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SUPPLEMENT ARTICLE

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Diabetic foot ulcer classifications: A critical review

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Abstract

Classification and scoring systems can help both clinical management and audit outcomes of routine care. The aim of this study was to assess published systems of diabetic foot ulcers (DFUs) to determine which should be recommended for a given clinical purpose. Published classifications had to have been validated in populations of > 75% people with diabetes and a foot ulcer. Each study was assessed for internal and external validity and reliability. Eight key factors associated with failure to heal were identified from large clinical series and each classification was scored on the number of these key factors included. Classifications were then arranged according to their proposed purpose into one or more of four groups: (a) aid communication between health professionals, (b) predict clinical outcome of individual ulcers, (c) aid clinical management decision making for an individual case, and (d) audit to compare outcome indifferent populations. Thirty-seven classification systems were identified of which 18 were excluded for not being validated in a population of >75% DFUs. The included 19 classifications had different purposes and were derived from different populations. Only six were developed in multicentre studies, just 13 were externally validated, and very few had evaluated reliability.Classifications varied in the number (4 - 30), and definition of individual items and the diagnostic tools required. Clinical outcomes were not standardized but included ulcer-free survival, ulcer healing, hospitalization, limb amputation, mortality, and cost. Despite the limitations, there was sufficient evidence to make recommendations on the use of particular classifications for the indications listed above.

KEYWORDS

diabetic foot, foot ulcer, classification, professional communication, outcome prediction, clinical decision-making, audit

List of Abbreviations: ABPI, ankle-brachial pressure index; AUROC, area under the receiver operating characteristic curve; CHS, Curative Health Services; CLI, chronic limb ischaemia; cm, centimetres; cu mm, cubic millimetres; DFU, diabetic foot ulcer; DIAFORA, Diabetic Foot Risk Assessment; DUSS, Diabetic Ulcer Severity Score; g, gram; Hz, Hertz; IDSA, Infectious Diseases Society of America; IWGDF, International Working Group on Diabetic Foot; LEA, lower extremity amputation; LOPS, loss of protective sensation; mmHg, millimetres of mercury; NDFA, UK National Diabetes Foot Care Audit; PAD, peripheral arterial disease; PEDIS, perfusion, extent, depth, infection, and sensation; S(AD)SAD, size (area, depth), sepsis, arteriopathy, and denervation; SCI-DC, Scottish Care Information—Diabetes Collaboration; SEWSS, Saint Elian Wound Score System; SIGN, Scottish Intercollegiate Guidelines Network; TBI, toe-brachial index; $TcPO_2$, transcutaneous oxygen pressure; UK, United Kingdom; USA, United States of America; WIfI, wound depth, ischaemia, and foot infection.

1 | INTRODUCTION

The term "diabetic foot ulcer" (DFU) is imprecise. It describes the presence of a break in the skin of the foot in a person with diabetes, which does not promptly heal, but indicates nothing of its type. There are multiple causes that lead to the break in the skin, and once the ulcer has developed, several factors impede its prompt healing. The causes of the break in the skin will vary from person to person, and the causes of the delay in healing will not only vary between people but also vary with time: different factors may be dominant in delaying healing at different stages in the healing process. Effective treatment of any one ulcer depends on the clinician being aware of which causes are most important at any given time and selecting an appropriate management strategy.

1.1 | Classifications for clinical practice and classifications for audit

One purpose of a classification for existing ulcers is to allocate a DFU to a particular group (mainly on the basis of defined causes) in order to facilitate more effective communication between health care professionals. Ideally, there should be just one classification that is used for general clinical practice, even though there is also a place for further systems within more specialist groups. Thus, a classification that is used in general clinical practice is likely to be based on the dominant factors—such as loss of protective sensation (LOPS), peripheral artery disease (PAD), and infection—but these may not be sufficiently detailed for record keeping and communication within tertiary care groups such as vascular or orthopaedic surgery.

Classifications could also be used to predict outcome in individual cases, and yet a third purpose of classification is unrelated to the management of particular episodes but is designed to collect data for the purposes of audit of a population. In this respect, the term "audit" does not refer to financial implications but to the characterization of all of the ulcers managed in a particular area or centre in order to study the outcome of the total population. Comparisons that are then made between different areas or centres can be adjusted to take into account any differences there may be in the types of foot ulcers that are being managed and of the people who have them. By comparing differences in management and outcome in case-mix adjusted populations, it will be possible to define key aspects of best practice with greater precision.

1.2 | Features of a classification for general clinical practice

Because of the complexity of the disease processes involved, it is inevitable that any classification will include documentation of a number of items. In a classification for existing ulcers, these details will have been previously shown to link to the anticipated likelihood of healing within a certain time, and these may be subcategorized into those that are person related (such as age, sex, and specific comorbidities), limb related (such as PAD and LOPS), and those that are ulcer related (such as infection, area, depth, and site on the foot).[1] In general, the signs and clinical tools used to establish the presence of such factors do not all need to be standardized because although this would be ideal, it is simply not possible in every culture and every locality where foot ulcers are managed. Instead, the intention is that the use of the classification will help the clinician to define which factors are present, to help communicate the nature of the problem, and to consider how these affect decisions regarding care.

1.3 | Features of a classification for audit

The features of a classification used for audit are essentially the same as those for clinical practice except that there is a greater need for economy of data collection. This is because audit is likely to include every person whose ulcer is managed in that service or area and it follows that participation can cause a substantial increase in workload unless the data collection is reduced to a minimum. The data should also not require any tests or investigations that are beyond the scope of routine clinical practice. This need to minimize data collection is necessary to reduce the extra workload not just of clinicians but also of those who later perform the analyses.

Given the multiplicity of aims and limitations, a sizeable number of classification systems have been promoted for use in the management of DFUs in recent years. However, there is no consensus on their use. The purpose of this review was to identify published classification and/or scoring systems for active foot ulcers in people with diabetes (population) and to evaluate them on the basis of the extent to which the classification predicts clinical outcome (healing, major amputation, minor amputation, and/or mortality).

