ABSTRACT

This publication represents a scheduled update of the 2019 guidelines of the International Working Group of the Diabetic Foot (IWGDF) addressing the use of systems to classify foot ulcers in people with diabetes in routine clinical practice. The guidelines are based on a systematic review of the available literature that identified 28 classifications addressed in 149 articles and, subsequently, expert opinion using the GRADE methodology. First, we have developed a list of classification systems considered as being potentially adequate for use in a clinical setting, through the summary of judgments for diagnostic tests, focusing on the usability, accuracy and reliability of each system to predict ulcer-related complications as well as use of resources. Second, we have determined, following group debate and consensus, which of them should be used in specific clinical scenarios. In conclusion of this process, in a person with diabetes and a foot ulcer we recommend:

1. for communication among healthcare professionals: to use the SINBAD (Site, Ischaemia, Bacterial infection, Area and Depth) classification (first option) or consider using WIfI (Wound, Ischaemia, foot Infection) system (alternative option, when the required equipment and level of expertise is available and it is considered feasible) and in each case the individual variables that compose the systems should be described rather than a total score;
2. for predicting the outcome of an ulcer in a specific individual: no existing system could be recommended;
3. for characterising a person with an infected ulcer: the use of the IDSA/IWGDF (first option) classification or consider using the WIfI system (alternative option, when the required equipment and level of expertise is available and it is considered as feasible);
4. for characterising a person with peripheral artery disease: consider using the WIfI system as a means to stratify healing likelihood and amputation risk;
5. for the audit of outcome(s) of populations: the use of the SINBAD score.

For all recommendations made using GRADE, the certainty of evidence was judged, at best, as being low. Nevertheless, based on rational application of current data this approach allowed the proposal of recommendations, which are likely to have clinical utility.

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LIST OF RECOMMENDATIONS

1a. In a person with diabetes and a foot ulcer, use the SINBAD system for communication between healthcare professionals about the characteristics of an ulcer, and clearly state the presence or absence of each of the composing variables. (Strength of recommendation: Strong; Certainty of evidence: Low)

1b. In a person with diabetes and a foot ulcer, when resources exist in addition to an appropriate level of expertise and it is considered feasible, consider using the WIfI system for communication about the characteristics of an ulcer between healthcare professionals, but with characterisation of each of the composing variables. (Conditional; Low)

2. Do not use any of the currently available classification/scoring systems to offer an individual outcome prognosis for a person with diabetes and a foot ulcer. (Strong; Low)

3a. To classify a person with diabetes and an infected foot ulcer, use the IDSA/IWGDF (2015 version) system. (Strong; Low)

3b. To classify a person with diabetes and an infected foot ulcer, when resources exist in addition to an appropriate level of expertise and it is considered feasible, consider using the WIfI system. (Conditional; Low)

4. In a person with diabetes, peripheral artery disease and a foot ulcer, consider using the WIfI system as a means to stratify healing likelihood and amputation risk. (Conditional; Low)

5. Use the SINBAD system score for any regional/national/international audits, to allow comparisons between institutions on the outcomes of people with diabetes and a foot ulcer. (Strong; Low)

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INTRODUCTION

It is estimated that diabetes affects 537 million people worldwide, 10.5% of the adult population, and the increase in prevalence is occurring at a faster rate in low- and middle-income countries (1). Up to one in three people with diabetes will develop a foot ulcer in their lifetime (2). The risk of developing a diabetes-related foot ulcer, and the factors associated with the development of complications (such as hospitalisation, lower extremity amputation, and mortality) may be patient-related, limb-related or ulcer-related. The impact of individual factors on the outcome of foot ulcers in people with diabetes will vary across communities and countries. For example, infection will more strongly influence the outcome in settings where antibiotics are not readily available, whereas ischaemia will have a greater impact in settings where peripheral artery disease is more prevalent. Of note, more than 80% of people with diabetes live in low- and middle-income countries, in which many diagnostic tools are not readily available and are not expected to become so in the near future (1).

