the official website of the Chinese Medical Association, the official website of the Chinese Medical doctor Association, and the official website of the Chinese Traditional Medicine Association. The search period is from 2017 to August 2022. The search terms included 'diabetes' and 'guidelines'.

2.2. Literature Screening and Data Extraction

Two researchers independently screened the literature, extracted the data, and cross-checked. In case of disagreement, it was decided by the third person. In the literature screening, duplicates were removed first, and irrelevant literature was excluded by reading the title and abstract, and the full text was further read to determine whether it was finally included. Information was extracted according to the designed table, including the general situation of the guidelines: name, year of publication, maker, number of pages, number of references, evidence-based evidence and the formation of recommendations.

2.3. Inclusion Criteria

(1) Diabetes as the main diagnosis. (2) Conform to guide definition. (3) The language is limited to Chinese.

2.4. Excluded Criteria

(1) Guide interpretation, abstracts, notes, points, statements, comments, abstracts or translations. (2) Publishers of non-domestic government agencies and related professional associations. (3) There are updated old version guides. (4) Interventions do not include drug interventions, but only

guidelines for prevention, screening, diagnosis, and technology.

2.5. Guide quality evaluation

In this study, AGREE II and AGREE-China were used to evaluate the overall quality of the included diabetes guidelines. The specific methods are as follows:

The AGREE II evaluation system consists of six areas (scope and purpose, participants, rigor of development, clarity, applicability, editorial independence) [6], each of which addresses a specific issue of quality evaluation of guidelines; a total of 23 main items and 2 overall evaluation items were involved, and the items were graded according to 7 points (1-represent very disagree, 7-represent very agree). According to the AGREE II scoring method: each domain score = (actual score-minimum possible score) / (maximum possible score-minimum possible score) × 100 %, maximum possible score = maximum score (7 points) × number of domain entries × number of evaluators, minimum possible score = minimum score (1 point) × number of domain entries × number of evaluators. Finally, taking into account each evaluation standard, an accurate comprehensive judgment was made on the quality of the guidelines. The recommendation level was divided into three levels: the standardized total score of the six fields was ≥ 60%, which was A level (recommendation); the number of fields with standardized total score ≥ 30% is greater than or equal to 3, but the average score of some fields is less than 60%, which is grade B (recommended after modification). If the number of fields with standardized total score < 30% is greater than or equal to 3, it is C level (not recommended).

The AGREE-China evaluation criteria include five areas [5]: scientific / rigor, effectiveness / safety, economy, availability / feasibility, and conflict of interest. A total of 15 items and guidelines were recommended, focusing on the field of 'scientific / rigorous' quality evaluation (8 items). According to the Likert rating scale, each item was scored 0-5 points, and the weight coefficient was 0.5-2 according to the importance of the item. Scoring rate of each field = (the sum of evaluator's score and / the sum of highest possible score) × 100 %; the highest possible score = the highest score (5 points) × weight coefficient of each item × number of evaluators × number of field items; the total score rate is the sum of the weighted scores of each field. The overall recommendation level of the guide was divided into three levels: strong recommendation level A (total score rate ≥ 50%), weak recommendation level B (20% ≤ total score rate < 50%) and non-recommendation level C (total score rate < 20%).

2.6. Statistical Analysis

IBM SPSS Statistics 22 software was used to calculate the intraclass correlation coefficient (ICC) to test the consistency of the evaluation results of the two evaluators. ICC < 0.4 means poor consistency, 0.4 ≤ ICC ≤ 0.75 means medium consistency, ICC > 0.75 means good consistency [7]. Microsoft Excel was used for data collation and descriptive analysis of the characteristics of the included literature.

3. Result

3.1. Literature Retrieval Results

A total of 1245 articles were obtained in the initial search. After layer-by-layer screening, 14 guidelines were finally

included. The literature screening process and results are shown in Figure 1.

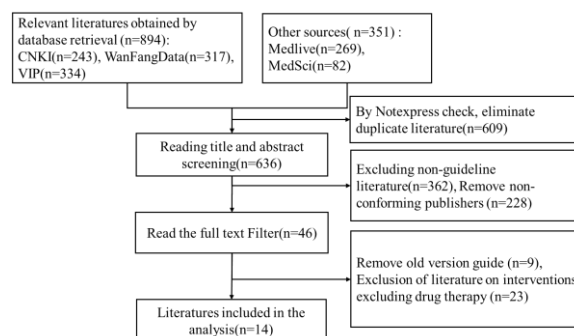


Figure 1. Literature Screening Process and Results

The publication time of the included guidelines is mainly concentrated in 2021 and 2022, of which 11 guidelines are based on evidence-based evidence and 3 guidelines are based on expert consensus. The basic characteristics of the included guidelines are shown in Table 1.

