Table 3: WIfI system

Wound

Grade	DFU	Gangrene
0	No ulcer	No gangrene
	Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.	
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
	Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.	
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
	Clinical description: major tissue loss salvageable with multiple (≥ 3) digital amputations or standard TMA ± skin coverage.	
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer ± calcaneal involvement	Extensive gangrene involving forefoot and /or midfoot; full thickness heel necrosis ± calcaneal involvement
	Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or non-traditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect	

Ischaemia

Grade	ABI	Ankle systolic pressure (mmHg)	TP, $TcPO_2$ (mmHg)
0	≥ 0.80	> 100	≥ 60
1	0.6 – 0.79	70 – 100	40 – 59
2	0.4 – 0.59	50 – 70	30 – 39
3	≤ 0.39	< 50	< 30

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Foot Infection

Grade	Clinical manifestations
0	No symptoms or signs of infection Infection present, as defined by the presence of at least 2 of the following items: • Local swelling or induration • Erythema > 0.5 to ≤ 2 cm around the ulcer • Local tenderness or pain • Local warmth • Purulent discharge (thick, opaque to white, or sanguineous secretion)
1	Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). Exclude other causes of an inflammatory response of the skin (e.g., trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis)
2	Local infection (as described above) with erythema >2 cm, or involving structures deeper than skin and subcutaneous tissues (e.g., abscess, osteomyelitis, septic arthritis, fasciitis), and No systemic inflammatory response signs (as described below)
3	Local infection (as described above) with the signs of SIRS, as manifested by two or more of the following: • Temperature > 38°C or < 36°C • Heart rate > 90 beats/min • Respiratory rate > 20 breaths/min or $PaCO_2$ < 32 mm Hg • White blood cell count > 12,000 or < 4000 cu/mm or 10% immature (band) forms

ABI: Ankle-Brachial Index; $PaCO_2$: Partial Pressure of Carbon Dioxide; SIRS: Systemic Inflammatory Response Syndrome; $TcPO_2$: Transcutaneous Partial Oxygen Pressure; TMA: Transmetatarsal Amputation; TP: Toe Pressure

FOR PREDICTING THE OUTCOME OF AN ULCER IN A SPECIFIC INDIVIDUAL

Clinical question: In a person with diabetes and a foot ulcer, which classification system(s) is/ are the best to assess the prognosis of an individual person with diabetes and a foot ulcer?

Recommendation 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)

Rationale: We can use systems in a clinical setting to stratify people by a similar probability of developing a certain event and to create more homogenous groups that should receive similar healthcare or to estimate the individual probability of a specific person with a certain number of characteristics. A good example of the latter is the Framingham Risk Score for cardiovascular disease (20). This model uses six different variables and estimates the individual's risk at 10 years of developing or dying of cardiovascular disease.

To be used as a prognostic tool, a classification system needs to be complex enough to provide individualised outcome prediction yet quick to use within a busy clinical service, ideally not requiring measurements in addition to those performed for routine clinical care. The classification also needs to

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be widely validated for the population in which its use is proposed, as the dominant factors for poor outcomes in foot ulcers in people with diabetes vary worldwide due to differences in the population, the local context and available resources for clinical care. This validation should include how well the classification system predicts both ulcer healing and risk of amputation. However, we found insufficient reporting of accuracy measures of the classifications and, even when they were described, they had wide confidence intervals, due to high variability, small sample sizes and low event rates (eg. for major amputation).

For this purpose we considered that likelihood ratios (both positive and negative) would be the more informative accuracy measures, as they summarise (in this context) how many times it is more (or less) likely for patients to develop the clinical outcome of interest than not developing it when they are classified to be at high risk (or low risk, respectively), and are not affected by the outcomes' prevalence (in contrast to the predictive values) (21).

In the rare cases in which positive likelihood ratios were reported (4) they were below 5, while negative likelihood ratios were around 0.2-0.4, indicating only small changes in the pre- to post-test probability of the clinical outcomes of interest would occur (22). A classification or scoring system should also have good inter- and intra- observer reliability to provide consistency of prognostic outcomes and allow for monitoring of progress with any intervention. None of the systems evaluated met these criteria, and so further research may be required, to either appropriately validate an existing classification, or to develop a classification/ scoring system according to these criteria.

The quality of evidence for the prediction of foot ulcer-related outcomes is weak (4) and thus the applicability of the accuracy of a classification system in predicting individual patient outcomes is poor. This has led to our current strong recommendation against the use of any system for prediction of individual patient outcomes.

FOR CLASSIFYING A PERSON WITH AN INFECTED ULCER

Clinical question: In a person with diabetes and an infected foot ulcer, which classification system(s) is/ are the best to predict clinical and health resources outcomes?