The clinical questions behind this review were as follows:

- In individuals with an active DFU, which classification system should be considered for use in communication between health professionals to optimize referral?
- In individuals with an active DFU, which classification/scoring system should be considered when assessing an individual patient to estimate his/her prognosis?
- In individuals with an active DFU, which classifications/scoring system aids decision making in specialty areas to improve clinical outcome?
- In individuals with an active DFU, which classification/scoring system should be considered for regional/national/international audit to allow comparisons between institutions?

Other outcomes might be considered relevant in some circumstances (eg, time to healing/ulcer-free days, morbidity/functional status, and cost [to either family or health care services]) but were not included in the assessment because data evaluating existing classification systems in patients with DFUs are limited. Classifications used to

define the risk of ulcer onset (of new or recurrent ulceration) and to assess Charcot foot were not considered.

2 | METHODS

A system was considered as a classification when people were stratified into groups according to the presence or absence of one or several risk factors. A system was considered as a scoring system when a points system was used, providing different weights for the impact of the presence of each risk factor on the patients' outcome. We included only those classifications created for the purpose of guiding clinical care and/or conducting audit/registries that were derived or validated in articles that described populations with a foot ulcer where at least 75% of subjects had diabetes or presented an analysis of the ability of the classification system to predict outcomes within a subgroup with diabetes. Classification systems that were meant to be used only for the purpose of selecting populations for prospective research and which have not been validated for clinical outcomes were excluded. Broad methodological standards have been published in detail elsewhere.[1]

Reports of studies of large clinical cohorts[2-8] were considered to identify factors most important in predicting clinical outcomes of DFU (namely, healing, major amputation, minor amputation, and/or mortality). These variables were then divided into three major groups[1]: person related, which included presence of end-stage renal disease, increasing age, heart failure, and nonambulatory status; limb related, which included presence of PAD, LOPS, prior minor amputation, and oedema; and ulcer related, which included area, depth, location (forefoot or hind foot), number (single or multiple), and presence of infection. The group selected eight variables by consensus, mainly on consistency between published results as well as on the magnitude of effect and aiming for a balance between completeness and practicability. These factors were as follows:

a. Patient factors: end-stage renal failure
b. Limb factors: PAD; LOPS
c. Ulcer factors: area; depth; location (forefoot/hind foot); number (single/multiple); infection.

To identify all the classifications ever used to classify DFUs, it was decided not to conduct a formal systematic review due to the existence of several recent published systematic and nonsystematic reviews with the same purpose as this document.[9-14] The most recent of these reviews was published in 2016, so a search was conducted in PubMed using the terms “diabetic foot [Mesh]” and “classification” or “scoring systems” to identify possible classifications that could have been published after 2016. We have also consulted experts inside and outside the group to identify all the classifications ever proposed for DFUs.

After the classifications to be included in our review were selected, a search for validation and reliability assessment studies was made using the same procedure. Related references were also searched.

The focus was to extract and assess the currently available evidence against the presence of the eight core variables, complexity, reliability, evidence level, and possible bias. Complexity was assessed by considering the number of included variables and the quality of their description; for evidence level, by considering the stage of the classification development (derivation, internal validation, or external validation conducted); and for possible bias based on the reporting standards of studies and articles on the prevention and management of foot ulcers in diabetes.[1]

The following information was extracted from each classification: clinical setting of the system development, sample size, clinical outcome (primary and secondary), included variables, internal validation, external validation, reliability assessment, complexity, number of included measures, ease of measurement in routine practice, and bias.

Data were collated in an evidence table by pairs of reviewers. Disagreement or differences between reviewers were discussed until general consensus was reached. Individual committee members were not involved in the evaluation of their own work.

3 | RESULTS

In total, 37 classifications were identified (see Figure 1). After a critical review of the articles proposing and validating each classification, 18 were excluded.

A brief description of 19 included DFU classifications, in alphabetical order, is provided. More detailed information on included variables, description, validation, and assessment of reliability of each classification is presented in Tables S1 and S2.

3.1 | Curative Health Services

The Curative Health Services (CHS) system is a descriptive wound classification system. It was created in 2002 and has six grades,[15] based only on depth, infection, and gangrene; it resembles a modified Wagner scale (see Table 1).

The CHS system has been validated three times by the same group,[15-17] in the United States of America (USA), in predicting healing of neuropathic DFUs at 20 weeks of care, and once by a different group in predicting lower extremity amputation (LEA) (total and major).[18]

All studies showed an association between CHS classification and the target outcomes (see Table S2). No reliability assessment has been published.

3.2 | Depth, extent of bacterial colonization, phase of healing, and associated aetiology

This system was proposed by a Jordan University Hospital, in 2004, and creates a score according to depth (D), extent of bacterial colonization (E), phase of healing (P), and associated aetiology (A) (see Table 2).[19] Each component can be scored, according to its severity, from 1 to 3, and a total score ranging from 4 to 12, which is further stratified into three different risk groups linked to management guidelines.[15]