Table 1. Basic characteristics of inclusion guidelines

No.	Guide Name	Published time	Published magazine	Publishing agencies	Formation of evidence and recommendations	No. References	No. pages
1	Chinese guidelines for the prevention and treatment of diabetic kidney disease(2021) [8]	2021	Chinese Journal of Diabetes	Diabetes Society of Chinese Medical Association	GRADE	207	23
2	Guidelines for critical drug use in type 2 diabetes mellitus [9]	2021	Chinese Journal of General Practitioners	Chinese Medical Association	/	6	16
3	Guidelines for primary diagnosis and treatment of type 2 diabetes(2019) [10]	2019	Chinese Journal of General Practitioners	Chinese Medical Association	/	18	9
4	National primary diabetes prevention and management guidelines(2022) [11]	2022	Chinese Journal of Internal Medicine	Diabetes Society of Chinese Medical Association	Ⅱ	19	14
5	Chinese Guidelines for the Prevention and Treatment of Type 2 Diabetes(2020) [12]	2021	International Journal of Endocrine Metabolism	Diabetes Society of Chinese Medical Association	self-defined rd	700	67
6	Clinical guidelines for the prevention and treatment of type 2 diabetes in the elderly in China(2022) [13]	2022	Chinese Journal of Internal Medicine	Endocrine Metabolism Branch of Chinese Geriatrics Society	ESC+self-defined rd	368	39
7	Chinese Guidelines for the Diagnosis and Treatment of Elderly Diabetes(2021) [14]	2021	Chinese Journal of Diabetes	National Geriatrics Center Chinese Medical Association Geriatrics Branch China Geriatric Health Association	ESC	227	33
8	Chinese guidelines for clinical diagnosis and treatment of diabetic kidney disease [15]	2021	Chinese Journal of Kidney Disease	Society of Nephrology, Chinese Medical Association	GRADE	472	50
9	Guidelines for diagnosis and treatment of diabetes combined with hyperlipidemia [16]	2021	World Traditional Chinese Medicine	Professional Committee of Endocrine and Metabolic Diseases, Chinese Medical Doctor Association Branch of Integrative Medicine	OCEBM+GRADE+expert consensus	97	9
10	Diagnosis and Treatment Guidelines for Diabetic Nephropathy [17]	2022	Journal of Traditional Chinese Medicine	Professional Committee of Endocrine and Metabolic Diseases, Chinese Medical Doctor Association Branch of Integrative Medicine	OCEBM	83	8
11	Guidelines for diagnosis and treatment of diabetic retinopathy [18]	2021	World Traditional Chinese Medicine	Professional Committee of Endocrine and Metabolic Diseases, Chinese Medical Doctor Association Branch of Integrative Medicine	GRADE+OCEBM	92	8
12	Guidelines for diagnosis and treatment of diabetic peripheral neuropathy [19]	2021	Journal of Traditional Chinese Medicine	Professional Committee of Endocrine and Metabolic Diseases, Chinese Medical Doctor Association Branch of Integrative Medicine	OCEBM	102	12
13	Clinical diagnosis and treatment guidelines of traditional Chinese medicine for diabetic peripheral neuropathy [20]	2017	Journal of Traditional Chinese Medicine	Diabetes Branch of Chinese Medical Association	Jumping Lira+Grade	74	12
14	Guidelines for diagnosis and treatment of type 2 diabetes mellitus [21]	2020	Journal of Traditional Chinese Medicine	Chinese Medical Association Physician Branch of Integrative Medicine	Jumping Lira+Grade	102	8

3.2. Consistency

The intra-group correlation coefficients of the evaluation results of AGREE II and AGREE-China between the two researchers were all above 0.75, with good consistency.

