Diabetes, Metabolic Syndrome and Obesity

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REVIEW

Quality of Clinical Practice Guidelines for Diabetic Foot Management: A Systematic Review Using the AGREE II and AGREE-REX Instruments

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Objective: To evaluate the methodological quality and the excellence of recommendations in clinical practice guidelines (CPGs) for diabetic foot ulcer (DFU) management, and to synthesize their clinical treatment recommendations.

Methods: A systematic search of PubMed, EMBASE, Web of Science, and guideline databases was conducted to identify DFU guidelines published between January 1, 2015, and May 1, 2025. The quality of included guidelines was appraised by reviewers using the AGREE II and AGREE-REX instruments. Domain scores are presented as median (interquartile range). Recommendations for DFU clinical treatment were synthesized, and the supporting evidence was graded using the OCEBM system.

Results: Fifteen CPGs were included (6high-quality, 9moderate-quality). The highest AGREE II domain score was for Editorial Independence (100.00% [97.22–100.00%]), followed by Scope and Purpose (96.30% [88.89–100.00%]), Clarity of Presentation (96.30% [92.59–100.00%]), Rigor of Development (75.69% [41.67–93.06%]), and Stakeholder Involvement (74.07% [62.96–-83.33%]). The lowest scoring domain was Applicability (52.78% [36.11–59.72%]). The lowest AGREE-REX score was for Values and Preferences (47.22% [43.06–52.78%]), while Clinical Applicability (79.63% [66.67–81.48%]) and Implementability (77.78% [72.22–80.56%]) scored respectably. Seventeen key DFU treatment recommendations were synthesized, mostly Grade B recommendations supported by moderate-quality evidence.

Conclusion: Existing DFU guidelines are developed using systematic methods but show limitations in applicability, stakeholder involvement, and rigor of development. The quality of recommendations is inconsistent, with notably low scores in the domain of values and preferences. Enhancing these aspects and improving the underlying evidence quality are crucial strategies for future guideline development and implementation.

Keywords: diabetic foot ulcer, clinical practice guidelines, AGREE II, AGREE-REX, systematic review

Introduction

Diabetic foot ulcer (DFU) refers to a foot ulcer occurring in individuals with a current or previous diagnosis of diabetes, typically accompanied by lower-limb peripheral neuropathy and/or peripheral arterial disease.[1] As one of the most common and severe chronic complications of diabetes, DFU is a leading global cause of lower-extremity amputation, disability, and mortality among patients.[2] Data released by the International Diabetes Federation (IDF) in 2025 indicated that approximately 589 million adults were living with diabetes worldwide, a number projected to rise to 853 million by 2050.[3] Against this backdrop, the challenge of DFU prevention and management is formidable. It is estimated that over

https://doi.org/10.2147/DMSO.S586150
Received: 10 December 2025
Accepted: 23 February 2026
Published: 23 March 2026

one million amputations are performed annually worldwide due to diabetic foot complications, equating to one amputation every 20 seconds,[4] severely impairing patients' quality of life.

Furthermore, DFU management imposes a substantial economic burden on global healthcare systems. In 2017, the cost of DFU treatment reached a staggering $727 billion in the United States and $110 billion in China.[5] Despite these enormous expenditures, the associated risks have not been significantly mitigated. Patients with DFU face a markedly high mortality risk, which reportedly surpasses that of many malignancies.[6] Given its high incidence, disability rate, mortality rate, recurrence rate, and cost, identifying effective strategies for DFU prevention and treatment to improve limb salvage rates and reduce mortality has become a pressing clinical and public health priority.[5–7] Numerous clinical practice guidelines (CPGs) suggest that effective, standardized, and multidisciplinary management can reduce its incidence and mortality.

Clinical practice guidelines (CPGs) are systematically developed statements designed to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. As one of the most relevant documents for integrating scientific evidence into health decision-making,[8] their core function is to inform clinical policy, support healthcare professionals and patients in making appropriate choices, and contribute to the improvement of healthcare systems by providing evidence-based recommendations.[9,10] High-quality guidelines can enhance patient care quality, reduce unwarranted practice variation, narrow healthcare disparities, improve patient adherence, and influence public policy.[9] However, achieving these goals is contingent upon the guidelines' focus on clinical outcomes, rigorous evidence-based development, and proper implementation.[11] Although guideline quality has improved in recent years, CPGs are not immune to biases, limitations, and conflicts of interest,[12] leading to considerable variability in their quality and posing challenges for healthcare practitioners in selecting appropriate guidelines for use. To address these challenges, a rigorous methodological appraisal of included CPGs is imperative.

The concurrent application of the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument and the Appraisal of Guidelines for Research and Evaluation-Recommendation Excellence (AGREE-REX) tool[13] enables the identification of guidelines developed through a scientifically robust process and the selection of the most excellent and practical recommendations. This combined approach facilitates a more comprehensive and multi-dimensional assessment of CPGs and promotes their clinical application. Utilizing these widely accepted tools to evaluate the strengths and weaknesses of CPGs is therefore of paramount importance for clinicians in selecting high-quality guidelines.

The objective of this study is to critically appraise the methodological quality of existing DFU CPGs and the excellence of their recommendations using the AGREE II and AGREE-REX instruments. This appraisal aims to determine the quality ranking of these guidelines and elucidate the clinical value, feasibility, and limitations of their recommendations. Ultimately, this work seeks to identify the most trustworthy evidence-based guidance for DFU clinical practice and foster the transition of guidelines from being "methodologically rigorous" to being "clinically applicable." Furthermore, this study synthesizes the principal recommendations concerning DFU treatment from these guidelines and regrades the supporting evidence and strength of recommendations using the Oxford Centre for Evidence-Based Medicine (OCEBM) levels of evidence.

Methods

Study Design

The study protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (registration number CRD420251229627), and was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[14] The AGREE II and AGREE-REX instruments were used to comprehensively assess and analyze the quality and recommendations of clinical practice guidelines (CPGs) for the management of diabetic foot ulcers (DFU).[13]

Literature Search Strategy and Guidelines' Selection

A systematic literature search was performed in the electronic databases of PubMed, EMBASE, and Web of Science. To account for updates in medical research, the search was limited to the period from January 1, 2015, to May 1, 2025. The

search terms included: "diabete*" OR "diabetic" for diabetes, "foot" OR "foot ulcer" OR "skin ulcer" OR "ulcer" OR "foot gangrene" for foot conditions, and "guideline*" OR "statement*" OR "recommendation*" OR "consensus" for guidelines. The search was restricted to the title field. Initially, Boolean logical operators "OR" was used to combine subheadings within each conceptual group (diabetes, foot, guidelines). Subsequently, the search query was formulated as: ("diabete*" OR "diabetic") AND ("foot" OR "foot ulcer" OR "skin ulcer" OR "ulcer" OR "foot gangrene") AND ("guideline*" OR "statement*" OR "recommendation*" OR "consensus"). To ensure comprehensive retrieval, the reference lists of included studies were also reviewed, and a manual search was conducted to identify any potentially relevant DFU guidelines that might have been missed.