A classification system may be defined as a descriptive tool that aims to divide patients into groups while not necessarily relating to the risk of adverse outcome(s), whereas a scoring system will attribute a scale by which the contribution of factors within the system is quantified and scores can be amalgamated to produce an overall (usually numerical) score with an increased score being associated with a higher risk of adverse outcome(s). In other words, classification systems tend to focus on discrimination (the ability to separate data/individuals into classes), while scoring systems tend to focus on calibration (a measure of the closeness of the estimated probability of a certain event to the underlying probability of the population under study) (3). With both types of tools, one can attempt to create more homogeneous groups of patients for which similar levels of care should be provided and also to standardize the modifiable factors that one should focus on to improve clinical outcomes. This does not mean that we should provide the same care to all patients within the same strata, but that the urgency and use of resources should be prioritised for those in most need. This approach does not invalidate clinical experience, knowledge, and the overall approach that we should provide for a person with an established diabetes-related foot ulcer but is designed to help us standardize communication among healthcare professionals and to facilitate more rational use of available resources (independently of their nature). On the other hand, the correct application of such systems is dependent on knowledge and experience of the required procedures to collect each of the variables that compose a system, and on how to apply the overall system.

Due to its frequency, complexity, and limited resources to treat diabetes-related foot ulcers, it is vital to accurately characterize them, understand their severity and to direct patients at most need to specialized care. To do so, healthcare providers should use the classification(s) that have evidence of their accuracy, reliability, and potential impact on clinical care.

In our systematic review (4), we found numerous proposed classification and scoring systems for foot ulcers in people with diabetes (n=28), and this suggests that none is ideal for routine use in populations worldwide. This also highlights the differing purposes of diabetes-related foot ulcer classification and scoring systems that can be used for: (a) communication among healthcare professionals (independent of the level of clinical care); (b) clinical prognostication of the outcome of an individual ulcer; (c) the

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assessment of a person with infection; (d) the assessment of a person with peripheral artery disease; and (e) clinical audit of outcomes across units and populations.

The intended use of a classification or scoring system will influence its content. A system designed to assess the risk or prognosis for an individual with diabetes and an ulcer on their foot will necessarily require a certain level of detail. In contrast, a system seeking to compare outcomes between populations will need to minimise data input by busy clinicians and should have a less burdensome requirement for data collection and processing, if it is to be usable in clinical practice. While classifications used for communication among healthcare professionals should ideally be simple to memorise and use. This guideline aims to provide recommendations on the use of classifications of established foot ulcers in people with diabetes for the various purposes on behalf of the International Working Group of the Diabetic Foot (IWGDF).

WHAT'S NEW

We have made several changes to the recommendations included in this updated 2023 diabetes-related foot ulcer classification guideline when compared to the previous 2019 guideline (5). The main changes are the following:

- Used a systematic review instead of a critical review to support our recommendations;
- Used a more thorough GRADE methodology approach by grading effect sizes, grading certainty (quality) of evidence with 'very low' as an option, developing summary of findings tables and developing summary of judgement tables;
- Added new important outcomes, including hospitalization, health-related quality of life, diabetes-related foot ulcer and amputation free survival, and costs;
- Added the use of alternative options for communication between healthcare professionals and management of for complex cases (such as in the presence of infection or peripheral arterial disease) acknowledging the differences in access to equipment and detail needed according to the settings.

METHODS

In this guideline we have followed the key steps of the GRADE evidence-to-decision framework, including: i) establishing a diverse expert panel to develop the guideline, ii) defining key clinical questions and important outcomes in the PI/ECO-format (Patient-Intervention/Exposure-Comparison-Outcome), iii) performing systematic reviews and rigorous appraisals of all available evidence that address the questions, iv) assessing key summary of judgements items for each question, v) developing recommendations and their rationale based on these summary of judgements, and vi) consulting external stakeholders on each step (6, 7). The methodology for this guideline is summarised below; we refer those seeking a more detailed description on the methods for developing and writing these guidelines to the 'IWGDF Guidelines development and methodology' document (8).

