Practical guidelines on the prevention and management of diabetes-related foot disease (IWGDF 2023 update).

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RESEARCH ARTICLE

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Practical guidelines on the prevention and management of diabetes-related foot disease (IWGDF 2023 update)

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Abstract

Diabetes-related foot disease results in a major global burden for patients and the healthcare system. The International Working Group on the Diabetic Foot (IWGDF) has been producing evidence-based guidelines on the prevention and management of diabetes-related foot disease since 1999. In 2023, all IWGDF Guidelines have been updated based on systematic reviews of the literature and formulation of recommendations by multidisciplinary experts from all over the world. In addition, a new guideline on acute Charcot neuro-osteoarthropathy was created. In this document, the IWGDF Practical Guidelines, we describe the basic principles of prevention, classification and management of diabetes-related foot disease based on the seven IWGDF Guidelines. We also describe the organisational levels to successfully prevent and treat diabetes-related foot disease according to these principles and provide addenda to assist with foot screening. The information in these practical guidelines is aimed at the global community of healthcare professionals who are involved in the care of persons with diabetes. Many studies around the world support our belief that implementing these prevention and management principles is associated with a decrease in the frequency of diabetes-related lower-extremity amputations. The burden of foot disease and amputations is increasing at a rapid rate, and comparatively more so in middle to lower income countries. These guidelines also assist in defining standards of prevention and care in these countries. In conclusion, we hope that these updated practical guidelines continue to serve as a reference document to aid healthcare providers in reducing the global burden of diabetes-related foot disease.

KEYWORDS
daily practice, diabetic foot, foot ulcer, guidelines, implementation, IWGDF

International Working Group on the Diabetic Foot (IWGDF); www.iwgdfguidelines.org.

1 | INTRODUCTION

In these practical guidelines of the International Working Group on the Diabetic Foot (IWGDF), we describe the basic principles of prevention and management of diabetes-related foot disease. This document is a summary of the following evidence-based IWGDF Guidelines (2023 update):

1. Prevention of foot ulcers in persons with diabetes[1]
2. Classification of diabetes-related foot ulcers[2]
3. Diagnosis and treatment of foot infection in persons with diabetes[3]
4. Diagnosis and management of peripheral artery disease in persons with a foot ulcer and diabetes[4]
5. Offloading foot ulcers in persons with diabetes[5]
6. Interventions to enhance healing of foot ulcers in persons with diabetes[6]
7. Acute Charcot neuro-osteoarthropathy (CNO)[7]

The authors, as members of the editorial board of the IWGDF, have summarised the information from these seven guidelines, and also provided additional advice based on expert opinion in selected areas for which the guidelines were not able to provide evidence-based recommendations. These practical guidelines should be considered as a shortened and simplified document to be used as a basic summary of the key management principles of prevention and treatment of diabetes-related foot disease. We refer the reader for details and background to the different guidelines[1–7] and their underlying systematic reviews.[8–18] Should this summary text appear to differ from the information of any of these guidelines, we suggest the reader defers to that specific guideline. The seven evidence-based guidelines were developed following the GRADE methodology as described in a separate document.[19] For readability, we did not include the strength of recommendations according to GRADE (i.e. strong or conditional) nor their detailed considerations in these practical guidelines. Because terminology in this multidisciplinary area can sometimes be unclear, we also refer the reader to our separate IWGDF Definitions and Criteria document.[20]

Compared to the previous version of these practical guidelines (the 2019 update:[21]), the following is new in the 2023 update: several new recommendations in various sections based on the updated guidelines, re-ordering of the ulcer treatment principles, based on the order for clinical decision-making, and a summary of the IWGDF guidelines on the diagnosis and management of acute CNO. We now include an appendix on the measurement of ankle and toe blood pressures. The 2023 update supersedes any previous version of these practical guidelines.

The information in these practical guidelines is aimed at the global community of healthcare professionals involved in the care of persons with diabetes and diabetes-related foot disease. The principles outlined may have to be adapted or modified based on local circumstances, taking into account regional differences in the socio-economic situation, accessibility to and sophistication of healthcare resources, and various cultural factors.