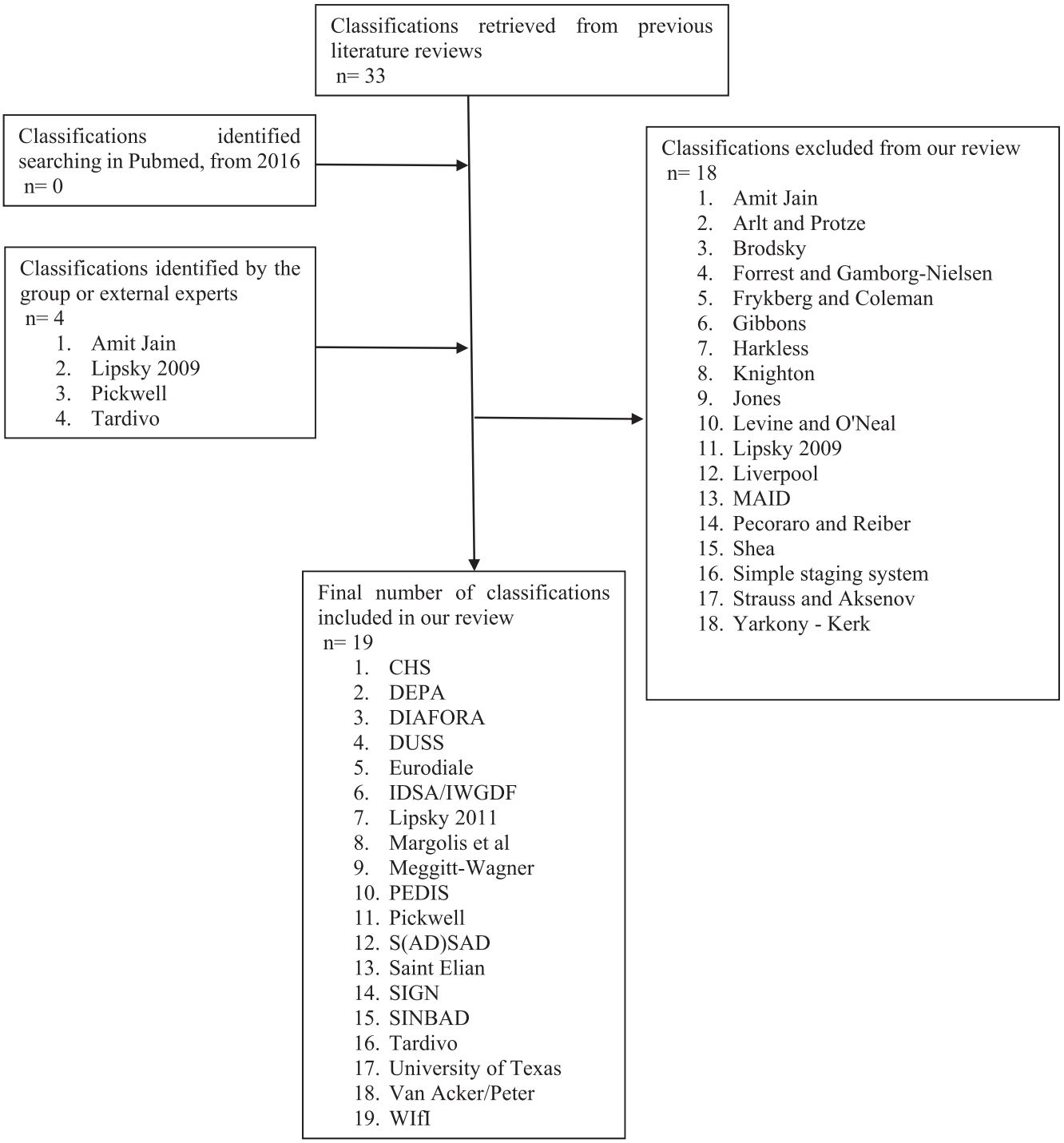

FIGURE 1 Classifications identification and selection flowchart

Although simple, the lack of detailed definition of some components may undermine its reliable application.[10,18] In the original internal validation,[19] all subjects categorized as being at low risk healed in less than 10 weeks, while those categorized as being at high risk underwent an LEA. Accuracy measures are calculable using the available data.[11] Two external validation studies have compared this classification with others,[18,20] using LEA as outcome. Both studies have also reported accuracy measures (see Table S2). No reliability assessment has been published.

3.3 | Diabetic Foot Risk Assessment

The Diabetic Foot Risk Assessment (DIAFORA) tool was created in 2016, in Portugal, and includes eight variables.[21] It is a classification that can be divided into two sections with different purposes. The use of the first four foot-related variables was intended to predict ulcer onset while the use of the complete form including all eight variables is used to predict LEA in people with an existing DFU. It uses a point system to stratify groups of risk (Table 3). There has been no external validation nor reliability assessment.

3.4 | Diabetic Ulcer Severity Score

The Diabetic Ulcer Severity Score (DUSS) classification was intended to estimate the chance of healing of existing ulcers (as well as to predict the need for and costs of hospitalization for treatment) and has four components (presence of pedal pulses, probing to bone, and ulcer location [toes vs foot] and the presence of multiple DFUs), each of which may be either present (score 1) or absent (score 0) and which can be combined to give a total score between 0 and 4, creating an easy-to-use score.[22]

Internal validation for prediction of healing was conducted in a cohort of 1000 patients attending an outpatient wound care unit at a university hospital, in Germany.[22] Four external validation studies have been conducted (in China, India, and Portugal).[18,20,23,24] Two used LEA as outcome[18,20] and provided accuracy measures, while the other two[23,24] used healing as outcome and only provided association measures (Table S2). No reliability study has been published.

3.5 | Eurodiale

The Eurodiale studies comprised several analyses, using prospective data collected from 14 European diabetic foot centres in 10 different countries. In one of the studies, a multivariable predictive model was proposed to predict minor LEA and suggested the following formula: (4 points if male sex) + (18 points if deep ulcer) + (5 points if infected) + (6 points if ischaemic).[25] Ischaemia, infection, and depth were diagnosed using the perfusion, extent, depth, infection, and sensation (PEDIS) criteria (see below for description).[26] This is a fairly simple-to-use system.

No interpretation for the model was provided, and no external validation or reliability assessment has yet been published.

TABLE 1 Curative Health Services system description

Grade	Description
1	Partial thickness involving only dermis and epidermis
2	Full thickness and subcutaneous tissues
3	Grade 2 plus exposed tendons, ligament, and/or joint
4	Grade 3 plus abscess and/or osteomyelitis
5	Grade 3 plus necrotic tissue in wound
6	Grade 3 plus gangrene in the wound and surrounding tissue

3.6 | Infectious Diseases Society of America/ International Working Group on Diabetic Foot

This is a classification only of infection affecting DFUs and was originally developed through expert consensus as part of the PEDIS classification for research purposes. It grades infection into uninfected, mild, moderate, and severe infection.[27] Its purpose is to be used as a framework for managing infected DFUs (see Table 4).

Although it only has four grades, the description of each is complex. One study validated this classification for hospitalization and LEA,[28] one for LEA (total and major),[18] and another for LEA (minor and major) prediction.[29] Higher risk of LEA was observed in all studies with increasing severity of infection. Only the study from Monteiro-Soares et al reported accuracy measures[18] (see Table S2). Measures of agreement were described in two studies. Bravo-Molina et al showed a κ coefficient[29] of 0.574, and Hazenberg et al of 0.44,[30] both indicating moderate agreement between raters who evaluated the same ulcers.

A new version of this classification has been proposed in the new International Working Group on Diabetic Foot (IWGDF) infection guidance document.[31] However, it has not yet undergone any validity or reliability assessment.