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First, a diverse multidisciplinary working group of independent international experts in developing, assessing, or disseminating classification or scoring systems for diabetes-related foot ulcers (the authors of this guideline) was invited by the IWGDF Editorial Board to develop and author this guideline. International experts were defined as those having significant experience in practising or studying classification or scoring systems to characterise diabetes-related foot ulcers and published on the topic in the previous four years. The working group comprised endocrinologists, internal medicine physicians, physiatrists, podiatrists and vascular surgeons from the United States of America, Europe, Asia and Australia.

Second, the working group devised important clinical questions and associated outcomes, building on the last version of the guideline, to be answered using the GRADE approach. The questions and outcomes were reviewed and prioritised with the help of nine external clinical experts and two persons with lived diabetes-related foot ulcer experience from various geographical regions, and the IWGDF Editorial Board. The aim was to ensure the questions and outcomes were of relevance to a wide range of healthcare professionals and people with the disease so as to provide the most useful clinical information on how to classify foot ulcers in people with diabetes. The working group classified the outcomes as critically important or important, aligning with international diabetes-related foot ulcer standards (9) or the expert opinion of the working group if definitions did not exist.

As stated in our systematic review (4), critically important outcomes were grouped and defined as

a. clinical outcomes
    - lower extremity amputation: resection of a segment of a limb through a bone or through a joint in the lower extremity,
    - wound healing: achieving intact skin, meaning complete epithelialization without any drainage of a previous foot ulcer site,
    - hospitalization: care in a hospital that requires admission as an inpatient and usually requires an overnight stay,
    - survival: the state or fact of continuing to be alive or exist,
    - health-related quality of life: a person's perceived physical and mental health,
b. post-baseline clinical outcomes
    - ulcer-free period: time that a person is alive and without a foot ulcer,
    - lower extremity amputation-free period: time that a person is alive and without amputation,
c. usability
    - facilitate referral and communication: the act of referring someone or something for consultation, review, or further action,
    - feasibility: the state or degree of being easily or conveniently done,
    - reliability: the extent that the instrument yields the same results over multiple trials,
    - audit: the ability to compare outcomes between institutions,
    - guide management/ interventions, and
d. use of resources: requirements of physical, personnel or financial costs.

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The following outcomes were considered important but not critical and therefore not included: future infection, well-being, functionality/physical functioning, pain, acceptability, costs (direct/indirect) related to the implementation of the system, cost-effectiveness, and satisfaction/ patient preference.

Third, we systematically reviewed the literature and appraised all studies addressing the above agreed upon clinical questions (4). Due to the expected low number of validation studies per classification, along with high heterogeneity of the clinical settings, follow-up periods, and clinical outcome reporting and definition, the group decided not to perform a meta-analysis. Finally, we developed summary of findings tables, including evidence statements, for each assessable outcome for each question which we presented in full in the systematic review. The systematic review supporting this guideline is published separately (4).

Fourth, based on the systematic review, summary of findings tables and expert opinion, teams of two members of the working group developed summary of judgements tables for each question following GRADE (see supplemental information).

However, in comparison with the remaining guidelines developed by the IWGDF, this one is different in three main respects. First, we did not raise clinical questions relating to treatment/intervention, but prognostic questions, and this requires a major difference in the way that the clinical questions are formulated. Second, within the prognostic clinical questions, we focused on validity measures (namely, accuracy and reliability) creating a methodological approach between the diagnostic (discriminative properties) and prognostic (ability to estimate the likelihood of a specific event). Consequently, we have used the GRADE approach for diagnostic questions and respective "summary of judgments" (10). Third, although in our systematic review we have provided a summary of the available evidence and an evidence statement for each available classification and have therefore created a summary of judgments for each classification, we considered that it would not be beneficial to suggest recommendations for each of them. Instead, we have used this process to be able to recommend one classification as the first line and, whenever appropriate, a second line (alternative) classification to be used for each of the specified four clinical contexts. For one of the scenarios (assessment of a person with a foot ulcer and peripheral artery disease) we have determined that the "Peripheral Artery Disease" group should provide guidelines as to which system to recommend and so this was not addressed by our group (11). However, to provide readers with all the information about which classifications to use we have copied the information present on the "Peripheral Artery Disease" group guidelines.