2 | DIABETES-RELATED FOOT DISEASE AND ITS PATHOPHYSIOLOGY

Diabetes-related foot disease includes one or more of the following in the foot of a person with current or previously diagnosed diabetes mellitus: peripheral neuropathy, PAD, infection, ulcer(s), neuro-osteoarthropathy, gangrene, or amputation. Foot ulceration is among the most serious complications of diabetes and is a source of reduced quality of life as well as financial costs for the person involved. Moreover, it places a considerable burden on the person's family, healthcare professionals and facilities, and society in general.

Although both the prevalence and spectrum of diabetes-related foot ulceration vary in different regions of the world, the pathways to ulceration are similar in most people. These ulcers usually develop in a person with diabetes simultaneously having one or more risk factors, such as diabetes-related peripheral neuropathy and/or PAD, in combination with a precipitating event. Neuropathy leads to an insensitive and sometimes deformed foot. Loss of protective sensation, foot deformities, and limited joint mobility can result in abnormal biomechanical loading of the foot. This produces high mechanical stress in some areas, the response to which is usually thickened skin (callus). The callus then leads to a further increase in the loading of the foot, often with subcutaneous haemorrhage and eventually skin ulceration (see Figure 1). In addition, in people with neuropathy, minor trauma (e.g., from ill-fitting shoes, or an acute mechanical or thermal injury) can precipitate ulceration of the foot. Whatever the primary cause of ulceration, continued walking on the insensitive foot impairs healing of the ulcer.

The vast majority of persons with a diabetes-related foot ulcer will have neuropathy. PAD, generally caused by atherosclerosis, is present in up to 50% of these patients and is an important risk factor for impaired wound healing, gangrene and lower-extremity amputation. A small percentage of foot ulcers in patients with severe PAD is purely ischaemic; these are usually painful and may follow minor trauma. The majority of foot ulcers, however, are either purely neuropathic or neuro-ischaemic, that is, a combination of neuropathy

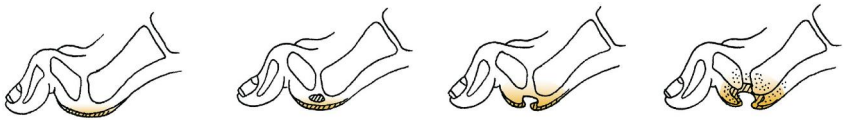

FIGURE 1 Mechanism of ulcer developing from repetitive or excessive mechanical stress.

and ischaemia. In people with diabetes with neuro-ischaemic ulcers, symptoms may be absent because of the neuropathy, despite severe pedal ischaemia. Although diabetes-related microangiopathy can be observed in the foot, it does not appear to be the primary cause of either ulcers or of poor wound healing.

To reduce the burden of diabetes-related foot disease, strategies are required that include elements of prevention, patient and staff education, standardised assessment and classification, multidisciplinary treatment, and close monitoring. The core of these strategies is described in the following sections of these practical guidelines.

3 | FOOT ULCER PREVENTION

If a person with diabetes without a foot ulcer presents at your clinic, there are five key elements that underpin efforts to prevent foot ulcers, as described in the IWGDF Prevention Guideline[1]:

1. Identify the person with an at-risk foot
2. Regularly inspect and examine the feet of a person at-risk for foot ulceration
3. Provide structured education for patients, their families, and healthcare professionals
4. Encourage routine wearing of appropriate footwear
5. Treat risk factors for ulceration

3.1 | Identifying the person with an at-risk foot

Screening is done in people with diabetes at very low risk of foot ulceration (IWGDF risk 0) annually for signs or symptoms of Loss of protective sensation (LOPS) and PAD to identify if they have become at-risk for foot ulceration. The absence of symptoms in a person with diabetes does not exclude foot disease; they may have asymptomatic neuropathy, PAD, pre-ulcerative signs, or even an ulcer. Yearly foot screening includes assessing or examining the following:

1. Foot ulcer: assess if the foot is ulcer-free
2. LOPS: assess with one of the following techniques (see Appendix A for details):
   - 2.1 Pressure perception: Semmes-Weinstein 10 g monofilament
   - 2.2 Vibration perception: 128 Hz tuning fork
   - 2.3 When monofilament or tuning fork is not available test tactile sensation: lightly touch the tips of the toes of the patient with the tip of your index finger for 1–2 s
3. Vascular status: history of intermittent claudication and palpation of pedal pulses

If a person has LOPS or PAD, they are at-risk of ulceration (Table 1), and further examination is required. LOPS is usually caused by diabetes-related polyneuropathy. If diagnosed for the first time, it is usually necessary to elicit further history and conduct further examinations into its causes and consequences; however, these aspects are outside the scope of this guideline.

Prior to any surgical procedure on the foot in a person with diabetes, the presence of LOPS and PAD status should be established in order to assess the suitability for and risks of the procedure.

3.2 | Regularly inspecting and examining the person with an at-risk foot (IWGDF risk 1 or higher)

If the yearly foot screening identifies a person as 'at-risk', perform a more comprehensive examination. This includes the following assessments or examinations in order to assess risk in more detail and to inform further management:

1. Detailed history: determine foot ulcer and lower-extremity amputation history, diagnosis of end-stage renal disease, previous foot education, social isolation, poor access to healthcare and financial constraints, foot pain (with walking or at rest) or numbness, and mobility;
2. Vascular status: in case of absent foot pulses or other signs of PAD, consider performing pedal Doppler waveforms in combination with measurement of the ankle pressure and ankle-brachial index (ABI) and toe pressure and toe-brachial index (TBI) (see Appendix B);
3. Skin: assess skin colour, temperature, presence of callus or oedema, fungal infection, pre-ulcerative signs such as haemorrhage or fissures;
4. Bone/joint: check for deformities (e.g., claw or hammer toes), abnormally large bony prominences, or limited joint mobility. Examine the feet with the patient both lying down and standing up;
5. Cognitive disorders
6. Footwear: ill-fitting, inadequate, or lack of footwear;
7. Poor foot self-care, for example, improperly cut toenails and unwashed feet;
8. Physical limitations that may hinder foot self-care (e.g. visual acuity, obesity);
9. Foot care knowledge.

Following examination of the foot, stratify each patient using the IWGDF risk stratification category system shown in Table 1 to guide subsequent preventative screening frequencies and management. Areas of the foot most at-risk are shown in Figure 2. A person with a healed foot ulcer has the highest risk of ulceration and the foot should be considered in remission. This requires lifelong ulcer prevention strategies with an appropriately trained team of healthcare professionals that addresses all ulcer prevention cornerstones as part of integrated care. Any foot ulcer identified during screening should be treated according to the principles outlined in Section 4.

TABLE 1 The IWGDF 2023 risk stratification system and corresponding foot screening frequency.

Category	Ulcer risk	Characteristics	Frequency[a]
0	Very low	No LOPS and no signs of PAD	Once a year
1	Low	LOPS or PAD	Once every 6–12 months
2	Moderate	LOPS + PAD, *or* LOPS + foot deformity *or* PAD + foot deformity	Once every 3–6 months
3	High	LOPS or PAD, *and* one or more of the following: - history of a foot ulcer - a lower-extremity amputation (minor or major) - end-stage renal disease	Once every 1–3 months

Abbreviations: LOPS, Loss of Protective Sensation; PAD, Peripheral Artery Disease.

[a]Screening frequency is based on expert opinion since there is no published evidence to support these intervals.