The inclusion criteria were as follows: (1) the most recent version of DFU guidelines; (2) CPGs indexed in English-language databases; (3) full-text articles; (4) provision of recommendations and a clear description of the development methodology. The exclusion criteria were as follows: (1) duplicate guideline publications; (2) non-latest versions; (3) incomplete existing versions or those containing only informational summaries; (4) studies focusing on a single intervention for DFU treatment; (5) documents that were reviews, interpretations, or summaries of DFU guidelines.

Data Extraction and Guidelines' Assessment

All retrieved articles were uploaded to the reference management software EndNote (Version X9). First, one reviewer (Z.Q.W) manually removed duplicates using the software. Then, two reviewers (Z.Q.W and X.B.L) independently screened the titles and abstracts against the inclusion and exclusion criteria. Following this, the full texts of all potentially relevant studies were assessed according to the same criteria. Any discrepancies during the screening process were resolved through discussion. Unresolved disagreements were adjudicated by a third reviewer (W.Q.L).

Data extraction was performed independently by one reviewer (C.Z) and verified for consistency by a second reviewer (T.Q). The extracted data included: guideline title, author/organization, publication year, development methodology, conflicts of interest, guideline type (de novo, adaptation, update, or revision), target country/region, and the grading system used for recommendations.

Three trained assessors (Y.S, Z.F.C, and G.X.Y) independently evaluated the methodological quality and the quality of recommendations of the included guidelines using the AGREE II and the AGREE-REX tools. The final version of AGREE II comprises 23 items categorized into six quality domains (Scope and Purpose, Stakeholder Involvement, Rigour of Development, Clarity of Presentation, Applicability, Editorial Independence), each rated on a 7-point Likert scale.[15–18] AGREE-REX includes nine items within three domains (Clinical Applicability, Values and Preferences, and Implementability).[17,19] Prior to the assessment, all assessors completed the AGREE online tutorial and familiarized themselves with the AGREE II and AGREE-REX user manuals. Both instruments use a 7-point scoring system: 1 indicates "Strongly Disagree" (item criteria are poorly reported or absent), 7 indicates "Strongly Agree" (the quality of reporting is high and all criteria are fully met), and scores of 2–6 represent varying degrees of criteria fulfillment, with higher scores indicating closer adherence to the criteria. The overall assessment included a rating for overall quality and a judgment on whether the guideline was recommended for use in clinical practice. After the three assessors completed their independent evaluations, one assessor (T.Q) performed preliminary data consolidation. For items with a scoring discrepancy greater than 2 points, consensus was reached through discussion and communication among the assessors.

Data Analysis and Synthesis

The scores from the three assessors were submitted to a statistician. The scaled domain scores for both AGREE II and AGREE-REX were calculated according to the formula recommended in their respective user manuals: (Obtained Score - Minimum Possible Score) / (Maximum Possible Score - Minimum Possible Score) × 100%. Domain scores were categorized as "High" (≥80%), "Moderate" (60–79%), "Low" (40–59%), and "Very Low" (<40%). As the six domains of AGREE II are independent, the calculated score represents the sum of the individual item scores within each domain. Furthermore, the three assessors independently rated the overall quality of each guideline. The final overall quality score was the mean of the three assessors' ratings. Since AGREE II does not provide specific cut-off points for overall quality categorization, and referring to relevant published study,[20] we defined the assessment criteria for overall guideline quality as follows: scores <3 indicated low quality (not recommended), scores ≥3 and <6 indicated moderate quality

(recommended with modifications), and scores ≥ 6 indicated high quality (recommended). For the AGREE-REX tool, the scaled domain scores and the overall scaled score were calculated using the same method described above for AGREE II. All scaled scores are presented as the median (interquartile range).

Descriptive statistical analysis was employed. Domain scores were calculated by summing the scores of all items within that domain and converting them into a standardized percentage relative to the maximum possible score for that domain. To evaluate the level of agreement among the three assessors overall and for each CPG, an intraclass correlation coefficient (ICC) analysis was performed using IBM SPSS Statistics (Version 26.0). Based on previously published standards,[21] the degree of consistency was interpreted as follows: 0.00–0.20, slight; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; and 0.81–1.00, almost perfect. A p-value <0.05 was considered statistically significant.

Key Guideline Treatment Recommendations and Current Best Evidence

Key treatment recommendations were extracted and analyzed based on items that received relatively high scores in the AGREE II and AGREE-REX assessments. Concurrently, the available evidence cited by each guideline to support its recommendations was identified. The highest current level of evidence for each recommendation was determined, and the evidence provided by the guidelines was graded using the Oxford Centre for Evidence-Based Medicine (OCEBM) levels of evidence and recommendation system (Tables S1 and S2, see Appendix 1).

Results

Characteristics of the Guidelines

A systematic search of databases and websites, supplemented by a review of the references within identified guidelines, yielded 473 records. After removing duplicates (n=168), 305records underwent title and abstract screening. This led to the exclusion of 230 records, with 75 remaining for full-text review. Ultimately, 15Clinical Practice Guidelines (CPGs)[22–36] that met the pre-defined inclusion and exclusion criteria were included in the analysis (Figure 1).

The basic characteristics of the 15 included CPGs are summarized in Table 1. These guidelines were published between 2015 and 2025, with a median publication year of 2020. The geographical distribution of the developing organizations was as follows: four were developed by Chinese organizations or associations,[24,26,27,33] four by

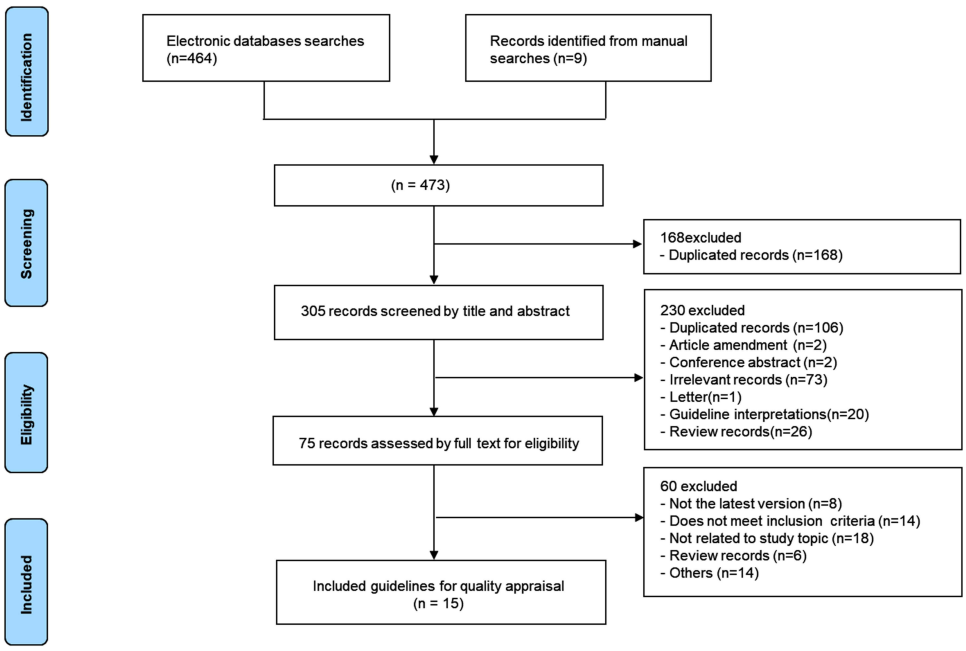

Figure 1 Flow chart of study selection.