The summary of judgments for diagnostic questions included the following items: problem priority, test accuracy, desirable effects, undesirable effects, the certainty of the evidence of test accuracy, the certainty of the evidence of the effects of the test, the certainty of the evidence of management's effect, certainty of the evidence of the link between the test result and management, the certainty of any effect on management, value, the balance of effects, resources required, the certainty of the evidence of required resources, cost-effectiveness, equity, acceptability to stakeholders and feasibility. All these items were assessed independently by two reviewers and then presented and discussed within the entire group.

The group determined that the diabetes-related foot ulcer problem has high priority, given the first step for our systematic review and creation of the guidelines was the selection of critical outcomes within

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this field by the editorial board, experts, and patient representatives from several countries (further details in the acknowledgments section). For similar reasons, the group determined that there is probably no important uncertainty or variability in the way people value the main outcome(s).

The accuracy of each classification was based on the results of the systematic review, emphasising those studies in which direct comparison between classifications was conducted. The group considered direct improvement of care in any of the five clinical scenarios as desirable effects, and adverse events directly linked to the application of the classification as undesirable effects. For the certainty of test accuracy, the group used the information collected from the systematic review and mostly based their decision in the risk of bias of the retrieved studies, inconsistency of results, and indirectness and imprecision.

Most of the evidence found determined only the accuracy of classifications. Strong evidence that implementing the use of a specific classification in clinical practice could have a true impact on decision making, change a management plan and consequently the person's prognosis was lacking. Due to either lack of any evidence, or evidence that was limited to the availability of indirect evidence only, the certainty of the evidence of test's effects, management effect, or the link between test result and management were mainly based on expert opinion.

For the balance of effects, the group assessed all these items together and determined if, at this point, there was enough information in favour or against the use of each specific classification.

For the resources required, the group considered potential financial or human resources directly linked to the collection of the information required for each classification. As, however, there was no specific detail about these in the systematic review the available evidence was very low.

Taking into consideration the balance of effects and the resources required, the group reflected on the potential cost-effectiveness of each classification. However, we highlight that these outcomes were not considered as critically important and so were given less priority in our selection of the systems to recommend.

The group defined equity in this context as the ability of all people with diabetes and a foot ulcer (i.e. on a societal level) to have equitable access to the procedures required for the classification application.

Acceptability to stakeholders was based on expert opinion and consideration of whether there was balance in the classification between its completeness, simplicity, and objectivity.

Feasibility was determined based on the groups' experience and the ease of use of each classification.

After this entire process, having considered the available evidence, those systems that were considered to be unsuitable to be used in routine clinical practice were excluded from the list of systems that could be chosen as first or second line in each of the four specific scenarios. The reasons for recommending or not recommending a specific system are described in Appendix 1.

The summary of judgments for all the 28 systems are reported in Appendix 2 (Supplementary tables 1 to 28). In Table 1, we present the summary of judgments for each of the classifications that passed this first stage (6 of 28), meaning those we considered that, in face of the available evidence, could be

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conditionally or strongly recommended: DIAFORA, Infectious Diseases Society of America (IDSA)/IWGDF, SINBAD, University of Texas Wound Classification System (UTWCS), (Meggitt-)Wagner and WIfI (Wound, Ischaemia, foot Infection).

All of these systems were considered to be accurate, to have moderate desirable effects, small to trivial undesirable effects, with a balance of effects that probably favours their use in clinical practice and is likely to be acceptable to stakeholders. The overall level of certainty of the evidence for the different aspects of the judgments made about these systems varied between very low and low.