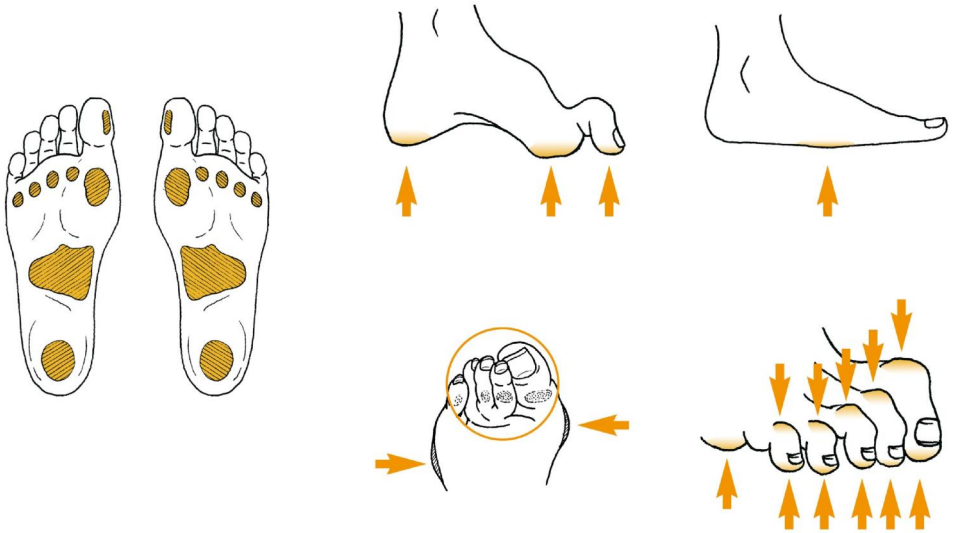

FIGURE 2 Areas of the foot at highest risk for ulceration.

3.3 | Providing structured education for patients, their family, and healthcare professionals about foot care and support to perform foot self-care

Education, presented in a structured, organised and repeated manner, is widely considered to play an important role in the prevention of diabetes-related foot ulcers. The aim is to improve a person's foot self-care knowledge and self-protective behaviour, and to enhance their motivation and skills to facilitate adherence to this behaviour. In particular, those persons stratified as IWGDF risk 1 or higher should be encouraged to wash and examine their feet daily and to learn how to recognise (pre-) ulcerative lesions. In case of such lesions, patients should rapidly contact an appropriately trained health professional for further advice. They should be encouraged to use emollients to moisturise dry skin and to always walk with socks and shoes, whether indoors or outdoors. Specific emphasis should be placed on educating that only wearing socks indoors will not protect the feet, as both socks and shoes are needed. The educator should demonstrate specific skills to the person, such as how to cut toenails appropriately (straight across). A member of the healthcare team should provide structured education (see examples of instructions in Appendix C) individually or in small groups of people, in multiple sessions, with periodical reinforcement and preferably using a mixture of methods. This education should be culturally appropriate, account for gender differences, and align with a person's health literacy and personal circumstances. It is essential to assess whether the person with diabetes (and, optimally, any close family member or carer) has understood the messages, is motivated to act and adhere to the advice and has sufficient self-care skills. Furthermore, healthcare professionals providing these instructions should receive periodic education to improve their own skills in the care of people at risk for foot ulceration.

3.4 | Encourage routine wearing of appropriate footwear

In persons with diabetes and IWGDF risk category 1 or higher, wearing inappropriate footwear or walking barefoot are major causes

of foot trauma leading to foot ulceration. Persons with LOPS must have (and may need financial assistance to acquire) appropriate footwear, and should be encouraged to wear this at all times, both indoors and outdoors. All footwear should be adapted to conform to any alteration in foot structure or foot biomechanics affecting the foot.

For footwear to be considered appropriate, the inside length of the shoe should be 1–2 cm longer than the foot and should not be either too tight or too loose (see Figure 3). The internal width should equal the width of the foot at the metatarsal phalangeal joints (or the widest part of the foot), and the height should allow enough room for all the toes. Evaluate the fit with the patient in the standing position, preferably later in the day (when they may have foot swelling). If there is no off-the-shelf footwear that can accommodate the foot (e.g., if the fit is poor due to foot deformity) or if there are signs of abnormal loading of the foot (e.g., hyperaemia, callus, and (previous) ulceration), prescribe therapeutic footwear, possibly including extra-depth shoes, custom-made footwear and custom-made insoles. This may also include the prescription and fabrication of (toe) orthoses.