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

Recommendation 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)

Rationale: The IDSA/IWGDF classification consists of four grades diabetic foot infection (see Table 4). It was originally developed as part of the PEDIS classification for research purposes (23) and is used as a guideline for management, in particular to identify which patients require hospital admission. Although the components of each grade may be considered complex, and a previous study has shown only moderate reliability (4), the criteria are widely used.

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Table 4: IDSA/IWGDF system

Clinical manifestations	Infection severity	PEDIS grade
Wound lacking purulence or any manifestations of inflammation	Uninfected	1
Presence of ≥ 2 manifestations of inflammation (purulence, or erythema, tenderness, warmth, or induration), but any cellulitis/erythema extends ≤ 2cm around the ulcer, and infection is limited to the skin or superficial subcutaneous tissues; no other local complications or systemic illness	Mild	2
Infection (as above) in a patient who is systemically well and metabolically stable but which has ≥ 1 of the following characteristics: cellulitis extending >2cm, lymphangitic streaking, spread beneath the superficial fascia, deep-tissue abscess, gangrene, and involvement of muscle, tendon, joint or bone	Moderate	3
Infection in a patient with systemic toxicity or metabolic instability (e.g. fever, chills, tachycardia, hypotension, confusion, vomiting, leucocytosis, acidosis, severe hyperglycaemia, or azotaemia)	Severe	4

In our systematic review, we found eight studies validating this system and, although most were at high risk of bias, they showed that an increase in the severity of the infection was associated with a lower incidence of ulcer healing, higher incidence of amputation, hospital admission(s) and having longer length of in-hospital stays (24).

In 2019, this classification underwent a modification during the process of developing the IWGDF guidelines (25). However, this updated version was derived from a study classified as being at high risk of bias (26) and so, at present, we cannot recommend its use.

Of note, whilst the IDSA/IWGDF is incorporated into WIfI (see Table 3), in situations where only infection is being assessed and equipment is not available to use WIfI, the IDSA/IWGDF infection classification can stand alone. On the other hand, in a case of suspected or confirmed infected ulcer complicated by ischaemia, meaning when in the presence of previously diagnosed peripheral artery disease or in a setting in which surgeons with vascular surgery expertise are available, the use of the WIfI classification could be considered.

The studies conducted to validate the UTWCS system have clearly shown that the concomitant presence of infection and peripheral artery disease in a person with diabetes and an ulcer has an incremental effect on the risk of poor clinical outcomes (such as non-healing, delay in healing, or amputation) as well as in costs (19, 27-36). For example, it is well known that oral antibiotic therapy is less effective in people with limited vascular supply. So, the group considered that, when resources and clinical expertise are available, vascular status should be ascertained.

As discussed for the first clinical scenario (communication between healthcare professionals), when comparing the WIfI with the UTWCS system we considered that the certainty of evidence is similar (low for both) (4), but the level of detail of the WIfI system and the direct link to clinical management

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favors its use in comparison to UTWCS. In our opinion, the remaining classifications do not provide enough information to allow an accurate characterization of an infected foot ulcer.

We would like to emphasise that this recommendation is intended to classify the severity of infection in people with diabetes and an ulcer of the foot only, and not the severity of any lower limb infection overall. In addition, our focus was to base our recommendation on the available evidence of the accuracy of the systems to predict clinical outcomes and health resource use and not to direct health care professionals to clinical management decisions. We draw attention to this, as these differences may create disparities between our recommendations and the strength of these recommendations in comparison to the ones from the infection group (37).

FOR CLASSIFYING A PERSON WITH AN ULCER AND PERIPHERAL ARTERY DISEASE

Clinical question: In a person with diabetes, peripheral artery disease and a foot ulcer, which classification system(s) is/ are the best to predict clinical and health resources outcomes?

Recommendation 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)

Rationale: Given that 1) there is a specific group to create recommendations on how to diagnose and treat peripheral artery disease in people with diabetes, 2) the importance of aligning the recommendations between groups within the IWGDF, and 3) the similarity of the population used (although the peripheral artery disease group included people with gangrene of the foot whereas our populations was restricted to ulcers of the foot alone) and the most important outcomes selected (prediction of healing and amputation), we have shared the results of our systematic review with the peripheral artery disease group and agreed that this group should make the recommendation on which system to use in this specific clinical context.

The peripheral artery disease working group has recommended the use of the WIfI classification to estimate the likelihood of healing and amputation (11). The choice of this system aligns with the classification working group's selection for the other purposes for which recommendations were made (see recommendation 2 and Table 3).