3.3. Rating Results for AGREE II

The evaluation results of the 14 guidelines AGREE II are shown in Table 2, and the evaluation results of the 14 guidelines are all grade B (recommended after modification). (1) Among them, two guidelines [10,11] did not clearly describe the overall purpose of the guidelines, and seven guidelines had low scores due to insufficient clarity in describing health issues and lack of accuracy in describing the population to which the guidelines apply. (2) Participants: On the whole, the included guidelines have a low score due to the lack of attention to the views and wishes of the target population. Among them, the clinical guidelines in the field of traditional Chinese medicine [17-23] have a higher degree of rationality among the development team members, and the guidelines users are more clearly defined, so the score is higher. (3) Conscientiousness: In this field, most of the guidelines do not systematically retrieve evidence; at the same time, there is a lack of clear description of the criteria for selecting evidence, the strength and limitations of evidence, the method of forming recommendations, the relevance of recommendations and supporting evidence, and

the update steps of the guidelines. (4) Clarity: The scores in this field were not significantly different. The scores of the two guidelines were lower than the average score, and the scores of the six TCM-related guidelines [17-23] were lower. (5) Application: In this field, many guidelines have low scores due to the lack of description of the promotion and hindrance factors in the application, the description of the application recommendation suggestions, and the potential related resource suggestions. Among them, the six guidelines in the field of traditional Chinese medicine [17,22] are particularly obvious. (6) Independence: The field scored the highest, with 11 guidelines scoring the highest field score of 83.33 %, and 3 guidelines [14,18,21] scoring the lowest field score of 33.33 % due to lack of conflict of interest records.

Table 2. Rating results for AGREE II

Guideline	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6	>60	<30	Grade
1	72.22%	44.44%	29.17%	80.56%	27.08%	83.33%	3	2	B
2	30.56%	19.44%	11.46%	36.11%	6.25%	83.33%	1	3	B
3	47.22%	19.44%	11.46%	58.33%	31.25%	83.33%	1	2	B
4	75.00%	44.44%	13.54%	63.89%	27.08%	83.33%	3	2	B
5	86.11%	2.78%	29.17%	83.33%	47.92%	83.33%	3	3	B
6	77.78%	19.44%	31.25%	75.00%	33.33%	33.33%	2	1	B
7	86.11%	25.00%	50.00%	75.00%	22.92%	83.33%	3	2	B
8	72.22%	47.22%	32.29%	80.56%	18.75%	83.33%	3	1	B
9	80.56%	61.11%	63.54%	47.22%	10.42%	83.33%	4	1	B
10	30.56%	47.22%	22.92%	63.89%	10.42%	33.33%	1	2	B
11	27.78%	47.22%	44.79%	63.89%	14.58%	83.33%	2	2	B
12	36.11%	52.78%	21.88%	58.33%	10.42%	83.33%	1	2	B
13	38.89%	52.78%	48.96%	47.22%	10.42%	33.33%	0	1	B
14	58.33%	41.67%	28.13%	50.00%	6.25%	83.33%	1	2	B
Average Score	58.53%	37.50%	31.32%	63.10%	19.79%	72.62%	/	/	/

3.4. Rating Results for AGREE-China

Table 3. Rating results for AGREE-China

Guideline	Area 1	Area 2	Area 3	Area 4	Area 5	Total Score	Grade
1	36.36%	75.00%	60.00%	93.33%	100.00%	57.00%	B
2	8.18%	45.00%	0.00%	60.00%	100.00%	27.50%	B
3	15.45%	45.00%	0.00%	50.00%	100.00%	30.00%	B
4	18.18%	45.00%	60.00%	66.67%	100.00%	37.00%	B
5	40.91%	80.00%	60.00%	100.00%	100.00%	61.50%	A
6	48.18%	45.00%	0.00%	100.00%	60.00%	53.50%	B
7	44.55%	80.00%	0.00%	100.00%	100.00%	60.50%	A
8	30.91%	65.00%	0.00%	93.33%	100.00%	49.00%	B
9	79.09%	5.00%	0.00%	100.00%	100.00%	64.50%	A
10	43.64%	80.00%	0.00%	93.33%	60.00%	57.00%	B
11	45.45%	60.00%	0.00%	93.33%	100.00%	56.00%	B
12	52.73%	60.00%	0.00%	93.33%	100.00%	60.00%	A
13	73.64%	0.00%	0.00%	80.00%	60.00%	55.50%	B
14	44.55%	15.00%	0.00%	73.33%	100.00%	43.50%	B
Average Score	41.56%	50.00%	12.86%	85.48%	91.43%	50.89%	/

