

Best Practice Statement

Care of the person with diabetes
and lower limb ulcers

2021



Foundation of education

Person-centred care

Prompt referral

Standard of care

Treatment pathway

Supported shared care

**BEST PRACTICE STATEMENT:
CARE OF THE PERSON WITH
DIABETES AND LOWER LIMB
ULCERS**

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Foreword

The growing burden of diabetes and its complications has led to a national diabetes strategy with the aim to commission equitable and accessible services for lower limb ulceration (NHS England, 2020). The aim is to reduce unwarranted variation of care, increase the use of evidence-based care and discourage the over-use of therapies for which there is insufficient evidence, thereby resulting in higher healing rates (Gray et al, 2018; The National Wound Care Strategy Programme [NWCSP], 2020).

While the COVID-19 pandemic has shifted priorities of the workforce and reduced access to services, for some, it has accelerated initiatives towards greater patient- and carer-supported self-management (NHS England and NHS Improvement, 2020). The NWCSP (2020) also seeks to support greater shared care with patients and their carers as an opportunity to improve quality in care, healing rates and patient quality of life.

An Expert Working Group encompassing a diverse range of specialities met online to discuss the care of people living with diabetes and lower limb ulceration. This Best Practice Statement document reflects on the *Best practice recommendations for the implementation of a DFU treatment pathway* (Allam et al, 2018) and addresses the challenges that clinicians continue to face when attempting to implement consistent care. The Expert Working Group also updated the treatment pathway from Allam et al (2018) to continue to make it relevant for today's challenges and to ensure it can be used by all health professionals involved with the care of people with a lower limb ulcer and living with diabetes (page 16).

This new document is for all health professionals that care for people with diabetes with or at risk of ulceration to facilitate early detection and referral to a specialist or specialist team. The treatment pathway particularly encourages all clinical and support staff to work collaboratively to deliver consistent care to patients and reduce variation across geographies.

Graham Bowen, Chair

Chapter 1: Foundation of education

Everyone who cares for, and including, the individual with diabetes-related lower limb ulceration (on the leg or foot) should have the education and knowledge to enable them to determine the urgency of referral. This includes an understanding and awareness of the key indicators of a diabetes-related lower limb ulcer and the red flags that require immediate specialist attention.

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Definition of a lower limb ulcer

Lower limb ulcers are chronic wounds on the lower leg (below the knee) and foot (NWCSP, 2020). Diabetes and related complications, such as diabetic neuropathy, peripheral arterial disease (PAD) and biomechanical abnormalities, increase the risk of foot/limb ulceration and stalled healing. For patients with peripheral diabetic neuropathy, loss of sensation increases the risk of injuries, that, if undetected, may lead to foot ulceration (Alexiadou and Doupis, 2012). A diabetes-related lower limb ulcer can develop anywhere on the foot or leg, but it is most likely to develop on high-pressure areas, such as the toe, plantar, mid-foot, heel or below the malleolus (**Figure 1**).

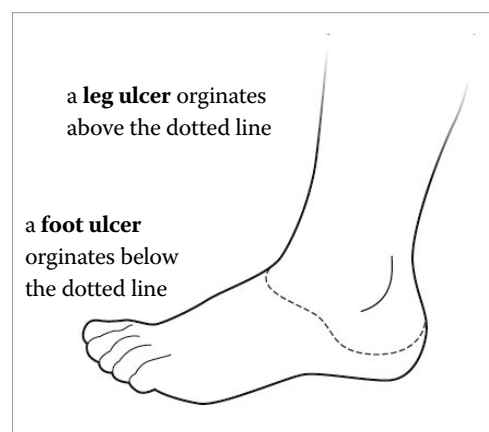


Figure 1: Location of the wound (NWCSP, 2020)

People with diabetes are 23 times more likely to have a leg, foot or toe amputation than someone without diabetes, and both ulceration and amputation are associated with high mortality (Kerr, 2017). Lower limb wounds among people living with diabetes can also increase in severity very rapidly. As a result, NICE (2019a) and the NWCSP (2020) recommend that patients should be referred promptly to a specialist multidisciplinary foot team (MDFT) within 1 working day to reduce the risk of amputation and cost of treatment. Early referral to specialist services has been shown to be associated with better patient and wound outcomes at 12 weeks, and ulcer severity is higher among those

who wait the longest for referral (National Diabetes Foot Audit, 2019).

Indicators of ulcer severity

Ulceration among people with diabetes is a time-sensitive, fast-moving situation with serious life- and limb-altering consequences if intervention is delayed. Therefore, all clinical staff involved in the care of people with diabetes should be familiar with the key identifiers of serious ulceration:

- **Wound depth and tissue loss:** All patients with a diabetes-related lower limb ulcer share a single common issue of tissue loss. If the wound is deep, there is a greater increase in the risk of infection, hospitalisation and involvement of deeper tissue structures, including bone. The aims of wound care are to decrease or remove non-viable tissue (e.g. gangrene or necrosis), promote healthy tissue growth and prevent soft tissue loss.
- **Ischaemia:** Ischaemia is a decrease in arterial blood supply to the tissues, which results in a decrease in oxygen and nutrients and leads to serious consequences on the affected tissues. The presence of diabetes greatly increases the risk and accelerates the course of PAD, making these patients more susceptible to ischaemic events compared to those without diabetes (Thiruvoipati et al, 2015). Recent estimates show PAD is a complicating factor in the management of nearly 65% of all lower limb wounds among people with diabetes (Hinchliffe et al, 2012). If the blood flow to the lower limbs becomes severely restricted, the limb is at risk of chronic limb-threatening ischaemia (CLTI). The symptoms of ischaemia depend upon how quickly the blood flow is interrupted and where it occurs. Early symptoms of CLTI include pain or numbness in the feet; pale, shiny, smooth and dry skin (**Table 1**).
- **Neuropathy:** Peripheral neuropathy (damage to peripheral nerves) increases the risk of ulceration through loss of protective sensation and foot deformities. It is also commonly

associated with dry skin, which can cause cracking, fissures and calluses, leading to ulceration (Table 1).