Table 1 Characteristics of the Identified Guidelines for the Diabetic Foot Guidelines

Author/ Organization	Short Name	Year	Country Applied	Version	Title	Funding	Grading System Used	Development Method
SVS, et al[22]	SV	2016	USA	Original version	The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine	Not reported	GRADE	EB
Arun Bal, et al[23]	AR	2017	India	Original version	Multispecialty consensus statement for primary care management of diabetic foot disease in India	Smith & Nephew Healthcare Pvt. Ltd.	No	CB
CDS, et al[24]	CD	2019	China	Original version	Chinese guideline on prevention and management of diabetic foot (2019 edition)(I–V)	National Natural Science Foundation of China	Unclear	EB
J East, et al[25]	JE	2019	Jamaica	Original version	Guidelines on Management of the Patient with Diabetic Foot Infection	Not reported	No	EB
Aiping Wang, et al[26]	AI	2020	China	Original version	Guidelines on multidisciplinary approaches for the prevention and management of diabetic foot disease (2020 edition)	National Natural Science Foundation of China	GRADE	EB
Maoquan Li, et al[27]	MA	2021	China	Revised version	Guidelines and standards for comprehensive clinical diagnosis and interventional treatment for diabetic foot in China (Issue 7.0)	Not reported	No	CB
Eliud Garcia Duarte Junior, et al[28]	EL	2023	Brazilian	Original version	Brazilian Society of Angiology and Vascular Surgery 2023 guidelines on the diabetic foot	Not reported	The European Society of Cardiology system	EB
Pam Chen, et al[29]	PA	2023	International	Revised version	Guidelines on interventions to enhance healing of foot ulcers in people with diabetes (IWGDF2023update)	AOTI, Essity, Mölnlycke, Reapplix, and Urgo Medical	GRADE	EB
Nicolaas C. Schaper, et al[30]	NC	2023	International	Revised version	Practical guidelines on the prevention and management of diabetes-related foot disease (IWGDF2023update)	AOTI, Essity, Mölnlycke, Reapplix, and Urgo Medical	GRADE	EB
Sicco A. Bus, et al[31]	SI	2023	International	Revised version	Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF2023update)	AOTI, Essity, Mölnlycke, Reapplix, and Urgo Medical	GRADE	EB
NICE[32]	NI	2024	UK	Revised version	Diabetic foot problems: prevention and management	NICE	GRADE	EB
CSE, CEMSA[33]	CS	2024	China	Original version	Expert consensus on wound treatment of diabetic foot ulcer (2024)	Not reported	No	CB
WHS[34]	WH	2024	USA	Revised version	WHS (Wound Healing Society) guidelines update: Diabetic foot ulcer treatment guidelines	Not reported	Unclear	EB
Éric Senneville, et al[35]	ER	2024	International	Revised version	IWGDF/IDSA guidelines on the diagnosis and treatment of diabetes-related foot infections (IWGDF/IDSA2023)	AOTI, Essity, Mölnlycke, Reapplix, and Urgo Medical	GRADE	EB
Taiki Isei, et al[36]	TA	2025	Japan	Revised version	Wound, pressure ulcer, and burn guidelines – 3: Guidelines for the diagnosis and treatment of diabetic ulcers and gangrene, second edition	The Japanese Dermatological Association	Edited by the Japanese Dermatological Association	EB

Abbreviations: SVS, Society for Vascular Surgery; CDS, Chinese Diabetes Society; NICE, National Institute for Health and Care Excellence; CSE, Chinese Society of Endocrinology; CEMSA, China Endocrinology and Metabolism Specialist Alliance; WHS, Wound Healing Society; AOTI, Advanced Oxygen Therapy Inc.; EB, evidence-based guideline; CB, consensus-based guideline.

https://doi.org/10.2147/DMSO.S586150

international organizations or associations,[29–31,35] two by organizations or associations from the United States,[22,34] and one each from the United Kingdom,[32] India,[23] Jamaica,[25] Brazil,[28] and Japan.[36]

Quality Assessment of the Guidelines

Among the 15 included guidelines, seven (47%) utilized the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) framework to assess the evidence and strength of recommendations.[22,26,29–32,35] Three guidelines (20%) provided recommendations based solely on expert consensus without employing a grading system.[23,27,33] Two guidelines (13%) graded the strength of recommendations and level of evidence but did not specify the system used.[24,34] Another two guidelines (13%) employed grading systems that are not internationally recognized.[28,36] One guideline (7%) presented graded recommendations and evidence levels without using a formal grading system.[25]

The standardized domain scores from the AGREE II instrument and the overall quality ratings for the included CPGs are summarized in Table 2. The domains of Clarity of Presentation, Scope and Purpose, and Editorial Independence received exceptionally high median scores of 96.30% (IQR, 92.59–100.00%), 96.30% (IQR, 88.89–100.00%), and 100.00% (IQR, 97.22–100.00%), respectively (Figure 2a). The domains of Stakeholder Involvement and Rigor of Development also received relatively high and consistent median scores of 74.07% (IQR, 62.96–83.33%) and 75.69% (IQR, 41.67–93.06%), respectively (Figure 2a). In contrast, the Applicability domain received the lowest median score of 52.78% (IQR, 36.11–59.72%) (Figure 2a).

The median overall quality score assigned by the three appraisers was 5.5 (range: 3.00 to 6.67) on a 7-point scale. Based on the pre-defined classification criteria, six CPGs (40%) were rated as "high quality"[26,29,31,32,35,36] and are recommended for use. The remaining nine CPGs (60%) were rated as "moderate quality"[22–25,27,28,30,33,34] and are recommended for use with modifications. Notably, three guidelines,[23,27,33] which were based on expert consensus and lacked support from high-quality research evidence, received relatively lower scores.