3.7 | Lipsky et al

This classification was specific for patients hospitalized with diabetic foot infections. It was proposed in 2011, based on statistical modelling of the results of a multicentre retrospective cohort study to predict LEA, conducted in the United States.[27]

TABLE 2 DEPA score

	Score		
DEPA Score	1	2	3
Depth of the ulcer	Skin	Soft tissue	Bone
Extent of bacterial colonization	Contamination	Infection	Necrotizing infection (infected ulcer with surrounding cellulitis or fasciitis)
Phase of ulcer	Granulating (evidence of granulation tissue formation)	Inflammatory (hyperaemic ulcer with no granulation tissue <2-week duration)	Nonhealing (nongranulating ulcer >2-week duration)
Associated aetiology	Neuropathy	Bone deformity	Ischaemia (clinical signs and symptoms of chronic lower limb ischaemia)
Grade of DFU	Low: score <6	Moderate: scores 7-9	High: scores 10-12 or DFU + wet gangrene

Abbreviations: DEPA, depth, extent of bacterial colonisation, phase of healing, and associated aetiology; DFU, diabetic foot ulcer.

TABLE 3 DIAFORA system

Variables	Definition	Points
Foot related		
Neuropathy	Inability to feel Semmes-Weinstein monofilament at ≥1 of 4 points (hallux pulp, first, third, and fifth metatarsal heads)	4
Foot deformity	Foot alteration increasing pressure in more than or equal to one site of the foot	1
Arteriopathy	Less than or equal to one palpable pedal pulse (posterior tibial and dorsalis pedis arteries)	7
Previous diabetic foot ulcer or lower extremity amputation	History of previous diabetic foot ulcer or lower extremity amputation	3
Diabetic foot ulcer related		
Multiple foot ulcers	Presence of ≥1-ft ulcers	4
Infection	Purulent discharge with another two local signs (warmth, erythema, lymphangitis, lymphadenopathy, oedema, or pain)	4
Gangrene	Presence of necrosis (dry or wet)	10
Bone involvement	Bone exposure identified through visual inspection, touch with sterile probe, and/or bone affection identified through X-ray	7
Risk groups		
<15 points	Low risk of lower extremity amputation	
15-25 points	Medium risk of lower extremity amputation	
>25 points	High risk of lower extremity amputation	

TABLE 4 IDSA/ IWGDF system

Clinical Manifestations	Infection Severity	PEDIS Grade
Wound lacking purulence or any manifestations of inflammation	Uninfected	1
Presence of more than or equal to two manifestations of inflammation (purulence or erythema, tenderness, warmth, or induration), but any cellulitis/erythema extends ≤2 cm 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 that has more than or equal to one of the following characteristics: cellulitis extending >2 cm, 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 (eg, fever, chills, tachycardia, hypotension, confusion, vomiting, leukocytosis, acidosis, severe hyperglycaemia, or azotaemia)	Severe	4

Abbreviation: PEDIS, perfusion, extent, depth, infection, and sensation.

The final model and score calculation was 0.1372 × (chronic renal disease or creatinine >3 mg/dL) + 0.1988 × (male sex) + 0.2830 × (temperature <96°F or >100.5°F) + 0.5477 × (age ≥50 years) + 0.5168 × (infected ulcer vs cellulitis) + 0.5020 × (LEA history) + 0.6203 × (albumin <2.8 g/dL) + 0.7485 × (PAD history) + 0.9596 × (white blood cell count ≥11) + 1.3845 × (surgical site vs cellulitis) + 1.6418 × (transferred from other acute care facility), where each value in parentheses equals 1 if present or 0 if absent.

A simplified version of the score was proposed by summing all the variables present on admission and creating five strata (0, 1-4, 5-11, 12-20, and ≥21). In those with 0 points, no LEAs occurred, while in those with 21 or more points, approximately 50% required an LEA. The observed risk for LEA, in the derivation and validation sample, in those with 1 to 4 points was roughly 5%, those with 5 to 11 points was 10%, and with 12 to 20 points ranged from 20% to 25%. "PAD history" was not defined.

A derivation and an internal validation were conducted simultaneously within this study by splitting the sample into unequal groups of 2230 and 778 participants while ensuring similar baseline characteristics across these groups. The results of these analyses showed good model discrimination and calibration values.[27] There have been no published studies of either external validity or reliability.

3.8 | Margolis et al

Different models were proposed by Margolis et al using data from 150 wound care facilities run by a single organization in the United States to predict healing of neuropathic ulcers at 20 weeks.[16] The simplest model comprised duration more than 2 months + area more than 2 cm^2 and CHS wound grade more than or equal to 3, with each component counting as 1 point. This score provided an area under the receiver operating characteristic (AUROC) curve of 0.8 for nonhealing

(including LEA and death) by 20 weeks in an internal validation study[16] and of 0.66 in a further study.[17] Of note, at 20 weeks, 35% of uncomplicated neuropathic DFUs were not healed,[16] and the outcome "not healed" in these studies included LEA and death.

This simplest model was externally validated only once, in a study also reporting accuracy measures[18] (see Table S2). No reliability assessment has been published.

3.9 | Meggitt-Wagner

This is the system that has been most used historically,[12] although less so in recent years. It was described by Meggitt in 1976,[32] and Wagner disseminated it in 1979.[33] This classification includes six grades but is based largely on wound depth and tissue viability (Table 5).