- **Neuroischaemia:** Neuroischaemia is the term for the combined effect of neuropathy and ischaemia. Neuroischaemia is challenging to treat as the symptoms of CLTI, such as severe pain, may be masked or altered in people with diabetes due to severe sensory neuropathic disturbances.
- **Wound infection:** Wound infection is one of the main contributors towards hospitalisation and amputation(s) among people living with diabetes, even without the presence of ischaemia.

Often patients presenting with severe infection require emergency surgical intervention. Where this is not appropriate, NICE (2019a) guidelines on antibiotic/antimicrobial treatment of diabetic foot infections should be considered to guide management. All clinicians must be aware of how to identify the signs of infection and who to contact. Rapid assessment at the earliest opportunity of presentation provides practitioners with the opportunity to stop the progression from mild infection to systemic infection (Table 1).

Table 1. Symptoms of limb ischaemia, neuropathy and diabetic foot infection

Ischaemia*	Stages of neuropathy	Clinical criteria of diabetic foot infection (Lipsky et al, 2012; NICE, 2019a)
Early symptoms <ul style="list-style-type: none"> ■ Pain or numbness in the feet ■ Shiny, smooth, dry skin of the legs or feet ■ Thickening of the toenails ■ Absent or diminished pulse in the legs or feet ■ Reduced peripheral hair presence ■ Intermittent claudication (pain in legs when walking that is relieved by rest) 	Mild <ul style="list-style-type: none"> ■ Numbness ■ Tingling ■ Pain 	Local diabetic foot infection is defined by the presence of at least two of the following: <ul style="list-style-type: none"> ■ Localised swelling or induration ■ Localised erythema ■ Localised tenderness or pain ■ Localised warmth ■ Purulent discharge
Moderate <ul style="list-style-type: none"> ■ Severe pain in legs and feet that continues at rest ■ Loss of muscle mass in the legs 	Moderate <ul style="list-style-type: none"> ■ Loss of coordination ■ 'Burning' or 'shooting' pains, which may worsen at night 	Severe diabetic foot infection is defined by the presence of local infection plus two of the following signs of systemic infection: <ul style="list-style-type: none"> ■ Temperature >38°C or <36°C ■ Pulse >90 bpm ■ Respiratory rate >20 breaths/min ■ PaCO₂ <32 mmHg ■ White cell count 12,000mm³ or <4,000mm³ ■ 0% immature leukocytes
Chronic limb-threatening ischaemia (CTLI) <ul style="list-style-type: none"> ■ Open sores, skin infections or ulcers that will not heal ■ Dry gangrene (dry, black skin) of the legs or feet 	Severe <ul style="list-style-type: none"> ■ Complete numbness/ loss of sensation ■ Muscle twitching and cramps 	
Acute limb ischaemia <ul style="list-style-type: none"> ■ Sudden-onset cold, pale, pulseless, painful limb, especially if also developing paresthesia or paralysis 		
* The development of worsening symptoms from ischaemia to CLTI depends upon how quickly the blood flow is interrupted and where it occurs.		

Red flags

Everyone involved in the care of people with diabetes and lower limb wound(s) should be aware of the red flags that require immediate attention from a relevant clinical specialist to reduce the risk of rapid deterioration or serious harm (NWCSP, 2020). These are:

- Acute infection of leg or foot (e.g. increasing unilateral redness, swelling, pain, pus, heat)
- Symptoms of sepsis
- Acute ischaemia or CLTI
- Suspected acute deep vein thrombosis (DVT)
- Suspected skin cancer.

Suspected infection should be treated in line with NICE (2020) antimicrobial guidelines, and in accordance with local clinical guidelines and policies. Some changes/exceptions to the care may be made for end-of-life patients; in this instance, advice must be sought from appropriate specialists, and the patients and their family.

Box 1 includes examples of ‘typical’ diabetes-related lower limb ulcers.

Box 1. Examples of ‘typical’ diabetes-related lower limb ulcers



A. Neuropathic plantar ulcer
 B. Neuropathic plantar ulcer
 C. Neuropathic toe ulcer
 D. Neuropathic plantar ulcer with infection



E. Ischaemic toe ulcer
 F. Ischaemic toe ulcer
 G. Ischaemic toe ulcer with infection
 H. Ischaemic foot with rubor (not infected)



I. Neuroischaemic ulcer
 J. Neuroischaemic ulcer (I) 6 weeks later
 K. Neuroischaemic ulcer on heel

Chapter 2: Individualised, person-centred care

Placing the patient at the centre of their care means that the specialist team constructs each care package around the individual patient's needs and preferences.

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The patient should be at the centre of care to ensure successful, person-centred care with collaboration between specialist services and all other clinical staff and carers involved in the individual's care to drive prompt specialist referral.

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The person at the centre of care is the most consistent and important member of their own care plan, so they should be supported with knowledge and education. Placing the patient at the centre of their care means that the specialist team constructs each care package around individual patients' needs and preferences. This may involve a paradigm shift from a paternalistic approach to a truly person-centred management plan, which is patient led and clinician supported.