The results of the evaluation of all included guideline recommendations using the AGREE-REX tool are presented in Table 3. The recommendations scored relatively high in the domains of Clinical Applicability and Implementability, with median scores of 79.63% (IQR, 66.67–81.48%) and 77.78% (IQR, 72.22–80.56%), respectively (Figure 2b). Unfortunately, the Values and Preferences domain received the lowest median score of 47.22% (IQR, 43.06–52.78%) (Figure 2b).

The inter-rater reliability, calculated using the Intraclass Correlation Coefficient (ICC), was 0.881 (95% CI, 0.854–0.908) for the AGREE II assessments and 0.767 (95% CI, 0.745–0.789) for the AGREE-REX assessments. Notably, the ICC for all three appraisers using the AGREE II instrument was greater than 0.8, indicating excellent agreement (Table 2). The ICC for appraisers using the AGREE-REX tool was greater than 0.7, indicating high agreement (Table 3).

Key Treatment Recommendations and Current Best Evidence in Diabetic Foot Practice Guidelines

To further analyze the heterogeneity in treatment recommendations for Diabetic Foot Ulcers (DFU) across different guidelines, this study extracted the principal recommendations from the 15 guidelines published in the last decade. Reference guideline,[26] which received a relatively high quality score, was used as a key reference. For each recommendation, the available evidence cited by the guidelines to support their proposals was identified, and the highest level of evidence supporting these key recommendations was synthesized (Table 4).

Discussion

Principal Findings

In this study, we conducted a rigorous evaluation of the methodological quality of DFU guidelines using the AGREE II and AGREE-REX instruments. A key finding was that the quality scores of all included guidelines were satisfactory. The majority of scores were distributed within the moderate quality range, with some falling into the high-quality category;

Table 2 Assessment of the Quality of the Included Guidelines Using AGREE II Instrument

No.	Guideline	Scope and Purpose	Stakeholder Involvement	Rigour of Development	Clarity of Presentation	Applicability	Editorial Independence	ICC	Overall Assessment	
1	SVS, et al[22]	100.00%	62.96%	72.92%	100.00%	27.78%	100.00%	0.906	5.17	RM
2	Arun Bal, et al[23]	88.89%	68.52%	34.72%	90.74%	48.61%	94.44%	0.927	3.00	RM
3	CDS, et al[24]	90.74%	74.07%	59.72%	94.44%	58.33%	100.00%	0.886	5.00	RM
4	J East, et al[25]	87.04%	57.41%	41.67%	92.59%	25.00%	88.89%	0.947	3.33	RM
5	Aiping Wang, et al[26]	100.00%	75.93%	87.50%	100.00%	54.17%	100.00%	0.876	6.33	R
6	Maoquan Li, et al[27]	83.33%	59.26%	27.08%	90.74%	36.11%	100.00%	0.916	3.33	RM
7	Eliud Garcia Duarte Junior, et al[28]	94.44%	72.22%	75.69%	96.30%	40.28%	97.22%	0.898	5.50	RM
8	Pam Chen, et al[29]	98.15%	94.44%	93.06%	100.00%	59.72%	100.00%	0.811	6.33	R
9	Nicolaas C. Schaper, et al[30]	94.44%	83.33%	73.61%	98.15%	61.11%	97.22%	0.808	5.67	RM
10	Sicco A. Bus, et al[31]	100.00%	92.59%	93.06%	100.00%	59.72%	100.00%	0.830	6.67	R
11	NICE[32]	98.15%	77.78%	88.19%	96.30%	73.61%	100.00%	0.831	6.00	R
12	CSE, CEMSA[33]	83.33%	53.70%	25.00%	64.81%	30.56%	100.00%	0.941	3.00	RM
13	WHS[34]	96.30%	70.37%	84.03%	94.44%	52.78%	100.00%	0.916	5.50	RM
14	Éric Senneville, et al[35]	100.00%	92.59%	94.44%	100.00%	62.50%	100.00%	0.820	6.67	R
15	Taiki Isei, et al[36]	100.00%	79.63%	93.06%	98.15%	51.39%	100.00%	0.899	6.67	R
	Median scores (inter-quartile range)	96.30% (88.89–100.00%)	74.07% (62.96–83.33%)	75.69% (41.67–93.06%)	96.30% (92.59–100.00%)	52.78% (36.11–59.72%)	100.00% (97.22–100.00%)	—	—	

Abbreviations: R, recommended; RM, recommended with modifications; NR, not recommended.

https://doi.org/10.2147/DMSO.S586150

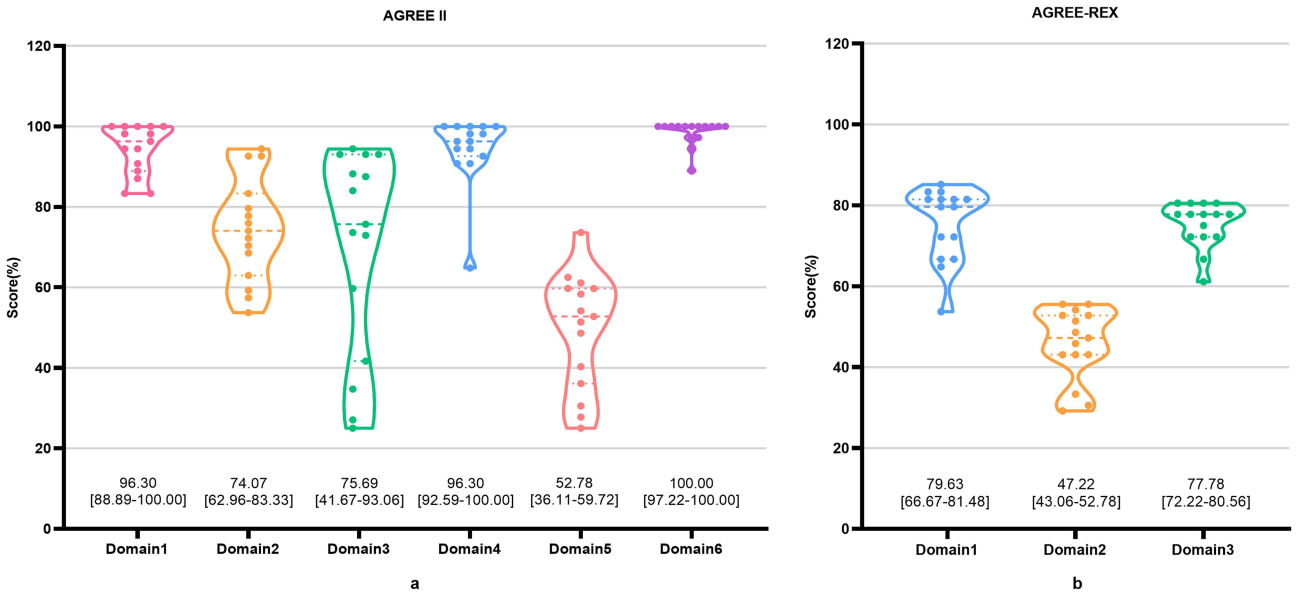

Figure 2 (**a**) Score distribution map of AGREE II; (**b**) Score distribution map of AGREE-REX.

no guidelines were rated as low quality. Furthermore, we identified notable variations in recommendations across different guidelines. Most guidelines lacked sufficient consideration of stakeholder values and preferences, as well as implementability aspects.