Table 1: Summary of Judgments for the classifications considered as suitable for clinical use

Classification/ judgment	DIAFORA	IDSA/IWGDF	SINBAD	UTWCS	Wagner	WIfI
Problem priority	Yes	Yes	Yes	Yes	Yes	Yes
Test accuracy	Accurate	Accurate	Accurate	Accurate	Accurate	Accurate
Desirable effects	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
Undesirable effects	Trivial	Small	Trivial	Trivial	Trivial	Trivial
Certainty of evidence of test accuracy	Low	Low	Low	Low	Low	Low
Certainty of evidence of test's effects	Very low	Very low	Very low	Very low	Low	Very low
Certainty of evidence of management's effect	Very low	Very low	Very low	Very low	Low	Very low
Certainty of the evidence of link between test result/management	Low	Low	Low	Low	Low	Low
Certainty of effects	Very low	Very low	Very low	Very low	Low	Very low
How much people value the main outcome	Probably no important uncertainty or variability	Probably no important uncertainty or variability	Probably no important uncertainty or variability	Probably no important uncertainty or variability	Probably no important uncertainty or variability	Probably no important uncertainty or variability
Balance of effects	Probably favors the intervention	Probably favors the intervention	Probably favors the intervention	Probably favors the intervention	Probably favors the intervention	Probably favors the intervention
Resources required	Negligible costs and savings	Moderate costs	Moderate savings	Moderate costs	Negligible costs and savings	Moderate savings
Certainty of evidence of required resources	Low	Low	Low	Low	Very low	Very low
Cost effectiveness	Does not favor either	Does not favor either	Probably favors the intervention	Does not favor either	Does not favor either	Probably favors the intervention
Equity	Probably no impact	Probably reduced	Probably increased	Probably reduced	Probably increased	Probably reduced
Acceptability (to stakeholders)	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes	Probably yes
Feasibility	Probably yes	Probably yes	Yes	Probably yes	Yes	Probably no

Note: For each colour a stronger shade implies a stronger assessment, Green filling represents a positive judgment (this is, supporting the use of the system), Blue filling represents a neutral judgment (this is, a balance between supporting or not the use of the system), and Red filling represents a negative judgment (this is, not favouring the use of the system). IDSA/IWGDF: Infectious Diseases Society of America/ International Working Group on the Diabetic Foot; UTWCS: University of Texas Wound Classification System.

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After careful weighing of the summary of judgements, the team proposed to the working group a direction, strength, certainty of evidence and wording of recommendation(s) and rationale to address the question concerned. Certainty of evidence was rated as 'high', 'moderate', 'low' or 'very low' based on the critical outcome(s) reviewed for the question in accordance with GRADE. Recommendations aimed to be clear, specific, and unambiguous on what was recommended, for which persons, and under what circumstances. Rationale for each recommendation was also provided and based on the summary of judgements tables (12, 13).

Fifth, summary of judgements tables and recommendations for each question were extensively discussed in online meetings with the working group. After discussion, a voting procedure was used for each recommendation to grade the direction of the recommendation as 'for' or 'against' the particular intervention, and the strength of each recommendation as 'strong' or 'conditional'. A quorum of 60% of members were needed to be present for a discussion and vote to go ahead and a majority vote of those present was needed for final decisions on each recommendation. The outcomes of the voting are provided in the supplementary material Appendix 2 and 3.

Finally, all recommendations, with the rationales, were collated into a consultation (draft) guideline manuscript that was reviewed by the same clinical experts and persons with lived experience who reviewed the clinical questions, as well as by members of the IWGDF Editorial Board. The working group then collated, reviewed, and discussed all feedback on the consultation manuscript and revised accordingly to produce the final guideline manuscript.

MANAGEMENT OF CONFLICT OF INTERESTS

The classification guideline working group is committed to developing trustworthy clinical practice guidelines through transparency and full disclosure by those participating in the process of guideline development. In order to prevent a major Conflict of Interest (COI) members of the guideline group were not allowed to serve as an officer, board member, trustee, owner, or employee of a company directly or indirectly involved in the topic of this guideline. Before the first and last meeting of the guideline working group, members were asked to report any COI in writing. In addition, at the beginning of each meeting this question was also asked and if answered yes, the members were asked to submit a COI form. These COIs included income received from biomedical companies, device manufacturers, pharmaceutical companies, or other companies producing products related to the field. In addition, industry relationships had to be disclosed each time and these included: ownerships of stocks/options or bonds of a company; any consultancy, scientific advisory committee membership, or lecturer for a company, research grants, income from patents. These incomes could either be personal or obtained by an institution with which the member had a relationship. All disclosures were reviewed by the chair and secretary of the working groups, and these can be found at *www.iwgdfguidelines.org*. No company was involved in the development or review of the guideline. Nobody else involved in the guideline received any payment or remuneration of any costs, except for travel and accommodation expenses when meeting on-site.