Engaging with individual patients meaningfully and productively remains a whole system challenge due to the wide range of socio-economic and health literacy inequalities present within the patient population. It may be that individuals living in areas of multiple deprivation require additional listening time and educational support to maximise personal engagement (Watt et al, 2012; Binning et al, 2019). Engaged and informed patients are more likely to feel confident to report both positive and negative experiences and have increased concordance with mutually agreed care management plans.

Engaged individuals are also enabled to make informed decisions about their care options. In addition, resources may be better used if they are aligned with the patients' priorities, and this is critical for the sustainability of health systems worldwide (World Health Organization, 2016).

Collaboration between specialist services and all other clinical staff, patients and carers involved in the patient's care

For an individual with diabetes, at risk of developing a lower limb ulcer or who has already developed an ulcer, a robust specialist approach to the effective assessment and management of the patient is crucial. The patient, as the central stakeholder in the provision of care, should be at the centre of discussions with the specialist team to establish person-centred care and goals based on what matters to each individual (Figure 2), rather than imposing organisational or professional outcomes on individuals.

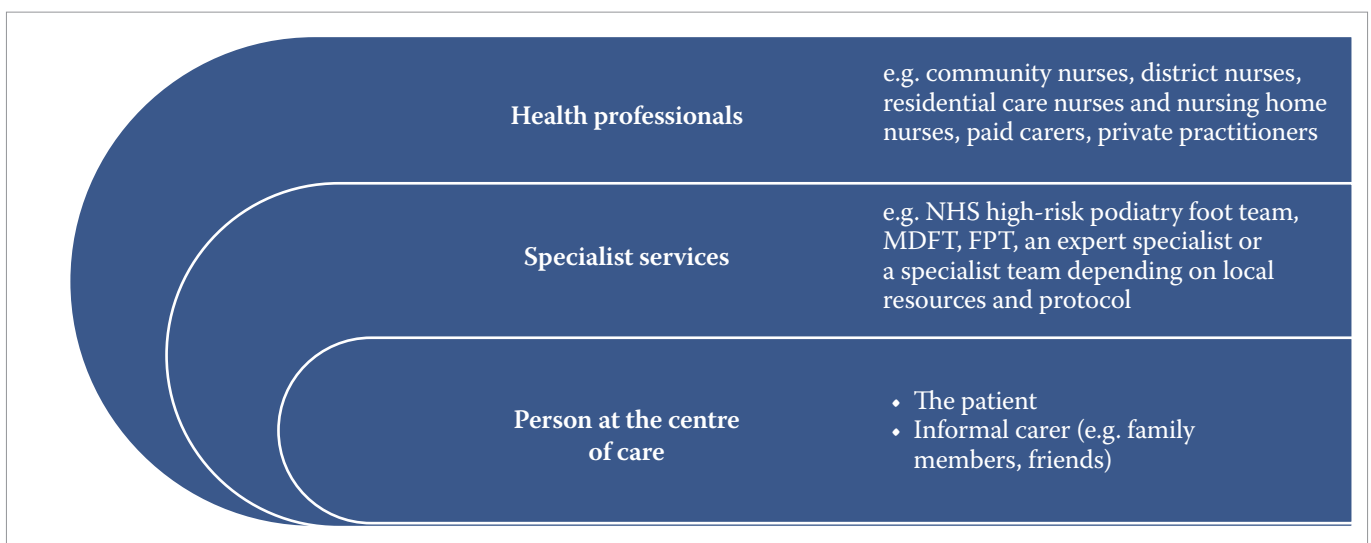


Figure 2: Collaboration between all those who care for people with diabetes and lower limb ulceration: the individual, specialist services and health professionals

Depending on local policy and resources, the specialist team may be an NHS high-risk podiatry foot team, foot protection team (FPT) or MDFT. The MDFT team involves many disciplines including podiatry, diabetes specialist nursing, vascular surgery, microbiology, orthopaedic surgery, biomechanics and orthoses, interventional radiology, casting and wound care (NICE, 2019a). It is imperative that they all work in conjunction with the patient and each other in order to fully meet the patient's needs.

The podiatrist or podiatry team tend to be best placed to co-ordinate care for people with lower limb ulcers, supported by direct or indirect access to health professionals with skills covered in the MDFT (NICE, 2019a). However, local resources and the care setting where the patient is treated (i.e. the NHS or private practice) will govern the availability and scope of the specialist team. For instance, in some areas, the specialist might be a Tissue Viability Nurse, a diabetes lead or diabetes champion.

The specialist team should provide a clear rationale for the evidence-based treatment plan to all clinicians and carers involved in the patient's care. The team should be available to provide advice and support if any complications or concerns develop. Health professionals and patients must be able to demonstrate that they understand the treatment plan and have implemented it in accordance with the specialist advice, and know to refer back to specialist services if they have any concerns or the wound deteriorates.

While it is recognised that lower limb diabetes foot care is integrated through the SCI-Diabetes system in Scotland, such a system is not available elsewhere in the United Kingdom. The group recommend that England, Wales and Northern Ireland should work towards the SCI-Diabetes model, so that health professionals can work collaboratively and

have shared access to patient records (with consent) and resources regardless of the care setting.

Inclusivity, empowerment and a universal language

All patients and their health professionals should be empowered to confidently access specialists and to build links with the specialist team. In some areas, self-referral to specialist services is available.

When building professional and patient links, it is important that the language used to communicate should be appropriate for all involved to avoid confusing and alienating individuals, while ensuring access to care is supported, particularly with respect to those living in socio-economically deprived areas (Hurst et al, 2020).

Chapter 3: Referral to specialist services

Patients and their families/carers should be given information on how to recognise signs of potential ulceration/limb changes or wound deterioration and how to access specialist advice promptly.