Guideline Quality Assessment via AGREE II

Domain 1: Scope and Purpose. The scope and purpose domain serves as a navigational tool within a guideline, enabling users to quickly and accurately identify the target population and the specific clinical questions addressed, thereby reducing the time needed to find optimal solutions. In this study, the median score for this domain was 96.3%, indicating a satisfactory result. All included guidelines[22–36] provided clear descriptions in this area. However, we recommend more

Table 3 Assessment of the Quality of Guideline Recommendations with the AGREE-REX Instrument

No.	Guideline	Clinical Applicability	Values and Preferences	Implementability	ICC	Overall Assessment
1	SVS, et al[22]	72.22%	43.06%	72.22%	0.834	RM
2	Arun Bal, et al[23]	64.81%	33.33%	72.22%	0.733	RM
3	CDS, et al[24]	72.22%	47.22%	77.78%	0.744	R
4	J East, et al[25]	66.67%	43.06%	72.22%	0.721	RM
5	Aiping Wang, et al[26]	81.48%	45.83%	80.56%	0.819	R
6	Maoquan Li, et al[27]	66.67%	30.56%	77.78%	0.815	RM
7	Eliud Garcia Duarte Junior, et al[28]	85.19%	52.78%	80.56%	0.707	R
8	Pam Chen, et al[29]	81.48%	55.56%	75.00%	0.761	R
9	Nicolaas C. Schaper, et al[30]	81.48%	48.61%	80.56%	0.794	RM
10	Sicco A. Bus, et al[31]	83.33%	51.39%	77.78%	0.806	R
11	NICE[32]	79.63%	55.56%	80.56%	0.753	R
12	CSE, CEMSA[33]	53.70%	29.17%	61.11%	0.792	RM
13	WHS[34]	79.63%	43.06%	66.67%	0.753	RM
14	Éric Senneville, et al[35]	83.33%	54.17%	77.78%	0.734	R
15	Taiki Isei, et al[36]	81.48%	52.78%	77.78%	0.738	R
	Median scores (inter-quartile range)	79.63% (66.67–81.48%)	47.22% (43.06–52.78%)	77.78% (72.22–80.56%)	—	—

Abbreviations: R, recommended; RM, recommended with modifications; NR, not recommended.

Table 4 Recommendations for the Treatment of Diabetic Foot Included in the Guidelines and Related Sources of Evidence

The Key Recommendations	The Best Evidence to Support the Recommendations at Present	Strength of Recommendation	Quality of Evidence	SV[22]	AR[23]	CD[24]	JE[25]	AI[26]	MA[27]	EL[28]	PA[29]	NC[30]	SI[31]	NI[32]	CS[33]	WH[34]	ER[35]	TA[36]
It is recommended that individuals with diabetes undergo annual systematic foot risk screening, with risk stratification management implemented based on the assessment results of loss of protective sensation (LOPS) and peripheral arterial disease (PAD).	A meta-analysis[31]	B	2a	●	●	●	●	●	□	●	–	●	●	●	●	□	–	□
Structured individualized education is advised for people with diabetes at risk of foot ulceration (IWGDF risk grades 1–3), emphasizing foot self-examination, hygiene practices, and avoidance of risk-related behaviors.	A RCT[36]	B	2b	●	□	●	●	●	●	●	–	●	●	●	–	□	–	●
Based on foot deformity and ulcer risk, therapeutic footwear with biomechanical offloading properties should be prescribed individually, and consistent long-term use should be encouraged to prevent ulcer occurrence and recurrence.	A RCT including 400 patients[22]	B	2a	●	●	□	●	●	●	●	–	●	●	□	–	●	–	●
Individualized debridement is fundamental in the management of diabetic foot ulcers, with sharp surgical debridement being the preferred approach.	Two systematic reviews and meta-analyses[26,32]	A	1a	□	□	●	●	●	●	–	●	□	–	●	●	●	–	●
Diabetic foot ulcers with moderate-to-severe infections, particularly those complicated by abscess, wet gangrene, or necrotizing fasciitis, necessitate urgent surgical debridement.	A retrospective study including 106 patients[33]	B	2b	●	–	□	–	●	□	–	–	●	–	–	–	–	●	–
It is recommended that all patients with diabetic foot ulcers (DFUs) receive prompt vascular assessment and revascularization when ischemia is suspected, peripheral artery disease (PAD) is present, or the ulcer fails to heal within 4–6 weeks despite optimal care.	A prospective study including 993 patients[22]	B	2b	●	–	●	–	●	●	●	–	●	–	–	–	–	–	–
In cases of an unsalvageable foot (eg., from irreversible ischemia, uncontrolled infection, failed revascularization, or extensive gangrene), early major amputation is warranted.	A prospective study including 187 patients[26]	B	2b	–	□	□	●	●	●	–	–	□	–	–	●	–	–	–
For DFUs refractory to standard therapy with no improvement over 4 weeks, Negative Pressure Wound Therapy (NPWT) may be considered as an adjunctive treatment.	A systematic review and meta-analysis[32]	A	1a	●	□	●	●	●	●	○	●	–	–	●	●	●	–	●

(*Continued*)

https://doi.org/10.2147/DMSO.S586150

https://doi.org/10.2147/DMSO.S586150

Table 4 (Continued).