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RESULTS

Overall, 5 clinical questions, each with up to 13 (critically) important outcomes, were finalised and addressed by this guideline. The accompanying systematic review identified 149 eligible studies, assessing 28 different systems. Based on the systematic review and expert opinion of the group, 28 summary of judgements tables were completed (see supplementary material Appendix 2) with 7 recommendations developed that address the clinical questions and have in consideration the existence of different clinical settings.

Furthermore, to guarantee the accuracy of most of the systems recommended to characterise foot ulcers, specific training, skills, and experience will be required. These specific skills and training are not described in the studies performed and may differ between centres and countries. Any recommendations, therefore, should be read in the understanding that the person applying the different systems should be an appropriately trained healthcare professional who, according to their national or regional standards, has the knowledge, expertise, and skills necessary to manage people with a diabetes-related foot ulcer following the IWGDF practical guidelines (14).

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RECOMMENDATIONS

FOR COMMUNICATION AMONG HEALTHCARE PROFESSIONALS

Clinical question: In a person with diabetes and a foot ulcer, which classification system(s) is/ are the best for communication among healthcare professionals and to optimise the process of referral?

Recommendation 1a: In a person with diabetes and a foot ulcer, use the SINBAD system for communication about the characteristics of an ulcer between healthcare professionals, and clearly stating the presence or absence of each of the composing variables. (Strength of recommendation: Strong; Certainty of evidence: Low)

Recommendation 1b: In a person with diabetes and a foot ulcer, when resources exist in addition to an appropriate level of expertise and it is considered feasible, consider using the WIfI system for communication about the characteristics of an ulcer between healthcare professionals, but with characterisation of each of the composing variables. (Conditional; Low)

Rationale: Standardising communication between healthcare professionals about the severity of a foot ulcer could greatly improve the quality of any triage process, referral, or follow-up for a person with a diabetes-related foot ulcer. For a classification system to be used by all healthcare professionals managing people with a diabetes-related foot ulcer to make an adequate referral and or triage a referral to them, it should be quick and simple to apply and preferably require no complex or expensive equipment. On the other hand, for it to be useful to the receiving professional, it should contain appropriate information to allow triage of patients to ensure timely review and this may require more detailed information in some settings. Such a classification system should also be confirmed to have a high interobserver reliability. Although most people with diabetes and a foot ulcer may benefit from referral to a multidisciplinary team without delay, factors necessitating urgent review should at least include the dimensions of the ulcer (area and depth), presence of infection, and ischaemia. Any classification system for use as a triage tool will therefore need to include these criteria without the need for measurements that require specialist equipment (e.g., toe pressures, transcutaneous oxygen pressure ($TcPO_2$)). However, in settings where this equipment is available and there is a suspicion or confirmation of the presence of peripheral artery disease, more detailed information is extremely relevant for the receiving professional.

For these recommendations, the group focused on the organizational aspects of the six selected systems, mainly on accuracy measures (retrieved from our systematic review (4)), feasibility, equity, resources, etc.

The SINBAD system grades Site, Ischemia, Neuropathy, Bacterial infection, Area, and Depth as either 0 or 1 point (see below), creating an easy-to-use scoring system that can achieve a maximum of 6 points (15), as described in Table 2

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Table 2: SINBAD system

Category	Definition	Score
Site	Forefoot	0
	Midfoot and hindfoot	1
Ischemia	Pedal blood flow intact: at least one palpable pulse	0
	Clinical evidence of reduced pedal flow	1
Neuropathy	Protective sensation intact	0
	Protective sensation lost	1
Bacterial infection	None	0
	Present	1
Area Ulcer	Ulcer $<1 cm^2$	0
	Ulcer $\geq 1\ cm^2$	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or deeper	1
Total possible score		0 – 6