The evaluation results of the 14 guidelines included in the AGREE-China evaluation are shown in table 3. The overall impression of 4 guidelines is strong recommendation, 10 guidelines are weak recommendation, and the quality of the guidelines is differentiated. (1) Scientificity/rigor: This field is the most important part, but the scoring rate is relatively low. In this field, most of the guidelines do not clearly explain the method from evidence to recommendation, do not explicitly mention external expert review before publication, and do not have a clear guideline update plan, so the score is low. (2) Effectiveness/safety: The score in this field is relatively low. Among them, the efficacy of the six guidelines [10-12,17,21,22] recommended regimens has no clear efficacy description and specific data, and the score is low; at the same time, three of the guidelines [17,21,22] had very low scores due to less mention of adverse reactions and no specific data. (3) Economy: The score in this field is the lowest and more extreme. There are only two scores, the highest score and the lowest score, with an average score of 12.86 %. Only

three guidelines [9,12,13] mention health economics, but there is no specific data, so the highest score in this field is 60.00 %. The remaining guidelines have no health economics evaluation, so the score is 0.00%. (4) Availability/feasibility: This field has a high score, and only one guide [11] has a minimum score of 50.00% due to the lack of domestic research evidence. (5) Conflict of interest: The highest score was in this field, with an average score of 91.43% and a maximum score of 100 %. Three guidelines [14,18,21] lacked 'conflict of interest statements', so the score was 60 %.

4. Discuss

4.1. Comparison of AGREE II and AGREE-China guidelines Evaluation Tools

AGREE II and AGREE-China have certain similarities as guidelines evaluation tools. Comparing the entries of the two, it is found that although the number of entries in AGREE-China is reduced by 8 compared with AGREE II, the evaluation content is highly consistent. Multiple entries are obtained by merging or adapting. The main difference is to delete the entry 'Guidelines provide monitoring and / or inspection standards', and add 'Guidelines retrieve and evaluate evidence for Chinese research' [22]. Both have their own advantages and disadvantages in use, mainly reflected in the practicality of domestic guidelines, clear recommendations, applicability and so on.

(1) Practicality: AGREE II evaluation tool has been widely used, but the explanation of the scoring criteria has not yet given the corresponding standard for each item score, which has higher requirements for evaluators, and the subjectivity of the evaluation results has a greater impact [23]. At the same time, the evaluation time is also longer, and the average time for evaluating a guide is 23 minutes. AGREE-China clarifies the scoring criteria at the time of formulation, and gives a quantitative score explanation for each item. Therefore, the consistency of the evaluation results is high, and the evaluation is more convenient and practical. It takes an average of 10 minutes to evaluate a guide. However, the scoring of AGREE-China also has some shortcomings. Some items only have three scoring levels (items 11,14,15), which widens the difference in domain scores between guidelines. (2) Clear recommendation: the highest score of AGREE II entry is 7 points, no weight coefficient, and no recommendation grade is given after evaluation. The highest score of AGREE-China items is 5 points, and each item gives a weight coefficient according to its importance. Therefore, the total score rate can be calculated according to the weight coefficient to give the final recommendation (strong, weak, no). (3) Applicability: It is undeniable that the AGREE II evaluation tool is widely recognized in the world, with high authority and universality. At present, it has been confirmed by many practical experiences in many countries and fields, but it has invalid entries, and some entries in China are still not able to do so [24]. The applicability is not high when applied to the evaluation of Chinese guidelines. AGREE-China was developed by the expert group to meet the needs of the evaluation of clinical guidelines in China at this stage [25]. It emphasizes the evaluation of Chinese evidence and has been adopted by associations such as the Chinese Medical Association to evaluate the quality of guidelines [26]. In contrast, it is more applicable to the evaluation of guidelines in China. The final recommendations of the two evaluation tools confirm that AGREE-China is more applicable, that is,

the recommendation level of the guide has a certain degree of differentiation. However, there is little practical experience in AGREE-China. At present, there are only four published literatures, and its universality needs to be further verified [25,27,28,29].