The Key Recommendations	The Best Evidence to Support the Recommendations at Present	Strength of Recommendation	Quality of Evidence	SV[22]	AR[23]	CD[24]	JE[25]	AI[26]	MA[27]	EL[28]	PA[29]	NC[30]	SI[31]	NI[32]	CS[33]	WH[34]	ER[35]	TA[36]
For neuro-ischemic or ischemic diabetic foot ulcers that have failed standard therapy, hyperbaric oxygen therapy (HBOT) should be considered as an adjunctive treatment.	Two systematic reviews and meta-analyses[32,33]	A	Ia	●	—	□	—	●	●	○	●	●	—	○	●	●	●	●
Effective offloading is fundamental for healing neuropathic plantar ulcers. Total contact casts or non-removable walkers serve as the first-line option, while removable devices are alternatives; conventional footwear should be avoided.	A systematic review and meta-analysis[32]	A	Ia	●	□	●	●	●	□	●	—	●	□	●	—	●	—	—
The antibiotic therapy for diabetic foot infections must be tailored individually, with the specific regimen (agent, dosage, route, and duration) based on a thorough clinical evaluation of the infection.	A meta-analysis[32]	A	Ia	—	●	●	●	●	●	—	—	●	—	●	●	●	●	●
Optimal glycemic control is crucial for promoting the healing of diabetic foot ulcers (DFUs) and thereby reducing the risks of infection and amputation.	Two systematic reviews and meta-analyses[22,26]	A	Ia	●	●	●	●	●	●	□	—	●	—	●	●	●	—	●
The acute management of Charcot neuroarthropathy should implement strict immobilization and offloading, ideally using non-removable devices. For cases progressing to severe deformity or instability, surgical fixation or reconstruction should be considered.	A prospective study including 33 patients[26]	B	2b	—	●	●	—	●	□	□	—	●	—	●	—	—	—	—
The surgical options for diabetic foot osteomyelitis include distal phalanx resection, toe disarticulation, metatarsal head resection, metatarsophalangeal joint disarticulation, partial metatarsal resection, sesamoidectomy, partial calcanectomy, total calcanectomy, and exostectomy.	Expert opinion[24]	D	5	—	—	●	—	—	—	—	—	—	—	—	—	—	—	—
For diabetic patients with non-healing plantar forefoot ulcers, surgical interventions such as Achilles tendon lengthening, arthroplasty, single or pan-metatarsal head resection, metatarsophalangeal joint arthroplasty, or osteotomy should be considered to prevent recurrence after the active ulcer has healed.	A case series analysis[32]	C	4	—	—	—	—	●	—	●	—	●	□	—	—	●	—	—
A thorough preoperative risk assessment is essential for enhancing the safety of diabetic foot-related surgeries.	A cohort study[26]	B	2b	—	—	—	—	●	●	□	—	—	—	□	—	—	—	—
A multidisciplinary team for limb preservation should be established for the provision of preventive care (eg., foot care, orthotics) and long-term follow-up.	A retrospective cohort study[26]	B	2b	—	—	□	●	●	●	●	—	●	—	●	□	—	—	—

Notes: ● Indicates being recommended definitely; □ indicates being mentioned; ○ indicates being not recommended; — indicates being not mentioned.

detailed descriptions regarding the clinical characteristics and subgroup classifications of the target population, as well as the specific clinical problems the guidelines aim to address.

Domain 2: Stakeholder Involvement. The median score for the stakeholder involvement domain was 74.07%, ranking it the second lowest among the six domains. Beyond including all relevant professional groups and target users in the guideline development group, the involvement of the target population (eg., patients, the public) is crucial. The perspectives and choices of the target population significantly influence a guideline's practicality and applicability. Unfortunately, most guidelines lacked consideration for the target population. Notably, the NICE and IWGDF guidelines[29–32,35] provided exemplary models in this regard. Consequently, we recommend that future guideline development processes systematically collect and integrate target population values and preferences through methods such as patient interviews, surveys, or the inclusion of patient representatives to enhance guideline utility.

Domain 3: Rigour of Development. Rigour of development ensures the reliability of guideline recommendations and strengthens clinicians' willingness to adhere to them. This domain achieved a median score of 75.69%, reflecting a moderate level of quality. Seven guidelines scored above 80%,[26,29,31,32,34–36] three scored above 70%,[22,28,30] while the remaining five scored below 60%.[23–25,27,33] Lower scores were primarily associated with deficiencies in search strategies, evidence selection criteria, methods for assessing evidence quality, and update procedures. Therefore, we recommend that guideline development should include a detailed methodology section, comprising comprehensive systematic literature search strategies, explicit evidence inclusion/exclusion criteria, justification for recommendations based on low-quality evidence (including clinical necessity and consensus process), and a clear evidence update plan.

Domain 4: Clarity of Presentation. This domain attained a median score of 96.3%, indicating a satisfactory outcome and ranking second highest among the six domains. Although all included guidelines received considerable scores in this area, we suggest that the judicious incorporation of auxiliary aids such as tables, figures, and flowcharts could further enhance the clarity and usability of the recommendations.

Domain 5: Applicability. Guideline applicability refers to the alignment of recommendations with real-world clinical settings. High applicability facilitates efficient comprehension and convenient implementation by healthcare professionals, promoting standardized care. In this study, the median score for applicability was 52.78%, the lowest among all domains. This finding is consistent with numerous previous guideline evaluation studies.[37,38] Low applicability scores were associated with insufficient consideration of facilitators, barriers to application, and required resources. Only three guidelines in this study adequately addressed applicability.[30,32,35] Thus, significant room for improvement remains in this domain. We recommend that guideline development processes include analysis of potential implementation barriers and corresponding strategies, incorporate discussions on resource implications and cost-effectiveness, and provide supporting implementation tools and patient education materials to improve applicability.

Domain 6: Editorial Independence. The median score for editorial independence was 100.00%, the highest among the six domains, with scores ranging narrowly from 88.89% to 100.00%. This indicates that most included guidelines provided detailed descriptions of funding bodies and conflicts of interest (COI) for development group members. Only four guidelines showed deficiencies in this area.[23,25,28,30] Although issues in this domain were minimal, we recommend that guideline development processes should include explicit declarations of COI for all individual panel members and clearly delineate the role and scope of influence of the funding body in the guideline development process.

Evaluation of Guideline Recommendations Using AGREE-REX

Clinical Applicability: This domain achieved the highest median score of 79.63% among the three AGREE-REX domains in this study. This indicates that the recommendations included in the guidelines demonstrate a certain level of applicability and can be adopted by a broad range of users. However, there remains room for improvement. We suggest supplementing individual recommendations with implementation roadmaps or operational flowcharts to clarify specific steps and responsible parties. Furthermore, incorporating resource-tiering suggestions to define applicability criteria for different levels of hospitals is recommended. Finally, the introduction of patient decision aids, such as patient education manuals and preference questionnaires, should be considered.

Values and Preferences: This domain received the lowest median score of 47.22%, with nine guidelines scoring below 50%.[22–27,30,33,34] This low score indicates that when patient and other key stakeholder involvement in the Clinical

Practice Guideline (CPG) development process is minimal, it is impossible to adequately assess the importance of outcomes or the interpretation of benefits and harms from their perspectives. This represents a critical area for improvement in future updates or development of DFU guidelines. Future guideline development should systematically incorporate representatives of patients and caregivers, with their roles and methods of participation explicitly described in the methods section. Recommendations should additionally include explanations of how patient values and preferences influence treatment choices, particularly when multiple options exist. Providing patient decision aids or communication templates can further facilitate shared decision-making between healthcare professionals and patients.