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A clinician who has the appropriate knowledge and clinical competencies can refer a patient to specialist services. The decision should be made after the following: discussion with the patient; assessment of the patient, wound and limb for any red flags (NWCSP, 2020) or limb changes; and in accordance with any protocols and guidelines.

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The National Diabetes Foot Audit (2019) has shown that when early referral to specialist care is made, wounds are less severe on arrival at the specialist team; this is associated with better healing outcomes at 12 weeks compared with delayed referral (NHS Digital, 2017). The longer the time from symptom onset to specialised care, the slower the rate of wound healing.

In order to avoid severe complications, clinicians and people with diabetes should be aware of the importance of prompt and appropriate referral to specialist teams (Guest et al, 2018). According to the *Integrated Diabetic Lower Limb Capability Framework*, all staff with Level A capabilities (e.g. healthcare technician, care home staff) should have a general knowledge of the nature of diabetes and risk of ulceration, the details of the appropriately skilled colleague to seek guidance from, and when and where to refer the patient (Short-life Working Group, 2019).

Risk of ulceration

The risk of ulceration alone does not determine which patients should be referred to specialist care. While a person with active diabetes-related ulceration should be referred to the specialist team, local policy will outline where patients are seen. **Table 2** gives an estimate of the proportion of patients in each risk group based on their risk of ulceration in the UK and how often they should be assessed (NICE, 2019a; Short-life Working Group, 2019). The patient needs to be made aware of their individual risk status.

Involving the person

The patient should be involved at all times in their assessment and in all decisions regarding their treatment. The practitioner's job is to explain the available options and work with the patient towards the clinically optimal choice. One of the most important factors is understanding the patient's motivation and activation, what is important to the patient in their life and

Table 2. Diabetes foot disease risk and frequency of assessment in the UK (Leese, 2011; TRIEPoD-UK, 2012; SIGN, 2017; NICE, 2019a; Short-life Working Group, 2019)

Diabetic foot disease risk (NICE, 2019a; SIGN, 2017)	Approximate proportion of patient group	Assessments at the following intervals (NICE, 2019a)
Patients with active diabetic foot disease: Presence of ulceration, or spreading infection, or chronic limb-threatening ischaemia, or gangrene, or suspicion of an acute Charcot neuro-osteoarthropathy, or unexplained hot, red foot with or without pain.	1–4%	Very frequently (for example, every 1 to 2 weeks) for people who are at high risk, if there is immediate concern.
High risk of diabetic foot disease: Patients with a history of diabetic foot ulceration or amputation, or more than one risk factor (e.g. loss of sensation, signs of peripheral arterial disease with callus or deformity, on renal replacement therapy).	4–8%	More frequently (for example, every 1 to 2 months) for people who are at high risk, if there is no immediate concern.
Moderate risk of diabetic foot disease: Patients with one established risk factor for diabetic foot disease (e.g. loss of sensation, signs of peripheral arterial disease without callus, or deformity).	20%	Frequently (for example, every 3 to 6 months) for people who are at moderate risk.
Low risk: Patients at low risk of diabetic foot disease with no symptoms (apart from callus alone).	70%	Annually for people who are at low risk.

Consider more frequent reassessments for people who are at moderate or high risk, and for people who are unable to check their own feet (NICE, 2019a)

their expectations of wound healing. At this stage, take into consideration whether telemedicine or a virtual consultation may be more appropriate, depending on geographical location, the patient's working life and mobility, and whether the patient is receiving end-of-life care.

ACT NOW assessment tool

The ACT NOW assessment tool is an example of a tool that can assist clinicians

to refer people living with diabetes to specialist lower limb services. The ACT NOW assessment tool has been developed for all NHS Primary and Secondary Care services to promote prompt and rapid referral to the specialist team (Edmonds et al, 2020; Phillips and Edmonds, 2021; **Figure 3**). If any of the ACT NOW checklist are present, this should activate a referral to a specialist.

ACT NOW! Checklist				
ASSESSMENT OF FOOT	Tick if present	Digital photo taken to include with referral	Date referred	Document referral to Specialist MDT
A - ACCIDENT? Recent or history of an accident or trauma?				
C - CHANGE? Is there any new swelling, redness or change of shape of the foot?				
T - TEMPERATURE? If there is a change in temperature present? Could this be an infection or possible Charcot?				
N - NEW PAIN? Is there pain present? Is it localised or generalised throughout the foot?				
O - OOZING? What colour is any exudate? Is there an odour?				
W - WOUND? Can you document the size, shape and position of the wound in the foot affected?				

Figure 3: ACT NOW assessment tool for people living with diabetes. Access the tool here: <https://tinyurl.com/2wnfwt4t> (Edmonds et al, 2020; Phillips and Edmonds, 2021)

Chapter 4: Standard of care – Specialist assessment

From the first presentation of a lower limb wound in a patient with diabetes, the patient must be assessed for any presenting red flags, such as infection or chronic limb-threatening ischaemia. Timely and appropriate referral should be made to a specialist team with diabetes and/or lower limb ulceration expertise.

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A suitably qualified professional should be able to conduct a toe pressure assessment and be aware that, if the ABPI is <0.5 and/or TBP is <30 mmHg, the patient should be referred urgently to a specialist clinician (Foot in Diabetes UK, 2020).

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All patients with lower limb wounds and diabetes should have a robust and timely holistic assessment of their history, their limb, their wound and their vascular supply undertaken by a competent health professional. The patient and their wound should be assessed at each dressing change and reassessed regularly by the specialist team every 4 weeks (Frykberg and Banks, 2016), depending on the care plan and patient circumstances.