The peripheral artery disease working group applies this recommendation to both people with a foot ulcer or gangrene, focusing on tissue loss. By supporting the use of this system for both types of population we consider that it will also facilitate its implementation as, in people with diabetes and peripheral artery disease, gangrene without an open ulcer is often seen.

The peripheral artery disease working group also reinforces the importance of taking a relevant history for peripheral artery disease and examining the foot pulses, but also that pedal Doppler waveforms in combination with ankle brachial index (ABI) and toe brachial index (TBI) measurements are preferable as methods to diagnose peripheral artery disease in people with diabetes and with foot ulcers. For a population with suspected peripheral artery disease, we endorse the peripheral artery disease group's statements of the importance of access to these diagnostic procedures but highlight the need for the

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clinical experts to perform them reliably and accurately. This method of grading ischaemia is included in the WIfI classification along with the ulcer depth and infection characterization, a system that is considered as relatively easy to apply and accurate when performed in settings where these resources are available.

FOR THE AUDIT OF OUTCOME(S) OF POPULATIONS

Clinical question: In a population of people with diabetes and foot ulcers and in which the purpose is to use for audit, which classification system(s) is/ are the best to predict clinical and health resources outcomes?

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

Rationale: The term "audit" refers to characterisation of all diabetes-related foot ulcers managed in a particular area or centre, to compare outcomes with a reference population or national standard and does not allude to the financial implications of care. Ideally, one classification system should be used internationally to allow comparisons of outcomes. In order to do this, such a classification system would need to accurately assess foot ulcer severity across the spectrum of aetiologies. Thus, healthcare systems where peripheral artery disease is a major contributor to nonhealing, and amputation can be compared with healthcare systems where infection is a major cause of amputation because of limited antibiotic availability. Further, the system should be simple to use, and require no specialist equipment, to allow the necessary clinical data to be collected routinely from all patients in all healthcare settings spanning the spectrum from low to high resource availability.

From the six pre-selected systems, only SINBAD and (Meggitt-)Wagner systems were considered to be clearly feasible. The Wagner classification, as stated previously, was the most frequently reported in the articles that we found in our systematic review (4). However, it is considered as having insufficient detail when compared with SINBAD.

Although none of the existing systems was designed, as far as we are aware, for audit, only the SINBAD score has actually been used for conducting a nationwide audit in the United Kingdom, within the National Diabetes Foot Care Audit (NDFA) of England and Wales. The 2021 annual report of the NDFA (38) reports the outcome of 76,310 people with diabetes with 108,450 ulcers at presentation and showed that a higher SINBAD score led to a lower chance of being alive and ulcer-free at 12 weeks and a higher chance of major amputation within 6 months. The group has determined that no other system should be suggested as an alternative option due to a lack of evidence of the remaining systems feasibility.

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FURTHER CONSIDERATIONS / FUTURE RESEARCH / KEY CONTROVERSIES

This document represents the update of our 2019 recommendations on the classification of foot ulcers in people with diabetes (5). Rather than just including new evidence published since that time, in this round we have conducted a systematic as opposed to a critical review and we have used the full GRADE approach (39) for the evidence analysis and development of the recommendations. This led to a change in the certainty of evidence in several scenarios. In fact, for all recommendations the certainty of evidence was graded as low.

Another change was the proposal of first line and second line systems to be used for communication among professionals and for the management of infected foot ulcers, which we believe will lead to a more tailored use of these systems in the different contexts across the world. With this process we have developed six recommendations as well as including one from the "Peripheral Artery Disease" working group which is embedded in our document (11).

In our systematic review (4) we retrieved 149 articles that assessed 28 different systems used to characterize foot ulcers in people with diabetes. However, the current available evidence remains limited due to a lack of articles directly comparing existing systems, with small sample sizes being common; most studies being graded at high risk of bias, frequently reporting only association measures (without multivariable adjustment); and focusing largely on healing or amputation. All of these aspects should be considered before conducting the much-needed future research on this topic to support the use of existing systems, instead of creating new ones that tend to be merely derivative.

Due to the limitations in the available evidence, we were only able to recommend the use of six (21%) out of the 28 systems found (DIAFORA, IDSA/IWGDF, SINBAD, UTWCS, Wagner and WIfI). Moreover, when choosing the ones more indicated for specific scenarios, DIAFORA, UTWCS and Wagner were not selected to be applied for clinical use or audits.