For people who have healed from a plantar foot ulcer, ensure that the therapeutic footwear has a demonstrated plantar pressure relieving effect during walking. When possible, demonstrate this plantar pressure relieving effect with appropriate equipment, as described in the prevention guidelines.[1] Instruct the person to never again wear the same shoe that has caused an ulcer. Take protective measures to prevent heel ulceration in (temporarily) bedridden patients (either at home or admitted to an institution).

3.5 | Treating risk factors for ulceration and pre-ulcerative signs in persons with IWGDF risk 1–3

Provide appropriate treatment for excess callus on the foot, for ingrown toe nails, and for fungal infections on the foot. Treat any (modifiable) pre-ulcerative sign on the foot, including protecting blisters or draining them if necessary. Consider coaching a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2–3) to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a foot ulcer. In case of an elevated temperature, ambulatory activity should be reduced and a member of the foot care team should be consulted. When excess callus or a pre-ulcerative lesion is present on the apex or distal part of a non-rigid hammertoe, consider digital flexor tendon tenotomy or consider prescribing orthotic interventions, such as toe silicone or (semi)rigid orthotic devices.

The risk for foot ulceration is not a barrier to participating in a physical training programme as long as appropriate footwear is worn, with a gradual increase in activity to an additional 1000 steps/day. In addition, a foot-ankle exercise programme may be considered.

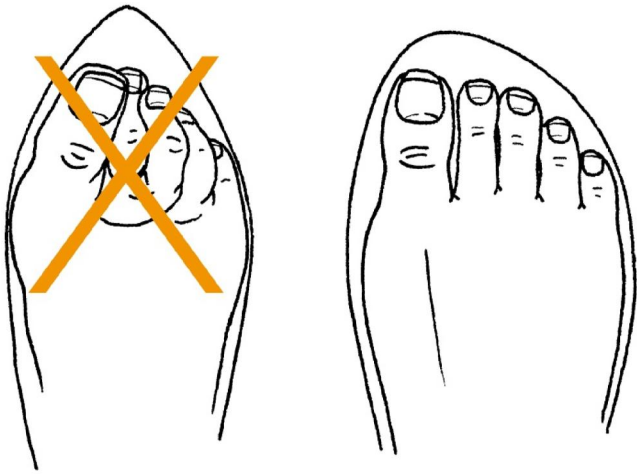

FIGURE 3 Footwear should be sufficiently wide to accommodate the foot without excessive pressure on the skin.

4 | ASSESSMENT AND TREATMENT OF FOOT ULCERS

If a person with diabetes presents with a foot ulcer, the ulcer should be assessed and treated immediately, with a consistent strategy and standardised protocol for assessment and treatment.

4.1 | Assessment

4.1.1 | Classification of the foot ulcer

As the first step, the foot ulcer should be classified following the assessment of the six items of the SINBAD system.[2] These items serve as a basic guide for further treatment and facilitate communication about the characteristics of an ulcer between health professionals. These six items of this acronym are:

1. "Site": Describe where the ulcer is located on the foot. This includes description of forefoot, midfoot or hindfoot, but it is also suggested to differentiate between plantar, interdigital, medial, lateral or dorsal.
2. "Ischaemia": Assess if pedal blood flow is intact (at least one palpable pulse) or if there is clinical evidence of reduced blood flow. Further, we examine the arterial pedal wave forms (with a Doppler instrument), measure the ankle and toe pressures, and calculate the ABI and TBI, as described in Appendix B. PAD is less likely in the presence of triphasic or biphasic pedal Doppler waveforms, an ABI 0.9–1.3, and a TBI ≥0.70. In selected cases, transcutaneous pressure of oxygen ($TcpO_2$) can be useful. The level of perfusion deficit can help estimate the likelihood of healing and amputation (see below), but better risk estimation is obtained when wound depth and foot infection severity are also taken into account, as in the WIfI scoring system.
3. "Neuropathy": Assess if protective sensation is intact or lost (see Appendix A).