Holistic patient assessment

The patient assessment must encompass:

- A full patient history (previous ulceration/ lower extremity amputation, claudication)
- Vascular supply
- Glycaemic status
- Skin health
- Current medication
- Nutritional status
- Known allergies
- Their level of activation to participate in shared care
- Weight management (Schaper et al, 2020)
- Psychological wellbeing (Schaper et al, 2020)
- Assessment of their footwear and footwear behaviour, as wearing ill-fitting shoes and walking barefoot can frequently lead to foot ulceration (Schaper et al, 2020). Some localities have access to a specialist orthotist specifically for this purpose
- Smoking status, with smoking cessation support offered where appropriate.

Vascular limb assessment

The IWGDF recommend palpation of pedal pulses to assess vascular status and severity of ischaemia (Schaper et al, 2020); however, it has its limitations. The absence of foot pulses is not included as a 'red flag' symptom because pulse palpation has poor sensitivity and specificity as a diagnostic sign for inadequate arterial supply (Callam et al, 1987). A range of non-invasive vascular diagnostic assessments for foot perfusion and suspected PAD can be carried out if the clinician is able and competent – e.g. Ankle Brachial Pressure Index (ABPI), ankle and pedal Doppler

arterial waveforms, and either toe systolic blood pressure (TBP) or transcutaneous oxygen pressure. Measuring the TBP is a quick and portable bedside assessment and is less affected by medial sclerosis of arteries, which is more prevalent among people with diabetes, and affects other measurements like ABPI (Wang et al, 2016).

Wound assessment

To ensure holistic assessment and treatment of people living with diabetes and a lower limb wound, the wound should be classified using a validated clinical tool (Frykberg and Banks, 2016; WUWHS, 2016). A classification system should encompass all the variables that contribute to wound severity and outcome. Classification systems grade ulcers according to the presence and extent of various physical characteristics, such as size, depth, appearance and location. They can help to plan and monitor treatment, predict outcomes, and to conduct research and audits. Classification systems should be used consistently across the healthcare team and be recorded appropriately in the patient's records. However, it is the assessment of the wound that informs management. Examples of classification systems include SINBAD, the University of Texas Foot Classification and WIfI; all have advantages depending on the purpose/need (Monteiro-Soares et al, 2020; Figure 4).

The WIfI classification system is a clinically verified, holistic approach to foot ulceration. It addresses the three main areas that need to be assessed and managed, and it helps to identify the most dominant risk: foot infection, wound/tissue loss and ischaemia. Furthermore, patients with peripheral neuropathy and ischaemia have higher re-ulceration and amputation rates than those with peripheral neuropathy alone (Apelqvist et al, 2011). Using the WIfI classification system requires specialist equipment to assess ischaemia; ABPI, Doppler and TBP assessment should be conducted as standard. All of these should be undertaken as part of the standard patient assessment.

SINBAD: A simple ulcer classification system for diabetes-related ulcers that grades ulcers according to Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth (Ince, 2008). Advocated by NICE (2019a) and used by the National Diabetes Foot Audit group, the SINBAD Classification System can identify improvement or deterioration of ulcers, assist in the planning and monitoring of treatment, and assist in predicting outcome. It is best used for auditing purposes.

SINBAD			
SINBAD	0	1	Score
Site	Forefoot	Midfoot and hindfoot	0/1
Ischaemia	Pedal blood flow intact, to at least one pulse palpable	Clinical evidence of reduced pedal blood flow	0/1
Neuropathy	Protective sensation intact	Protective sensation lost	0/1
Bacterial infection	None	Present	0/1
Area (ulcer)	<1 cm ²	>1 cm ²	0/1
Depth	Ulcer confined to skin and subcutaneous tissue	Ulcer reaching muscle, tendon or deeper	0/1

SINBAD score	Time to heal
0–2 (moderate)	Up to 77 days
3–6 (severe)	Range 126–577 days

University of Texas Foot Classification System: A classification system that assesses ulcer depth, presence of infection and presence of signs of lower-extremity ischaemia using a matrix of four grades combined with four stages (Lavery et al, 1996). It is used in Scotland and included in the Scottish Care Information Diabetes (SCI-Diabetes) ulcer management system – the system to record diabetes foot ulceration in Scotland.

UNIVERSITY OF TEXAS CLASSIFICATION SYSTEM				
	GRADE			
	0	1	2	3
A	Pre- or post-ulcerative lesion completely epithelialised	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	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia

Wifl: A classification system of ‘the threatened lower limb’, Wifl (Wound, Ischaemia, foot Infection) has been developed for people with a wound living with or without diabetes (Causey et al, 2016). Wifl outlines the three areas that need to be addressed and helps to identify which, at any one time, is the most ‘dominant’ risk(s): tissue loss, ischaemia and/or infection.

Wifl			
Wound	Ischaemia toe pressure/TcPO ₂	Foot infection	Score
No ulcer and no gangrene	>60 mmHg	Not infected	0
Small ulcer and no gangrene	40–59 mmHg	Mild (<2 cm cellulitis)	1
Deep ulcer or gangrene limited to toes	30–39 mmHg	Moderate (>2 cm cellulitis/purulence)	2
Extensive ulcer and extensive gangrene	<30 mmHg	Severe (systemic response/sepsis)	3

TcPO₂ = Transcutaneous oxygen pressure.

Figure 4: Foot classification tools/systems

Chapter 5: Standard of care – Management

All individuals with a lower limb ulcer should be assessed, treated or referred to an appropriate specialist according to an agreed evidence-based treatment pathway.