Other variables (such as LOPS) are not considered, and infected and/or ischaemic DFUs cannot be adequately differentiated by this classification system.[9,10,13]

Several authors consider this classification to be too linear and simplistic, leading to high levels of imprecision.[9,12]

Despite its weaknesses, there have been a number of studies that report an association between grade and LEA,[6,18,20,29,34-42] and accuracy measures have also been published (see Table S2). Regarding reliability assessment, Bravo-Molina et al reported a κ coefficient of 0.55, indicating a moderate level of agreement between raters who evaluated the same ulcers.[29]

3.10 | Perfusion, extent, depth, infection, and sensation

Perfusion, extent, depth, infection, and sensation was designed by the IWGDF in 2003 and updated in 2007, for selection of participants for clinical research.[26,43] However, it has also been used for clinical audit in one study.[26]

This system includes five components: perfusion (PAD), extent (area), depth, infection, and sensation (neuropathy). Detailed and complex definitions of all components are provided (Table 6), which makes it difficult to use in all contexts. Because it was designed as an aid for prospective research, it does not provide a defined outcome against which to assess ulcer types.[9,11]

TABLE 5 Meggitt-Wagner system

Grade	Description
0	Preulcerative or postulcerative site
1	Superficial ulcer
2	Ulcer penetrating to tendon or joint capsule
3	Lesion involving deeper tissues
4	Forefoot gangrene
5	Whole foot gangrene involving more than two thirds of the foot

One study has undertaken external validation of this classification for the prediction of wound healing in Tanzania,[34] while another in China assessed it for predicting a combined end point of nonhealing, LEA, or death.[36] The latter reported accuracy measures (see Table S2). One study reported single and multiple observer agreement using intraclass correlation coefficients, reporting a κ coefficient of 0.57, indicating a moderate agreement between raters.[44]

3.11 | Pickwell et al

In this classification, scores to predict both total amputation and amputation excluding those limited to the lesser toes (second to fifth) were created using data from individuals with an infected DFU included in the Eurodiale consortium studies.[45]

The authors provided not only a complete model but also a simplified version that includes the following variables (Table 7).

Peripheral artery disease was recorded using the PEDIS classification definition.[43]

Score may vary from 0 to 4.5 to predict any amputation and from 0 to 6.5 to predict amputation excluding those limited to the lesser toes. No instructions are given on how to stratify patients. The authors[45] report that, using the score to predict any amputation, only 6% of those in the lowest tertile had an event in comparison with 50% in those in the highest tertile. Using the score to predict amputation limited to the lesser toes, the respective percentages were 1% and 39%.

Only internal validation has been published,[45] providing AUROC values for the complete and simplified systems as well as for the PEDIS classification. No reliability assessment was found.

3.12 | Size (area, depth), sepsis, arteriopathy, and denervation

The size (area, depth), sepsis, arteriopathy, and denervation (S[AD]SAD) system was published in 1999 and was designed mainly for clinical audit.[46] This name derives from an acronym: size (area, depth), sepsis, arteriopathy, and denervation. The components are the same as those used in the PEDIS system, although each component is graded on a four-point scale according to severity (Table 8).

To detect and define ischaemia, the authors proposed the use of palpation of foot pulses and the presence of gangrene, criteria that have been criticized.[47] In the original description, assessment of LOPS was performed using the Neurotip, which may not translate well into current clinical practice as the most commonly used tool is the 10-g monofilament and/or tuning fork. Moreover, Charcot foot is included in the most severe grade of LOPS, but the aetiology of this deformity is complex with likely multiple causes.[9,47]

In 2004, the first external validation was conducted.[48] An overall score was calculated by adding the five component scores, which can vary from 0 to 3, and achieving a possible score between 0 and 15.

TABLE 6 PEDIS system

Grade	Description
Perfusion	
1	No symptoms or signs of peripheral arterial disease (PAD) in the affected foot, in combination with the following: • Palpable dorsal pedal and posterior tibial artery or • Ankle-brachial index 0.9 to 1.10 or • Toe-brachial index >0.6 or • Transcutaneous oxygen pressure ($TcPO_2$) >60 mmHg
2	Symptoms or signs of PAD but not of critical limb ischemia (CLI): • Presence of intermittent claudication (in case of claudication, additional non-invasive assessment should be performed), as defined in the document of the International Consensus on the Diabetic Foot or • Ankle-brachial index <0.9 but with ankle pressure >50 mmHg or • Toe-brachial index <0.6 but systolic toe blood pressure >30 mmHg or • Transcutaneous oxygen pressure ($TcPO_2$) 30 to 60 mmHg or • Other abnormalities on non-invasive testing, compatible with PAD (but not with CLI)
3	Critical limb ischaemia, as defined by • Systolic ankle blood pressure <50 mmHg or • Systolic toe blood pressure <30 mmHg or • $TcPO_2$ <30 mmHg
Extent/size	
1	Superficial full thickness ulcer not penetrating any structure deeper than the dermis
2	Deep ulcer, penetrating below the dermis to subcutaneous structures, involving fascia, muscle, or tendon
3	All subsequent layers of the foot involved, including bone and/or joint (exposed bone, probing to bone)
Infection	
1	No symptoms or signs of infection
2	Infection involving the skin and the subcutaneous tissue only (without involvement of deeper tissues and without systemic signs, as described below). At least two of the following items are present: • 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) Other causes of an inflammatory response of the skin should be excluded (eg, trauma, gout, acute Charcot neuro-arthropathy, fracture, thrombosis, and venous stasis).
3	Erythema >2 cm plus one of the items described above (swelling, tenderness, warmth, discharge) or infection involving structures deeper than skin and subcutaneous tissues such as abscess, osteomyelitis, septic arthritis, and fasciitis. No systemic inflammatory response signs, as described below.
4	Any foot infection with the following signs of a systemic inflammatory response syndrome. This response is manifested by two or more of the following conditions: • Temperature >38°C or <36°C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min • Partial pressure carbon dioxide ($PaCO_2$) <32 mmHg • White blood cell count >12.000 or <4.000/mm^3 • 10% immature (band) forms
Sensation	
1	No loss of protective sensation on the affected foot detected, defined as the presence of sensory modalities described below
2	Loss of protective sensation on the affected foot is defined as the absence of perception of the one of the following tests in the affected foot: • Absent pressure sensation, determined with a 10-g monofilament, on two out of three sites on the plantar side of the foot, as described in the International Consensus on the Diabetic Foot • Absent vibration sensation (determined with a 128-Hz tuning fork) or vibration threshold >25 V (using semiquantitative techniques), both tested on the hallux

Abbreviation: PEDIS, perfusion, extent, depth, infection, and sensation.

This classification was validated in three studies that assessed its ability to predict DFU healing,[40,48,49] with the outcome defined as healing percentage[34] or time to complete reepithelialization.[50] Association measures are reported in these analyses only for its constituent scales and not for the total score (see Table S2).