The SINBAD system is simple and quick to use, requires no specialist equipment beyond clinical examination alone, and contains the necessary information to allow for triage by a specialist team. It would therefore be feasible to employ this classification system in localities where such equipment, including non-invasive measures of perfusion, are not readily available, which is the case for most geographic settings where diabetes-related foot ulcers occur. If used for the purpose of communication among healthcare professionals, it is important to use the individual clinical descriptors and not merely the total score. This scoring system has been validated in 12 studies for several foot ulcer-related clinical outcomes (including healing, amputation, hospitalisation, death, etc.) with somewhat consistent results and also substantial to good reliability (4). Therefore, we consider the description of the presence or absence of the variables included in this system to be the minimum information to be shared for an adequate communication among healthcare professionals about the characteristics of a foot ulcer. For this purpose, we consider that the use of the final score is insufficient.

The classification proposed by Meggitt and modified by Wagner (16) is the oldest classification and grades wounds into pre- or post-ulcerative site (grade 0), superficial ulcer (grade 1), ulcer penetrating to tendon or joint capsule (grade 2), lesion involving deeper tissues (grade 3), forefoot gangrene (grade 4) and whole foot gangrene involving more than two thirds of the foot (grade 5). In our systematic review it was the system with the highest number of articles validating it (n=74) (4). Most of the articles, however, were considered to be at high risk of bias and some inconsistency was observed, along with a predominance of studies reporting association measures instead of accuracy measures. Also, our group considered this classification to have a poor clinical discrimination, as it does not include area, neuropathy, infection and peripheral artery disease individually. It is also rendered blunt by the major impact of gangrene in this classification.

The DIAFORA score includes four foot-related and four ulcer-related variables: neuropathy, foot deformity, arteriopathy, previous foot ulcer or lower extremity amputation; and presence of multiple ulcers, infection, gangrene and/or bone involvement, respectively. This system, like Wagner, also includes

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gangrene (17), but no external validation or reliability assessment was conducted (4) and therefore we could not recommend it for this purpose.

The UTWCS system was used in 30 articles (most at high risk of bias, using stage or grade separately and reported mostly association measures), while the WIfI system was used in 13 (with five being conducted in the same institution and with a larger population including previously reported participants plus additional participants) (4). For both systems the certainty of evidence was considered to be low. The WIfI system uses a combination of scores for wound (based on depth of ulcer or extent of gangrene), ischaemia (based on ankle pressure, toe pressure or $TcPO_2$), and foot infection (based on IDSA/IWGDF criteria), detailed in Table 3, to provide a 1-year risk for amputation and 1-year benefit for revascularisation, both stratified as very low, low, moderate, or high (18). This has benefit over perfusion pressures alone by including associated wound and infection criteria to provide a more holistic wound overview in revascularisation decision-making. UTWCS (19) and WIfI (18) both require equipment and clinical expertise to conduct the ankle-brachial index (ABI) as a minimum, which reduces equity and feasibility. In addition, false positives may lead to more anxiety, and thus we do not support the use of such tests without proper training. On the other hand, those individuals with previous signs and symptoms may already have a recent ABI test result or may be followed in settings in which vascular examination is possible and feasible. Neither UTWCS nor WIfI included loss of protective sensation (for which it is important to recommend offloading) as a variable.

In comparison with the WIfI system, the UTWCS system has less detail and classifies DFUs using a bidimensional 4 × 4 matrix, according to depth (Grades 0, 1, 2, and 3) and presence of infection (Stage B), ischaemia (Stage C), or both (Stage D) (19). The original publication (19) described a combination of clinical signs and symptoms, plus one or more non-invasive criteria (transcutaneous oxygen measurements, ABI, or toe systolic pressure) to assess perfusion. In addition,-size (area) is not included in this classification.

For these reasons, when resources exist in addition to an appropriate level of expertise and it is considered feasible, we recommend healthcare professional to also consider the use of the WIfI system for communication about the characteristics of an ulcer (see Table 3), focusing on the description of the grade of each composing variable.

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