Implementability: This domain attained a median score of 77.78%, which is generally satisfactory. We recognize that many methodological weaknesses identified during development, which led to lower AGREE-II scores, also contributed to the lower scores in the AGREE-REX tool. Although phrases such as "can be considered if resources are available" and various resource considerations[25,26,29–32,34,35] were frequently mentioned, specific implementation pathways, training materials, or tools were not provided. Therefore, we recommend developing implementation toolkits for individual recommendations, which could include flowcharts, patient education materials, and templates for nursing records. For healthcare professionals, providing links to training resources or suggested curricula would help them master new techniques. Concurrently, collaboration with health economics or reimbursement specialists to provide cost-effectiveness analyses and reimbursement advice would further promote the adoption of the recommendations.

Heterogeneity in the Clinical Management of Diabetic Foot

It is recommended that individuals with diabetes undergo annual systematic foot risk screening, with risk stratification management implemented based on the assessment results of loss of protective sensation (LOPS) and peripheral arterial disease (PAD). (Strength of recommendation: B; Level of evidence: 2a).[31]

This recommendation is consistent across ten guidelines.[22–26,28,30–33] Three guidelines[27,34,36] mention content related to this recommendation but do not provide an explicit endorsement, while two guidelines[29,35] do not address it. The highest-quality supporting evidence currently comes from a meta-analysis.[31]

Structured individualized education is advised for people with diabetes at risk of foot ulceration (IWGDF risk grades 1–3), emphasizing foot self-examination, hygiene practices, and avoidance of risk-related behaviors. (Strength of recommendation: B; Level of evidence: 2b).[36]

Regarding this recommendation, ten guidelines[22,24–28,30–32,36] are in agreement. Two guidelines[23,34] mention relevant content but do not explicitly recommend it, and three guidelines[29,33,35] do not address it. The strongest evidence to date is provided by a randomized controlled trial.[36]

Based on foot deformity and ulcer risk, therapeutic footwear with biomechanical offloading properties should be prescribed individually, and consistent long-term use should be encouraged to prevent ulcer occurrence and recurrence. (Strength of recommendation: B; Level of evidence: 2a).[22]

Ten guidelines[22,23,25–28,30,31,34,36] endorse this recommendation. Two guidelines[24,32] refer to related content without making a clear recommendation, and three guidelines[29,33,35] do not mention it. The current best evidence is derived from a randomized controlled trial involving 400 patients.[22]

Individualized debridement is fundamental in the management of diabetic foot ulcers, with sharp surgical debridement being the preferred approach. (Strength of recommendation: A; Level of evidence: 1a).[26,34]

Regarding this recommendation, nine guidelines[24–27,29,32–34,36] endorsed it. Three guidelines[22,23,30] mentioned content related to this recommendation but did not explicitly endorse it. Three guidelines[28,31,35] did not mention this recommendation. The best available evidence to date consists of two systematic reviews and meta-analyses on debridement.[26,34]

Diabetic foot ulcers with moderate-to-severe infections, particularly those complicated by abscess, wet gangrene, or necrotizing fasciitis, necessitate urgent surgical debridement. (Strength of recommendation: B; Level of evidence: 2b).[35]

Four guidelines[22,26,30,35] endorsed this recommendation. Two guidelines[24,27] mentioned related content but did not explicitly endorse it. The remaining nine guidelines[23,25,28,29,31–34,36] did not mention this recommendation. Currently, there is a lack of large-scale, high-quality randomized controlled trials; the best available evidence is based on a retrospective evaluation involving 106 patients with DFU.

It is recommended that all patients with diabetic foot ulcers (DFUs) receive prompt vascular assessment and revascularization when ischemia is suspected, peripheral artery disease (PAD) is present, or the ulcer fails to heal within 4–6 weeks despite optimal care. (Strength of recommendation: B; Level of evidence: 2b).[22]

Seven guidelines[23,24,26–28,30,32] endorsed this recommendation. The other eight guidelines[22,25,29,31,33–36] did not mention it. The best available evidence to date is a prospective study involving 993 patients.[22]

In cases of an unsalvageable foot (eg., from irreversible ischemia, uncontrolled infection, failed revascularization, or extensive gangrene), early major amputation is warranted. (Strength of recommendation: B; Level of evidence: 2b).[26]

Four guidelines[25–27,33] consistently endorsed this recommendation. Three guidelines[23,24,30] mentioned related content but did not explicitly endorse it. The other eight guidelines[22,28,29,31,32,34–36] did not mention this recommendation. Currently, high-quality research evidence is lacking; the best available evidence is a prospective study involving 187 patients.[26]

For DFUs refractory to standard therapy with no improvement over 4 weeks, Negative Pressure Wound Therapy (NPWT) may be considered as an adjunctive treatment. (Strength of recommendation: A; Level of evidence: 1a).[34]

This recommendation was relatively consistent across most guidelines.[22,24–27,29,32–34,36] One guideline[28] did not recommend it, and one guideline[23] mentioned related content without making an explicit recommendation. Additionally, two guidelines[30,31] do not address this topic. The best available evidence to date comes from a systematic review and meta-analysis.[34]

For neuro-ischemic or ischemic diabetic foot ulcers that have failed standard therapy, hyperbaric oxygen therapy (HBOT) should be considered as an adjunctive treatment. (Strength of recommendation: A; Level of evidence: 1a).[34,35]

Nine guidelines[22,26,27,29,30,33–36] endorsed this recommendation. However, two guidelines[28,32] disagreed with it. One guideline[23] mentioned related content without making an explicit recommendation, and three guidelines[24,25,31] did not mention related content. The best available evidence to date comes from two systematic reviews and meta-analyses.[34,35]

Effective offloading is fundamental for healing neuropathic plantar ulcers. Total contact casts or non-removable walkers serve as the first-line option, while removable devices are alternatives; conventional footwear should be avoided. (Strength of recommendation: A; Level of evidence: 1a).[34]

Eight guidelines[22,24–26,28,30,32,34] consistently endorsed this recommendation. Three guidelines[23,27,31] mentioned related content but did not make explicit recommendations. Four other guidelines[29,33,35,36] did not mention content related to this recommendation. The best available evidence to date comes from a systematic review and meta-analysis.[34]

The antibiotic therapy for diabetic foot infections must be tailored individually, with the specific regimen (agent, dosage, route, and duration) based on a thorough clinical evaluation of the infection. (Strength of recommendation: A; Level of evidence: 1a).[34]

The vast majority of guidelines[23–27,30,32,33,35,36] endorsed this recommendation. Only four guidelines[22,28,29,31] did not mention content related to this recommendation. The best available evidence to date comes from a meta-analysis,[34] which indicated that antibiotic therapy for DFI should be administered on a case-by-case basis.

Optimal glycemic control is crucial for promoting the healing of diabetic foot ulcers (DFUs) and thereby reducing the risks of infection and amputation. (Strength of recommendation: A; Level of evidence: 1a).[22,26]

This recommendation was relatively consistent across eleven guidelines.[22–27,30,32–34,36] One other guideline[28] mentioned related content without making an explicit recommendation, and three other guidelines[29,31,35] did not mention this recommendation. The best available evidence to date comes from two systematic reviews and meta-analyses,[22,26] which demonstrated that good glycemic control improves the efficacy of DFU healing.