TABLE 7 Pickwell et al simplified system

	Any Amputation (Points)	Amputation Excluding Lesser Toes (Points)
Sex		
Female	0	0
Male	0.5	1
Peripheral arterial disease		
No	0	0
Yes	1	1
Yes with ankle-brachial index <0.5	1.5	2
Pain or tenderness on palpation		
No		0
Yes		0.5
Ulcer size, cm^2		
<1		0
1-5		0.5
>5		1
Ulcer depth		
Superficial	0	0
Deep without probing to bone	1.5	1
Deep with probing to bone	2	2
Periwound oedema		
No	0	
Yes	0.5	

No reliability measures have been reported although one study stated that there was good agreement between two clinicians, using a subset of the sample, without providing any quantitative measures of agreement.[48]

3.13 | Saint Elian Wound Score System

This classification evolved from PEDIS, by including five additional variables: foot ulcer location (toes, metatarsal or tarsal), "topographic aspect" (dorsal, plantar, medial, lateral), number of affected "zones," healing phase (epithelializing, granulating, inflammatory), and foot oedema.[51] A score ranging from 6 and 30 is calculated (Table 9).

Ischaemia was diagnosed using foot pulse palpation, ankle-brachial systolic blood pressure index (ABPI), or toe-brachial index (TBI). Neuropathy was identified using the 10-g monofilament or a 128-Hz tuning fork.[51]

The internal validation study[51] included 235 subjects and was conducted in Mexico. There are several numerical discrepancies in the report, which may possibly be explained by a high attrition rate mainly in the "severe" group. In this study, a κ value of 0.8 was reported, using two observers to classify 235 DFUs.

This classification was externally validated in two studies, for amputation (total and major)[18] and for prediction of healing (including minor amputation).[39] Both reported accuracy measures (see Table S2). In Monteiro-Soares et al, this classification was compared with 11 systems to predict total amputation[18] and, along with SIGN/ SCI-DC, yielded the lowest AUROC curve values.

3.14 | Scottish Intercollegiate Guidelines Network/Scottish Care Information—Diabetes Collaboration

This system was created to predict DFU onset.[52] As a result, it does not include any ulcer characteristics such as area, depth, or infection (Table 10). By assessing foot pulses, monofilament sensation, foot deformity, ability to self-care, and history of DFU, this classification stratifies people with diabetes into three risk groups. It was, however, used in a single study of the prediction of healing of established ulcers.[52]

The system has been externally validated and was compared with 11 other systems.[18] For total amputation prediction, this classification along with Saint Elian Wound Score System (SEWSS) yielded the lowest AUROC curve values. No reliability assessment has been published.

3.15 | Site, ischaemia, neuropathy, bacterial infection, area, and depth

The site, ischaemia, neuropathy, bacterial infection, area, and depth (SINBAD) score was designed for audit of populations of ulcers and includes the same clinical variables as S(AD)SAD plus site and grades each one as absent (0 points) or present (1 point), creating an easy-to-use scoring system that can achieve a maximum of 6 points.[53]

Site is dichotomized as forefoot (0 points) vs midfoot or hind foot (1 point), absence of ischaemia as at least one pulse palpable (0 points) vs clinical evidence of reduced pedal blood flow (1 point), LOPS (detected using Neurotip or 10-g monofilament) as intact (0 points) vs lost (1 point), bacterial infection (defined using IWGDF criteria) as absent (0 points) or present (1 point), area as less than (0 points) vs equal to greater than 1 cm^2 (1 point), and depth as either confined to skin and subcutaneous tissue (0 points) vs reaching muscle, tendon, or deeper (1 point).[53] Ince et al in 2008 conducted a multicentre study comparing the ability of this system to predict time to heal in four different countries (United Kingdom [UK], Germany, Tanzania, and Pakistan).[53] Results varied by country, but a score equal or superior to 3 predicted a worse prognosis in all settings.

Three studies have externally validated the ability of this score to predict healing[36] and LEA,[18,20] reporting high-accuracy values (see Table S2). This system was chosen for the UK National Diabetes Foot Care Audit (NDFA).[9] The 2018 annual report of the NDFA included 19 453 patients with ulcers at presentation and showed that a higher

TABLE 8 Size (area, depth), sepsis, arteriopathy, and denervation (S[AD]SAD) system

	Size				
Grade	Area	Depth	Sepsis	Arteriopathy	Denervation
0	Skin intact	Skin intact	None	Pedal pulses present	Sensitivity intact
1	<1 cm^2	Superficial (skin and subcutaneous tissue)	Surface	Pedal pulses reduced or one missing	Sensitivity reduced
2	1-3 cm^2	Tendon, periosteum, joint capsule	Cellulitis	Absence of both pedal pulses	Sensitivity absent
3	>3 cm^2	Bone or joint space	Osteomyelitis	Gangrene	Charcot

TABLE 9 Saint Elian Wound Score System (SEWSS)

Anatomical	Aggravating Factors	Affected Tissues
Location (1-3) 1. Phalanges/digits 2. Metatarsal 3. Tarsal	Ischemia (0-3) 4. No 5. Mild 6. Moderate 7. Severe	Depth (1-3) 1. Superficial (skin only) 2. Deep ulcer (below dermis) 3. All layers (bone and joint)
Topographic aspects (1-3) 1. Dorsal or plantar 2. Lateral or medial 3. Two or more	Infection (0-3) 4. No 5. Mild. Erythema <2 cm, induration, tenderness, warmth, and purulent discharge 6. Moderate. Erythema >2 cm, muscle, tendon, or bone or joint infection 7. Severe. Systemic inflammatory response	Area (1-3) 1. Small <10 cm^2 2. Medium 10-40 cm^2 3. Big >40 cm^2
Affected zones (1-3) 1. One 2. Two 3. Entire foot (multiple wounds)	Oedema (0-3) 4. No 5. Periwound 6. Affected leg only 7. Bilateral secondary to systemic disease Neuropathy (0-3) 4. No 5. Protective sensation or vibration diminished 6. Loss of protective sensation or vibration 7. Diabetic neuro-osteoarthropathy—Charcot	Wound healing phase (1-3) 1. Epithelization 2. Granulating 3. Inflammatory
Score Sum	Grade	Prognosis
≤10	I. Mild	Likely successful wound healing
11-20	II. Moderate	Partial foot threatening; outcome related to "state-of-the-art" therapies used and associated with a good patient biological response
21-30	III. Severe	Limb and life threatening; outcome unrelated to "state-of-the-art" therapies because of poor biological patient response

score led to a lower chance of being alive and DFU free at 12 and 24 weeks.[5] In addition, one study reported single and multiple observer agreement using the intraclass correlation coefficient, with κ values of 0.44 and 0.91, respectively.[44]