Table 4. Main content of AGREE II and AGREE-China

Assessment Tool	Territory	No. Entries	Partial Contents Note
AGREE II	Scope and purpose	3	The overall purpose of the guidelines, specific health issues and target populations
	Participants	3	The rationality of the composition of the guide development team members can represent the views of the target users.
	Rigoroussness	8	Evidence collection and synthesis process, statement and update recommendation method
	Clearness	3	The language, structure and manifestation of the guide
	Application	4	The favorable conditions and potential unfavorable factors in the implementation of the guidelines and their improvement strategies, as well as the related resource issues involved in the application of the guidelines.
	Independence	2	The generation of recommendations recommended by the Guide is not affected and influenced by the competition of relevant interests.
AGREE-China	Scientificity / rigor	8	The rationality of the composition of the team members, the background, purpose and application objects of the guidelines, the process and results of the collection of evidence and the formation of recommendations, whether it is reviewed by external experts, and whether there is an update plan.
	Effectiveness / safety	2	In the process of guideline development, whether there are alternatives for the recommended scheme and the data of effect size are listed, whether the adverse reactions and safety are considered in the recommendation and the relevant data are listed.
	Economy	1	Whether to consider health economics issues
	Availability / Feasibility	3	The clarity of the expression of the guidelines, the clarity of the recommendations, the availability of the guidelines, the extensibility of the guidelines, and whether there is evidence to retrieve and evaluate Chinese studies.
	Conflict of interest	1	Whether there is a conflict of interest statement in the process of guideline formulation

4.2. The Methodological Quality of Diabetes Guidelines Needs to be Further Improved

According to the field scores of the two evaluation tools, the methodological quality of the diabetes guidelines needs to be further improved. The average score rate of AGREE II and AGREE-China evaluation tools is higher than 60 % in only two areas, namely, conflict of interest (editorial independence), usability / feasibility of the guidelines (clarity of expression). The domestic diabetes guidelines need to be further standardized:

(1) Clear description of the evidence to the formation of recommendations: At present, most of the domestic guidelines are summarized by expert opinions, which are highly subjective and ignore the scientific proof of the formation of recommendations. (2) Pre-publication review by external experts: Most of the current guidelines ignores this explanation. Before the publication of the guidelines, there should be an expert group other than the formulation group to review and explain the relevance, authority and composition of the experts. (3) Clearly state the update plan of the guidelines: Relevant studies have pointed out that the guidelines cannot guarantee the effectiveness of the guidelines after 3.6 years, so the effectiveness of the guidelines should be reassessed every 3 years [30]. In this study, only three guidelines explain the update of the guidelines but there is no specific plan. Some guidelines are updated versions, but lack updated plan introduction. (4) Increasing health economics evaluation: economy as a secondary indicator reflecting the level of clinical drug treatment is often ignored. In recent years, with the emphasis on drug economics in drug selection such as medical insurance directory access, it is necessary to consider health economics evaluation in the formulation of guidelines [31]. (5) Attach importance to the development of the primary version of the guidelines: China's grassroots doctors, some of the transformation of general practitioners need to apply the scientific system to develop clinical guidelines suitable for grassroots to solve specific problems and standardize clinical services [32]. The quality of the domestic grassroots guidelines included in the study is generally low, which is consistent with the results of other studies. More attention should be paid to the formulation of grassroots guidelines [33].

4.3. Limitations of the Study

(1) The study only included domestic literature published

in Chinese journals retrieved by computer, and may omit relevant research published in other channels. (2) The study only evaluated the quality of the 14 guidelines included. In order to further verify the advantages and disadvantages of the two guidelines evaluation tools, more researchers need to evaluate more guidelines issued by different types of diseases and then evaluate their evaluation effectiveness more comprehensively. (3) The evaluation of diabetes guidelines is limited to the quality of methodology, and high methodological quality is not equal to high clinical practicability. (4) The included guidelines may not fully present the whole content for many reasons, resulting in the quality of some guidelines being underestimated.

In summary, the methodological quality of domestic diabetes management guidelines needs to be further improved, especially the grassroots version of the guidelines. AGREE II has high authority and universality, but AGREE-China has higher convenience, stronger applicability to domestic guidelines, can give final recommendations, and is more suitable as a quality evaluation tool for Chinese guidelines. However, due to its less practical experience, its universality needs to be tested by practice. Scientific and objective evaluation of existing clinical practice guidelines can provide reference for the development / revision of new clinical practice guidelines in China. Therefore, guideline evaluation tools can be comprehensively applied to complete high-level guideline development.

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