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The minimum standard of care for diabetes should include the pillars of standard care:

1. Assessment of perfusion/ischaemia
2. Infection prevention and management
3. Evidence-based local wound care that includes debridement, cleansing and wound care treatments
4. Implementation of offloading and/or appropriate footwear
5. Managing underlying comorbidities.

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Evidence-based dressings and devices should be readily available for the patient and included in local formularies.

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The minimum standard of care for diabetes should include the pillars of standard care.

Assessment of perfusion/ischaemia

When a neuroischaemic or ischaemic ulcer does not show signs of healing, revascularisation should be considered. If the ABPI is <0.5 and/or TBP is <30 mmHg, then refer urgently to a specialist clinician.

Infection prevention, treatment and management

Removal of any necrotic or non-viable tissue following comprehensive assessment of infection severity and foot perfusion is required to assess the wound bed and to take microbiology samples if necessary. A sample should be taken from the base of the debrided wound before, or as close as possible to, the start of antibiotic treatment.

When there are local signs of infection, refer to local antibiotic guidelines, or, if none exist, refer to NG19 guidelines (NICE, 2019a). NICE (2019a) recommend to start antibiotic treatment for people with suspected diabetic foot infection as soon as possible. Empirical antibiotic therapy should be administered as per local antibiotic guidelines and a topical antimicrobial agent applied if appropriate for the patient and wound (NICE, 2019a).

Infection management protocols should be informed by an antimicrobial stewardship approach to address the growing global threat of antimicrobial resistance (Wounds UK, 2020). This includes infection prevention and the promotion of judicious use of antimicrobials to preserve their future effectiveness (NICE, 2015); there are no convincing data that prescribing antibiotic therapy for clinically non-infected ulcers either accelerates healing or reduces the risk of developing clinically apparent infection (Abbas et al, 2015).

Implementation of an evidence-based local wound care plan

Following a full holistic assessment of the patient and their wound, an evidence-

based, individualised treatment plan can be devised, which includes local wound care (including cleansing and debridement), exudate management, periwound skin care, treatment of infection if present, and management of wound aetiology and comorbidities, such as ischaemia (Schultz et al, 2003; Harries et al, 2016).

Frequent wound assessment, debridement and cleansing, and redressing should be undertaken based on the presentation and clinical history. It is important to remember that sharp debridement should be carried out by a suitably qualified practitioner and in accordance with local policies.

Dressing selection should be based on the ulcer characteristics (i.e. wound bed composition, size and depth, exudate consistency and level, signs of infection) and patient preference. It is important to remember that these factors have the potential to change at every review. To promote wound progression for diabetes-related ulceration, and, in particular in the case of neuroischaemic foot ulcers, evidence-based advanced dressings should be implemented – e.g. dressings with Technology Lipido-Colloid–Nano-Oligo Saccharide Factor (TLC-NOSE; Edmonds et al, 2018; NICE, 2019b).

The products used by clinicians vary across the UK due to variations in local formularies. Local formularies aim to: improve local care pathways in relation to medicines and the treatments available for prescribing; improve collaboration with clinicians and commissioners; and improve quality by reducing variations in clinical practice. In the majority of organisations, decisions relating to products to be included within a local formulary are taken by a formally constituted decision-making group and make the following considerations:

- Cost-effectiveness of the medicine or medical device
- Clinical evidence
- Impact on quality of life
- Local clinical pathways.

Implementation of offloading and/or appropriate footwear

Reduction of pressure (including vertical, friction and shear) is essential for ulcer protection and healing. For a person living with diabetes and a neuropathic, uninfected plantar forefoot or midfoot ulcer, the IWGDF recommend that a non-removable knee-high offloading device with an appropriate foot–device interface is the first choice of offloading treatment to promote healing of the ulcer (Bus et al, 2019). Non-removable, knee-high offloading devices consist of total contact casts (TCCs) and modified non-removable casts.

Forms of TCC offer the highest level of plantar pressure relief (Cavanagh and Bus, 2010), but the application of TCC and access to non-removable knee-high offloading devices can be inconsistent in the community due to locality variations and not all patients are suitable to be fitted for a non-removable devices.

If it is not possible to apply a TCC on the day of ulcer presentation, an alternative device should be provided (NICE, 2019a) to reduce plantar pressure, such as other types of knee-high modified casts, walkers or custom-made footwear (Munro et al, 2021).

Managing underlying comorbidities

The approach to manage underlying comorbidities that contribute to ulceration (e.g. hyperglycaemia, obesity, ischaemia) requires optimisation of glycaemic management through diet and medication, smoking cessation advice and support if necessary, and includes best medical management – e.g. statins, diabetes medication, anti-platelet therapy.

Deviating from standard care

It is important to remember that not all lower limb wounds will heal. The group discussed the instances when the treatment plan may have to deviate from standard care, for example:

- Patient choice
- The patient is receiving end-of-life care

- To improve quality of life
- To reduce pain
- To reduce risk of other complications associated with living with a chronic wound (such as repeated infections, renal impact).

The group agreed that any deviation from standard care should be led by the specialist services in conjunction with the patient and/or carer(s).

If deviation is deemed appropriate, the group agreed that the patient should be provided with the risks and benefits associated with the alternatives so that they can make an informed decision (e.g. continue with standard care but the ulcer may not heal; consider surgery; consider other treatments, such as outpatient parenteral antimicrobial therapy, intravenous antibiotics, long-term antibiotics, hospital admittance or forced rest).

Discussing amputation with a patient

While toe or limb amputation is often seen as a last resort and to be avoided, for some patients, amputation is a life-saving procedure from infection. A planned, elective amputation is associated with better patient outcomes than an emergency amputation, so if there is a risk of amputation, the conversation between patient and clinician should be started early as part of the patient's care plan.