3.16 | Tardivo algorithm

This classification was developed at a Center for Diabetic Foot in Brazil and corresponds to an extension of the Meggitt-Wagner system by adding PAD, classified according to PEDIS,[43] and DFU location.[54]

There are four grades of wound severity according to Meggitt-Wagner system: Grade 1 ulcers will be scored with 1 point, grade 2 with 2 points, grade 3 with 3 points, and grade 4 with 4 points. Adequate perfusion according to PEDIS is scored with 1 point, while those with clinical signs of ischaemia receive 2 points. An ulcer located in the toes is scored with 1 point, in the metatarsal regions with 2 points, in the midfoot with 3 points, and in hind foot with 4 points. The final score is a product of all these three scores and can vary from 1 to 32.

TABLE 10 SIGN/SCI-DC system

Low Risk	Moderate Risk	High Risk
Able to detect at least one pulse per foot AND Able to feel 10-g monofilament AND No foot deformity and physical or visual impairment No history of previous foot ulcer	Unable to detect both pulses in a foot OR Unable to feel 10-g monofilament OR Foot deformity OR Unable to see or reach foot No history of previous foot ulcer	Previous foot ulceration or amputation OR Absent pulses AND Unable to feel 10-g monofilament OR One of above with callus or deformity

TABLE 11 University of Texas system

Stage/Grade	0	1	2	3
A	Preulcerative or postulcerative lesion completely epithelized	Superficial wound, not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	With infection	With infection	With infection	With infection
C	With ischaemia	With ischaemia	With ischaemia	With ischaemia
D	With infection and ischaemia	With infection and ischaemia	With infection and ischaemia	With infection and ischaemia

Only an internal validation has been published,[54] and this concluded that those with a score equal or superior to 12 had an odds ratio for amputation of 152 compared with a score of 11 or lower. No reliability assessment was found.

3.17 | University of Texas

This classification system was developed at the University of Texas Health Science Centre in San Antonio in 1996[55] and validated in 1998.[56]

It classifies DFUs using a bidimensional 4 × 4 matrix, according to depth (grade 0, 1, 2, 3) and presence of infection (stage B), ischaemia (stage C), or both (stage D) (see Table 11), which is simple to apply.

Infection is defined as frank purulence and/or two or more of the following local signs: warmth, erythema, lymphangitis, lymphadenopathy, oedema, pain, and loss of function.[12]

Ischaemia is diagnosed using a combination of clinical signs and symptoms (claudication, rest pain, absent pulses, atrophic integument [skin], absence of pedal hair, dependent rubor, or pallor on elevation) plus one or more non-invasive criteria (transcutaneous oxygen measurements of <40 mmHg, ABPI of <0.80, or toe systolic pressure of <45 mmHg).[55]

Loss of protective sensation and size (area) are not included in this classification.[55]

This classification was internally validated in 1998[56] and externally validated by seven studies.[6,18,20,34,38,40,57] All showed an association between higher stage and grade and poor outcome. Two of these studies also provided accuracy measures using amputation as outcome (see Table S2).

A reliability assessment by Bravo-Molina et al presented a κ value of 0.513, indicating moderate agreement between raters assessing the same ulcers.[29] According to Forsythe et al, this classification has a reliability comparable with PEDIS and SINDAD.[44]

3.18 | Van Acker-Peter

This classification system is a modified version of the University of Texas system. It is also a two-dimensional matrix that grades depth in the vertical axis and foot characteristics in the horizontal axis. Additionally, it provides a chromatic code according to the DFU prognosis, from light to dark grey (see Table 12).

Loss of protective sensation is defined by abnormal monofilament and/or vibration perception, abnormal deep tendon reflexes, or abnormal electromyography.[41] Ischaemia is defined by any of the following criteria being present: systolic ankle blood pressure less than 50 mmHg, ABPI less than 0.9, or transcutaneous oximetry ($TcPO_2$) less than 50 mmHg.[41]

The extent of infection is classified as 1: extremely superficial ulcer without important signs of infection, 2: small ulcer with cellulitis without involvement of tendons and bone, 3: more severe infected ulcer with involvement of tendons and/or bone with/without abscess, 4: periostitis, involvement of the bone without signs of destructive osteomyelitis; typical, bone contact without visible defects on radiography, and 5: overt radiographic destructive osteomyelitis.[41] Charcot foot was included, even though it is considered a different clinical entity by several authors.[9,47]

One study conducted an internal validation of this system,[41] showing a good correlation with the Meggit-Wagner classification with healing as the outcome, and another externally validated it,[18] finding that this classification had similar accuracy compared with 11 others to predict LEA.

No reliability assessment has been conducted.

TABLE 12 Van Acker/Peter system

Type of Lesion	Superficial Epidermis Dermis	Minor Soft Tissue Dermis	Major Soft Tissue	Periostitis	Complicated Osteomyelitis (With Major Destruction and Fracture of Bone and Major Involvement of Soft Tissue or Bone Contact)
Degree of risk	1	2	3	4	5
Foot pathology					
A. Insensitive foot					
B. Insensitive plus bone deformations					
C. Charcot's foot					
D. Ischaemic foot					
E. Mixed insensitive plus vascular					

3.19 | Wound depth, ischaemia, and foot infection

This system is a threatened-limb classification system[58] proposed in 2014 that focuses on stratifying the 1-year risk of major amputation and predicting the likelihood that revascularization would be required for wound healing and limb salvage. The purpose behind the creation of this system was to provide more precise description of limb-related disease burden and thus more accurately assess outcomes across patients with similar characteristics and to serve as a guide for selection of therapies. Members of the Society of Vascular Surgery Lower Extremity Guidelines Committee used a Delphi technique to create strata of possible combinations of outcome predictors leading to four clinical limb stages corresponding, respectively, to a very low, low, moderate, or high risk of any individual requiring an LEA within 1 year and very low, low, moderate, or high likelihood of benefiting/requiring a revascularization (assuming infection can be controlled first).[58]

The classification system includes a DFU characterization using wound depth (W); degree of ischaemia (I) (based on ABPI, transcutaneous oxygen tension, and toe systolic pressure), and the presence or absence of foot infection (fI). Infection was graded using the Infectious Diseases Society of America (IDSA)/International Working Group on Diabetic Foot (IWGDF) criteria. Each one of the three components is scored from 0 to 3 (Table 13).