4. "Bacterial infection": Assess if clinical infection is present. Diagnose infection with the presence of at least two clinical signs or symptoms of inflammation (redness, warmth, induration, pain/tenderness) or purulent secretions. Unfortunately, these signs may be blunted by neuropathy or ischaemia, and systemic findings (e.g., pain, fever, leucocytosis) are often absent in mild and moderate infections. Infections should be classified using the IWGDF/IDSA grading as *mild* (superficial ulcer with minimal cellulitis), *moderate* (ulcer deeper than skin or more extensive cellulitis, with or without abcess), or *severe* (accompanied by systemic signs of sepsis) with or without osteomyelitis.

If not properly treated, infection can rapidly spread to the underlying tissues and foot compartments, in particular in the presence of PAD. Therefore, explore the depth of the ulcer (see below). An abscess is more likely in cases of fever and high C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR) levels, but normal findings do not exclude a foot abscess; when in doubt, perform MRI. Determine if it is possible to visualise or touch the bone with a sterile metal probe (probe-to-bone test). Obtain plain radiographs in persons with ulcers deeper than the skin, tissue gas, or foreign body. Osteomyelitis is likely in case of a positive probe-to-bone test in combination with abnormalities on plain X-ray; high levels of ESR, CRP, or procalcitonin further support this diagnosis. When in doubt perform an MRI or when this is not possible, consider other techniques (e.g., radionuclide or PET scans).

For clinically infected wounds, obtain a tissue specimen for culture (and Gram-stained smear, if available) by curettage or biopsy, avoid using a swab and consider bone biopsy in case of osteomyelitis. The causative pathogens (and their antibiotic susceptibilities) vary by geographic, demographic and clinical situations, but *Staphylococcus aureus* (alone, or with other organisms) is the predominant pathogen in most cases of superficial infections. Chronic and more severe infections are often polymicrobial, with aerobic gram-negative rods especially in warmer climates and obligate anaerobes accompanying the gram-positive cocci.

5. "Area": Measure ulcer area and express in cm^2.
6. "Depth": Assess ulcer depth and classify as confined to the skin and subcutaneous tissue, reaching muscle or tendon, or reaching the bone. Determining depth can be difficult, especially in the presence of an overlying callus or necrotic tissue. To aid assessment, debride any neuropathic or neuro-ischaemic ulcer that is surrounded by callus or contains necrotic soft tissue at initial presentation or as soon as possible. Do ***not***, however, debride a non-infected ulcer that has signs of severe ischaemia. Neuropathic ulcers can usually be debrided without the need for local anaesthesia.

Classification and type

By following this standardised assessment, the ulcer can be classified according to the SINBAD system.[2] The SINBAD system is simple and quick to use and contains the necessary information to allow for triage by a specialist team. In addition, infection severity should be classified according to the IWGDF/IDSA system and ischaemia as part of the WIfI system.[2] It is important to describe the individual variables of each of these systems.[2] In addition, the ulcer type can be described as neuropathic (LOPS, but no PAD), neuro-ischaemic (LOPS and PAD), or ischaemic (PAD, but no LOPS).

4.1.2 | Determining the cause of the ulcer

Always try to determine the precipitating event that led to ulceration; this information is relevant both for treatment plans and for prevention of recurrence. Look for abnormal walking patterns, deformities, bony prominences and other foot abnormalities (supine and standing) that could have contributed to ulceration. Wearing ill-fitting shoes and walking barefoot are practices that frequently lead to foot ulceration, even in patients with exclusively ischaemic ulcers. Therefore, meticulously examine shoes and footwear behaviour in every patient with a foot ulcer as part of cause determination.