The acute management of Charcot neuroarthropathy should implement strict immobilization and offloading, ideally using non-removable devices. For cases progressing to severe deformity or instability, surgical fixation or reconstruction should be considered. (Strength of recommendation: B; Level of evidence: 2b).[26]

Five guidelines[23,24,26,30,32] endorsed this recommendation. Two guidelines[27,28] mentioned related content but did not make explicit recommendations. The other eight guidelines[22,25,29,31,33–36] did not mention content related to this recommendation. Currently, there is a lack of relevant high-quality RCTs; the best available evidence comes from a prospective study involving 33 patients.[26]

 https://doi.org/10.2147/DMSO.S586150

The surgical options for diabetic foot osteomyelitis include distal phalanx resection, toe disarticulation, metatarsal head resection, metatarsophalangeal joint disarticulation, partial metatarsal resection, sesamoidectomy, partial calcanectomy, total calcanectomy, and exostectomy. (Strength of recommendation: D; Level of evidence: 5).[24]

One guideline[24] was consistent with this recommendation. Currently, the best available evidence is based on expert opinion,[24] indicating a low evidence level and a lack of high-quality randomized controlled trials.

For diabetic patients with non-healing plantar forefoot ulcers, surgical interventions such as Achilles tendon lengthening, arthroplasty, single or pan-metatarsal head resection, metatarsophalangeal joint arthroplasty, or osteotomy should be considered to prevent recurrence after the active ulcer has healed. (Strength of recommendation: C; Level of evidence: 4).[34]

Four guidelines[26,28,31,34] were consistent with this proposal. The other guidelines did not mention related content. Currently, there is a lack of high-reliability RCTs; the best available evidence comes from a case series analysis.[34]

A thorough preoperative risk assessment is essential for enhancing the safety of diabetic foot-related surgeries. (Strength of recommendation: B; Level of evidence: 2b).[26]

Two guidelines[26,27] were consistent with this recommendation. Two other guidelines[28,32] mentioned related content but did not make explicit recommendations. The other guidelines did not mention content related to this recommendation. Currently, the best available evidence comes from a cohort study,[26] indicating a lack of high-quality evidence.

A multidisciplinary team for limb preservation should be established for the provision of preventive care (eg., foot care, orthotics) and long-term follow-up. (Strength of recommendation: B; Level of evidence: 2b).[26]

Six guidelines[25–28,30,32] consistently endorsed this proposal. Two other guidelines[24,33] mentioned content consistent with this proposal but did not make explicit recommendations. The other seven guidelines did not mention related content. The best available evidence to date comes from a retrospective cohort study.[26]

In summary, the following recommendations are proposed to enhance the quality of DFU treatment guidelines: (1) Strengthen the evidence base and research methodologies. Currently, most recommendations for DFU treatment lack support from high-quality research evidence. It is suggested that relevant researchers initiate and conduct multi-center, high-quality studies to provide robust evidence for key recommendations in DFU management. (2) Clearly describe evidence standards during guideline development. The linkage between recommendations and their supporting evidence should be explicitly and transparently documented. (3) Establish a regular revision mechanism. Implement systematic reviews and updates of the guidelines to incorporate new evidence and adjust recommendations accordingly. Furthermore, the collection of real-world data and feedback on treatment outcomes in clinical practice should be encouraged to inform future revisions and optimizations. (4) Involve diverse stakeholders in the development process. This includes, but is not limited to, patients and the public. The perspectives and preferences of the target population should be explicitly identified and thoroughly considered during clinical guideline formulation.

Strengths and Limitations

This study possesses several strengths and limitations. The strengths of this study are as follows: (1) This is the first review of DFU guidelines utilizing both the AGREE II and AGREE-REX instruments. Our evaluation of the quality and applicability of the included Clinical Practice Guidelines (CPGs) can inform and guide future research. (2) This study systematically collated and analyzed the key treatment recommendations and associated evidence from the most recent DFU guidelines. The proposed suggestions for improvement may assist guideline developers and users in identifying gaps in practice and provide a reference for selecting more reliable guidelines. The limitations of this study are as follows: (1) The evaluation was restricted to guidelines published in English and Chinese. Guidelines published in other languages may have been omitted, potentially introducing selection bias. (2) The AGREE II and AGREE-REX instruments focus primarily on the methodological rigor of guideline development and the clinical applicability of recommendations. They do not assess the impact of these recommendations on patient clinical outcomes.

Conclusion

The quality of existing DFU guidelines is variable, yet the overall quality level is satisfactory. The methodological assessment of these guidelines revealed considerable heterogeneity, with notable deficiencies particularly in the domains of Applicability, Stakeholder Involvement, and Rigour of Development. Concurrently, the quality of the recommendations themselves was inconsistent, scoring lower in the Values and Preferences domain. Effectively addressing these issues is crucial for formulating high-quality recommendations in future DFU guidelines. Furthermore, the current guidelines are characterized by a lack of high-quality research evidence and divergent recommendations. Therefore, there is a pressing need for more high-quality randomized controlled trials to address the gaps in the current evidence base and to provide a foundation for developing higher-grade clinical recommendations.

Data Sharing Statement

All authors agree to share data from this review, which are available by contacting the corresponding author. Guo-Xun Yang, E-mail: 20211122@kmmu.edu.cn.

Author Contributions

All authors contributed to the preparation of this work and approved the final manuscript. Specifically, Y.S: Conceptualization, Methodology, Resources, Investigation, Writing – original draft; Z.F.C: Conceptualization, Data curation, Methodology, Investigation, Writing – original draft; Z.Q.W: Data curation, Formal analysis, Investigation, Validation, Writing – original draft; X.B.L: Data curation, Formal analysis, Investigation, Validation, Writing – original draft; W.Q.L: Supervision, Formal analysis, Software, Project administration, Writing – review and editing; C.Z: Software, Validation, Visualization, Formal analysis, Writing – original draft; T.Q: Software, Validation, Visualization, Formal analysis, Writing – original draft; S.S.Z: Visualization, Supervision, Validation, Software, Writing – original draft; X.L. W: Visualization, Software, Validation, Supervision, Writing – original draft; W.J.L: Supervision, Validation, Methodology, Project administration, Writing – review and editing; G.X.Y: Conceptualization, Funding acquisition, Project administration, Methodology, Writing – review and editing, finalized the manuscript and submitted it for publication. All authors had final responsibility for the decision to submit. All authors gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This work was supported by the construction project of clinical medical discipline team in the First Affiliated Hospital of Dali University (Project Approval Number DFYYB2025015).

Disclosure

All authors declare that they have no potential competing interests; no other relationships or activities that could affect the submitted work.

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