Wound area is not considered quantitatively. Ischaemia characterization requires moderate expertise and equipment, which, depending on the clinical setting worldwide, may not always be available. On the other hand, one of the main purposes of this classification was to increase the detail of perfusion status characterization to allow objective decision making of the need for revascularization. None of the descriptions of WIfI that we reviewed included LOPS as a classification criterion. In 2015, its internal validation was conducted,[59] showing an association between severity of its components and both time to DFU healing and major LEA occurrence. Since then, five studies have provided external validation of WIfI in populations where at least 75% of subjects had DFUs.[60-64] Four of them, however, were conducted in the same institution and with a larger population including previously reported participants plus additional participants, which may have the original sample from which the classification was developed.[60-62,64]

This classification has been shown to predict multiple pertinent DFU outcomes, including extent of healing, time to heal, LEA occurrence, LEA-free survival, need for revascularization, maintenance of ambulatory and independent living status, costs, and mortality.[59-62,64] Overall, its use has since been endorsed by many centres and societies worldwide.

One reliability assessment conducted by Tokuda et al[65] demonstrated impressively high levels of interobserver and intraobserver reproducibility of WIfI. This article though was not included in this review as fewer than 75% of subjects had diabetes.

4 | DISCUSSION

This work has reviewed classifications, which are used for established ulcers of the foot in people with diabetes. The use of classifications to define people with feet at risk of new (or recurrent) ulceration has not been considered. Similarly, little attention has been paid to descriptions of the criteria used for selection of ulcers for prospective research because these can be specified in the selection criteria and have been summarized elsewhere.[1]

Classifications for people with established ulcers have two main purposes: (a) to summarize the clinical details for the purposes of communication and in order to highlight the plans for management of individual cases and (b) to allocate ulcers to different broad groups in order to ensure that any attempt to demonstrate variations in outcome between populations takes into account any possible population differences. The first of these is likely to focus on subspecialty care in, for instance, the management of infection, specific types of wounds, and, in particular, the assessment and treatment of PAD. The second is most likely to be used in making retrospective comparisons in outcomes between different centres and regions (comparative audit). Some classifications may be more appropriate for one of these two purposes as opposed to the other, although different clinicians may use them in different ways.

TABLE 13 WIfI system

Wound			
Grade	DFU	Gangrene	
0	No ulcer	No gangrene	
	Clinical description: minor tissue loss. Salvageable with simple digital amputation (one or two 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 (one or two 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 transmetatarsal amputation (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 6 calcaneal involvement	
	Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or nontraditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect		
Ischaemia			
Grade	Ankle-Brachial Index	Ankle Systolic Pressure, mmHg	Toe Pressure, Transcutaneous Oxygen Pressure, 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
Foot infection			
Grade	Clinical Manifestations		
0	No symptoms or signs of infection Infection present, as defined by the presence of at least two 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 (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, and venous stasis)		
2	Local infection (as described above) with erythema >2 cm or involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, and 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 mmHg • White blood cell count >12 000 or <4000 mm^3 or 10% immature (band) forms		

Abbreviation: SIRS, systemic inflammatory response signs; WIfI, wound depth, ischaemia, and foot infection.

It should be emphasized that classifications may also be useful for continued surveillance and some should be repeated following an intervention and periodically to detect changes in the DFU, either improvement (healing) or worsening (eg, infection occurrence).

All identified classifications were scored using a list of eight features agreed by the authors as being those most closely associated with better or worse outcome of an ulcer. In addition, account was taken of whatever internal and external validation had been undertaken as well as any attempt to define reproducibility.

While the Wagner system was the first to be widely adopted, it is not well validated and does not distinguish well between ulcer types for either main purpose of classification. The University of Texas classification is well validated and has become widely used but suffers from lack of reference either to neuropathy or to ulcer area, which is considered to be one of the main determinants of time to healing.

Infectious Diseases Society of America/International Working Group on Diabetic Foot was originally developed as a guideline designed to aid decisions regarding hospital admission but was later evaluated not for this purpose but as a predictor of LEA (combined major and minor amputation). However, there is a possibility that this might to some extent have been self-fulfilling.

Overall, the system that scored most highly for prospective use in clinical management was the WIfI system for the expert assessment and reassessment of peripheral tissue perfusion. In contrast, the most highly scoring system for defining populations (of ulcers, limbs, and people) for the purpose of audit of clinical outcome was the SINBAD system. SINBAD is the most broadly validated system as judged by number of included participants and different contexts of validation research and with largely consistent results.

Although some classifications can be used in a specialist context (eg, to determine the need for detailed investigation of one component of the ulcer, such as PAD), it is important that the system adopted allows the care team to remain vigilant regarding other components and the associated care processes.

The selection of one system to be used is always controversial, as its performance and usability will vary according to geographic region (and consequent population characteristics) as well as to availability of resources. Nevertheless, it was decided that there was sufficient evidence available to make recommendations on the use of particular classifications for particular indications. It was concluded that for the purpose of communication between clinicians, the SINBAD classification should be used. It was also concluded that the IDSA/IWGDF system should be chosen for categorization of infection, while the WIfI system should be chosen for assessing perfusion and any likely benefit of revascularization. It was also concluded that there was no classification that could be used to define prognosis in any individual ulcer. Finally, for the audit of populations with DFU in order to compare presentation or outcome between different centres or areas, it was recommended that the SINBAD classification should be used.

Future research should be undertaken to establish whether increasing the complexity of classifications by the addition of features such as ESRD, single/multiple ulcers, more detailed site of ulcers (such as plantar/dorsum), or more detailed measures of limb ischaemia significantly improves the validity of the system to predict the outcome, without compromising reliability or clinical utility.

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CONFLICT OF INTEREST

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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