Care should be given when approaching the subject of amputation with the patient, and the conversation should be conducted by a senior, suitably qualified health professional. The conversation may include discussing the process itself, and aftercare (e.g. post-amputation physiotherapy and prosthetic intervention if the patient is suitable). Amputation is a life-changing procedure for the patient, and the patient may require or benefit from counselling, psychological support, or visiting amputee rehabilitation centres.

Chapter 6: Treatment pathway

Treatment pathways should be transferrable across all healthcare settings and evidence-based treatment made readily available to all.

Best Practice Statement

Incident reporting should be used to highlight where there is no appropriate management pathway, or there is non-adherence to a pathway leading to poor patient outcomes.

Best Practice Statement

The expert panel have developed the pathway from the 2018 recommendations (Allam et al, 2018) with the aim to help identify the patients most at risk of complications by adopting a holistic approach to the patient's initial assessment (Figure 5). The pathway was developed to be:

- Simple to use and understandable by health professionals, including support staff
- Transferrable to different settings, such as prisons, mental health centres and care homes
- Inclusive of the role of the patient and carers
- Inclusive of products, dressings and devices that are available to all
- Aligned with recent national and international guidelines – e.g. the IWGDF (2020) on telemedicine and COVID-19.

Pathway implementation

To successfully implement a treatment care pathway in an organisation, first the barriers must be identified and overcome (WUWHS, 2020b). These may include:

Lack of awareness and knowledge among health professionals

Examples of ways to overcome: provide education in multiple formats and tailored to individuals' learning styles and various levels of expertise; provide time for staff to attend educational events; have systems in place for updates and refreshing knowledge; provide opportunity for mentorship; collaborate closely with local care infrastructures involved with diabetes care.

Lack of acceptance and motivation among health professionals

Examples of ways to overcome: highlight importance to drive improvements in safe quality care for patients; improve knowledge, skills and confidence; share positive feedback from patients; encourage staff to 'buy in' to adoption by giving ownership to certain aspects of care; peer review of services (e.g. Paisley et al, 2019).

Logistical issues

Examples of ways to overcome: optimise the practicalities of use with planning, education and communication between specialists and support staff; use quality improvement methodology to aid implementation and sustainability.

TLC-NOSF dressings

Based on available clinical and economic evidence, dressings that contain TLC-NOSF impregnated in an open-weave polyester mesh were the first wound care product to be recommended for treatment of diabetic foot ulcers and venous leg ulcers (NICE, 2019b). The committee reviewed five empirical research papers, three of which were randomised controlled trials (RCTs) and identified that the use of TLC-NOSF dressings was found to be associated with improved patient-reported quality of life and increased rates of wound healing when compared with non-interactive dressings (Schmutz et al, 2008; Meaume et al, 2012; Münter et al, 2017; Edmonds et al, 2018).

It is anticipated that around 20 amputations could be avoided per 1,000 people with diabetes-related lower limb ulcers by using TLC-NOSF dressings rather than non-interactive dressings (NICE, 2019b). Using dressings with TLC-NOSF as part of the overall management of lower limb wounds was associated with a cost saving to the NHS of approximately £541 per patient per year with a chronic VLU and £342 per patient per year with a DFU (Meaume et al, 2012; 2017; Edmonds et al, 2018; Münter et al, 2017; NICE, 2019a; 2019b).

Telemedicine

Technology and use of digital platforms have been found to be useful both for patient care (telemedicine) and to facilitate team discussion. Telemedicine and weekly specialist team discussion with regards to complex wound management should be consistently embedded into everyday practice.