The systems varied considerably in the number (ranging from 3 to more than 30) and type of variables included. Some require blood samples and biomarkers analysis, others specific equipment, while others only use readily available data. The population for its intended use also varied greatly, from infected diabetes-related foot ulcers to chronic wounds of any type. Some had a bi-dimensional structure, other require the use of an app to improve feasibility, others presented an easy to calculate score, and others are a linear grading system. All of this has an impact on complexity, detail, acceptability and feasibility. Some of the choices made by the group may be debatable, but were transparent, carefully discussed and agreed within this group, and the IWGDF editorial board. Questions will inevitably arise as there is much less information about the process to develop recommendations in the diagnostic and prognostic field than in areas that are about therapeutics or other interventions.

One of the debatable decisions is the use of the Summary of Judgments devised for diagnostic clinical questions when we were actually evaluating prognostic clinical questions. However, we believe that we should focus on the use of these systems to change clinical management and not just on their ability to predict the clinical course of any individual. This leads to the acknowledgement that several of the items

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related to the assessment of the impact of implementing these systems in clinical practice had insufficient supporting evidence and were consequently graded mainly on expert opinion.

As expected, several members of the group had potential conflict of interest concerning some of the identified systems. By looking for experts in the field, it would be predictable that several of the members had any role in developing, validating, or discussing the existing classification systems. In such cases, those members that were authors or co-authors of an article developing a specific system were not able to score or grade any of the items in the risk of bias, summary of judgments, direction, or strength of recommendation in which such potential conflict of interest may have played a role. The group decided to not perform a meta-analysis, because we considered that the expected heterogeneity on the definition of outcomes, follow-up and clinical setting was too high to enable generation of a meaningful meta-analysis.

One of the scenarios for which we assign high priority for development is the potential for a classification to be used in the prognosis of clinical outcome in an individual. For this specific application we believe that a high level of detail would be required and that machine learning techniques (included in decision support systems) may be key. As an example, we have the models developed by Xie et al. (40), although their use may reduce equity, and further validation studies are required. Alternatively, there may be an option for refinement of existing systems. Also, SINBAD has not yet been assessed to improve stratification by including patient-related morbid factors such as the presence of end-stage renal failure or history of past amputation, and it is envisaged that such future determinations, potentially also combined with systemic validated biomarkers, may, at least at a group level, add clinical utility to such wound classification system alone in predicting foot ulcer outcomes.

As in the 2019 IWGDF classification guidelines, we continue to surmise that there may never be a single preferred foot ulcer classification system for people with diabetes, since the specification of any classification will depend heavily on its purpose and clinical setting. Furthermore, we stress the importance of assessing the impact of including the use of a system in clinical practice, such as that seen by the use of the SINBAD system within the UK-based NDFA, which has consistently found that faster referral to a specialist foot care service is associated with fewer severe ulcers and better 12 weeks outcomes (38). Consequently, being able to classify the severity of an ulcer easily and adequately and to communicate it quickly and in a standardized manner to the specialist foot care service is expected to have a positive impact on clinical outcomes.

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CONCLUDING REMARKS

Classification of foot ulcers in people with diabetes is of paramount importance in daily practice. It aims to help in communication among healthcare professionals, assessment/ alignment of broad risk categories and choice of best treatment strategy, as well as audit of clinical outcomes across units and populations.

Based on evidence and consensus judgement using the GRADE methodology, this guideline recommends the use of SINBAD as the priority wound classification system to utilise in people with diabetes and a foot ulcer, for inter-professional communication (describing each composite variable), clinical audits (using the full score), but the use of other more specific assessment systems for infection (IDSA/IWGDF) and peripheral artery disease (WIfI) or when resources exist in addition to an appropriate level of expertise (WIfI).

We encourage clinicians to use the classifications described in this guideline. To do so, specific diagnostic tools are required, standardised definitions (41) should be used and training should be promoted.

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CONTRIBUTION OF AUTHORS

The guideline working group was chaired by FG and MM-S acted as scientific secretary. All members are well-recognised experts in the field with the aim to create an international, multidisciplinary expert guideline committee, including the disciplines endocrinology, internal medicine, physiatry, podiatry and vascular surgery from the United States of America, Europe, Asia and Australia. The working group consisted of eight members in total (the authors of this guideline). All members of the guideline working group were involved in the evidence-to-decision framework process, mostly working in teams (see Methods), from summarising the available evidence in the supporting systematic review (4) to writing the recommendations and rationales. MM-S wrote the draft guideline, and all co-authors reviewed the draft and provided feedback, in writing and during online meetings, during which the content was discussed. All authors reviewed the final draft guideline document and agreed with the content and presentation of the definitive document. All members of the working group undertook Level I GRADE training, and the chair and secretary undertook Level 2 Guideline Methodology training (InGuide program, McMaster University).

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