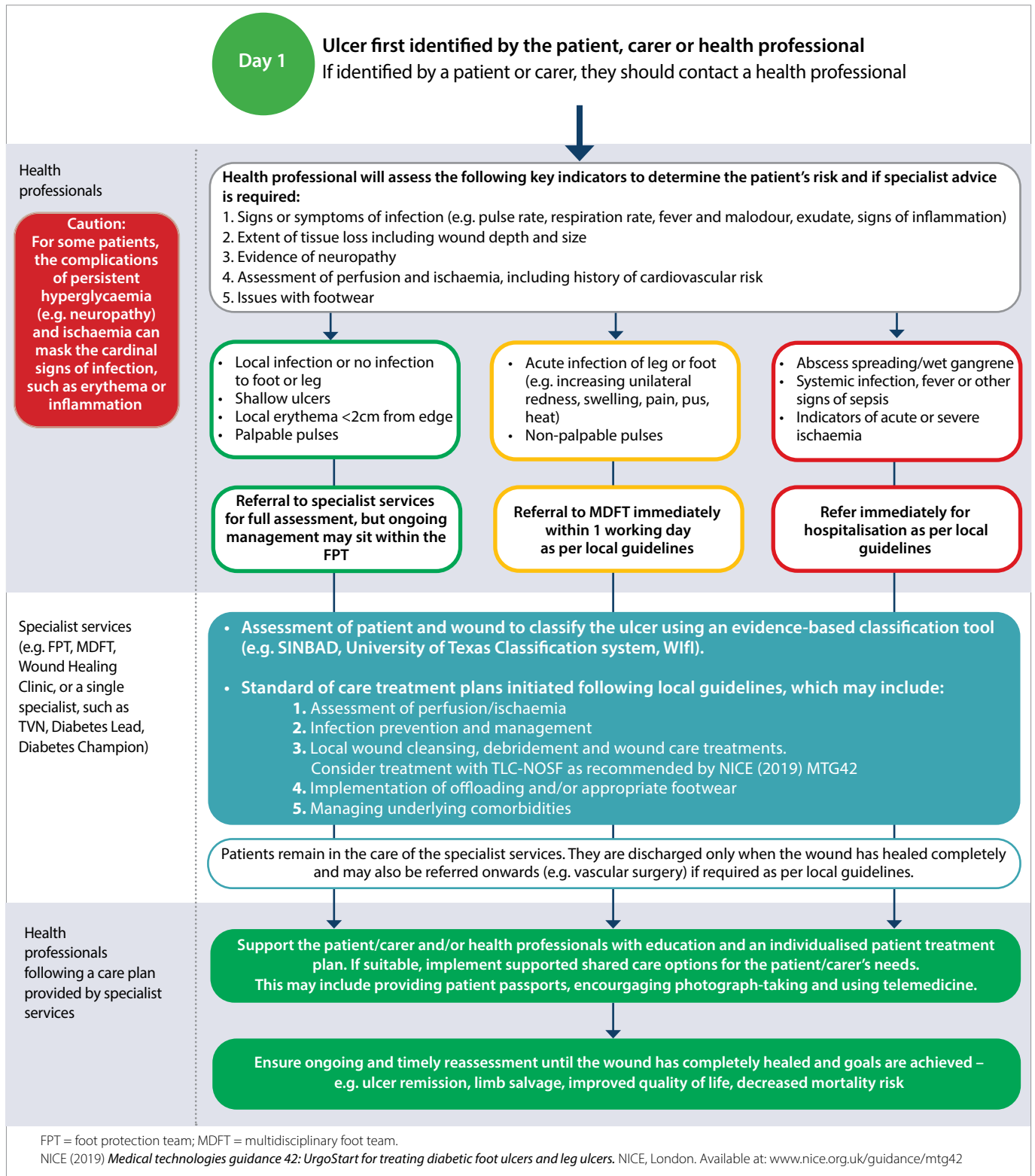


Figure 5: Treatment pathway for a person with a diabetes-related lower limb ulcer (Allam et al, 2018; Bowen et al, 2018; FDUK, 2020; Tickle, 2021)

Chapter 7: Supported shared care

The patient's activation level is key to determining their participation in shared care. A patient and informal carer's decision to not be involved in supported shared care should be respected.

Best Practice Statement

Patients and informal carers can be supported to adopt shared care and supported care regimens if they are willing and able.

Best Practice Statement

Supported shared care of patients and informal carers

Patients and informal carers taking an active role in care, known as shared care, is an established practice in the treatment of chronic conditions such as diabetes, incontinence, and stoma management. Since the COVID-19 pandemic, there is now an increased opportunity within diabetes foot care, and wound care as a whole, to explore adoption and wider standardisation of shared care approaches (Adderley et al, 2020).

Shared wound care encompasses approaches and interventions that enable patients and informal carers to participate in care planning and delivery, rather than just being a passive recipient of the services provided. Previously discussed as 'self-care', shared care does not mean less care for the patient; it is simply an alternative approach that has been shown to be beneficial to clinicians, patients and carers (Wounds International, 2012; Moore et al, 2016).

Suitability for shared care among patients and informal carers

Greater patient ownership is recommended by the NWCSP (2020) to improve outcomes. Effective engagement of patients and informal carers is not achievable unless they gain the necessary knowledge and skills and are educated about their condition (Tol et al, 2013). A patient's activation level for shared care and appetite

for involvement may vary across different patient groups, as a patient's condition progresses and throughout a patient's lifetime (Hibbard and Gilbert, 2014). It is important to regularly assess a patient's beliefs about and capacity to manage aspects of their wound care to identify when health goals and care planning needs re-adjustment (Kapp and Miller, 2015). It could be counter-productive if the patient is given education when they are not ready to be involved.

A caveat to greater patient ownership in diabetes foot care is when neuropathy is present. Pain is often a key driver to seek medical attention, but if the patient is unaware of an injury, it can impede the patient and informal carer's ability to identify the issue.

It is also important to remember that patients and informal carers will have varying levels of involvement (Table 3). When considering a patient and carer's suitability, it is important to discuss the following steps during a face-to-face clinical assessment (Moore et al, 2016):

- Seek patient views and understanding of their condition
- Identify any fears or concerns
- Establish what is important to the patient
- Assess the patient's level of activation to be involved in their care
- Assess the patient's ability to be involved in care.

Table 3. Levels of patient and informal carer involvement and suggestions for how the patient and informal carer could be involved (Moore et al, 2016)

Level of involvement	Examples
Fully involved: the patient feels confident and is capable of monitoring and managing the wound on a daily basis, supported by regular visits to a clinician, and is able to make decisions about their care	Removing dressings, cleaning the wound, reapplying dressings
Shared involvement: where the patient and the clinician have equal responsibility for the monitoring and management of the wound	Taking and receiving photos of the wound to monitor progress or identify deterioration
Not involved: where the patient is passive or unable to take on responsibility for their wound and relies on others to make decisions about his/her care. This may be caregivers in collaboration with the clinician or the clinician alone	Knowing how to identify deterioration and what to do

Shared care approaches should take into account the patient's cultural beliefs, life plans and levels of consent. Approaches may include:

- Motivational interviewing
- Coaching for activation
- The use of patient contracts/passports/individualised care plans considering what the patient wants to achieve from their life and realistic expectations of care
- Telemedicine may be suitable for some patients with access to technology.

Summary of the Best Practice Statement document

Evidence-based local wound care should be integral to the standard care of people living with diabetes and lower-limb ulceration. While the evidence base is still growing for diabetes lower limb care, it is believed that following such approaches would increase the potential for improved patients' quality of life and confidence in their treatment.

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