4.1.3 | Assessment of person-related factors

Apart from a systematic evaluation of the ulcer, the foot and the leg, also consider person-related factors that can affect ulcer healing and treatment. These factors include kidney function/end-stage renal disease, oedema, malnutrition, poor metabolic control, depression or other psycho-social problems, and frailty.

4.2 | Treatment of a foot ulcer

Foot ulcers will heal in the majority of patients if the clinician bases treatment on the principles outlined below. When treating a person with a foot ulcer, always involve the person and their carer(s) by providing information on the treatments provided, and supporting the person to perform appropriate foot ulcer self-care and how to recognise and report signs and symptoms of new or worsening infection (e.g., onset of fever, changes in local wound conditions, worsening hyperglycaemia). This information should also involve how to prevent foot ulcers on unaffected parts of the foot or the contralateral foot (see Section 3).

4.2.1 | Treatment of foot infection

Infection of the foot in a person with diabetes presents an immediate threat to the affected foot and limb. If infection is diagnosed during initial assessment (see 4.1), prompt treatment is required. Depending on a person's social situation, local resources and infrastructure, hospitalisation may be necessary. This hospitalisation may also involve amputation of a part of the foot or lower-extremity. Based on

the IWGDF/IDSA infection guidelines,[3] the following recommendations for treatment are made:

In a person with deep or extensive (potentially limb-threatening) infection (moderate or severe infection):

1. Urgently evaluate the need for immediate surgical intervention to remove necrotic tissue, including infected bone, release compartment pressure and drain abscesses;
2. Assess for PAD; if present consider urgent treatment including revascularisation once infection is under control;
3. Initiate empiric, parenteral, broad-spectrum antibiotic therapy aimed at common gram-positive and gram-negative bacteria, including obligate anaerobes;
4. Adjust (constrain and target, if possible) the antibiotic regimen based on both the clinical response to empirical therapy and culture and sensitivity results;
5. For soft-tissue infections, antibiotic treatment during 1–2 weeks will frequently suffice, a longer duration may be required in case of a slowly resolving infection or severe PAD; and
6. Consider conservative treatment for osteomyelitis with antibiotics when there is no need for incision and drainage to control infection.

In a person with a superficial ulcer with limited soft tissue (mild) infection:

1. Cleanse, debride all necrotic tissue and surrounding callus; and
2. Start empiric oral antibiotic therapy targeted at *Staphylococcus aureus* and β-haemolytic streptococci (unless there are reasons to consider other, or additional, likely pathogens).

4.2.2 | Restoration of tissue perfusion

Ischaemia in the lower-extremity affects the healing potential of a foot ulcer. If ischaemia has been found during assessment (see 4.1), its treatment should always be considered. Based on the intersocietal IWGDF/ESVS/SVS guidelines,[4] the following recommendations for treatment are made:

1. In a person with either an ankle pressure <50 mm Hg or an ABI <0.4 consider urgent vascular imaging, always with detailed visualisation of below-the knee and pedal arteries, and revascularisation. Also consider urgent assessment for revascularisation if the toe pressure is <30mmHg or $TcpO_2$ is <25 mmHg. However, clinicians might also consider revascularisation at higher pressure levels in patients with extensive tissue loss or infection, that is, with higher WIfI scores.
2. When an ulcer fails to show signs of healing within 4–6 weeks, despite optimal management, consider angiography and revascularisation, irrespective of the results of the vascular diagnostic tests described above.
3. If contemplating a major (i.e., above the ankle) amputation, first consider the option of revascularisation.
4. The aim of revascularisation is to restore in-line flow to at least one of the foot arteries, preferably the artery that supplies the anatomical region of the wound. But, avoid revascularisation in patients in whom the risk-benefit ratio for the probability of success is unfavourable.
5. Select a revascularisation technique based on both individual factors (such as morphological distribution of PAD, availability of autogenous vein, patient co-morbidities) and local operator expertise.
6. After a revascularisation procedure, its effectiveness should be evaluated with an objective measurement of perfusion.
7. Pharmacological treatments to improve perfusion have not been proven to be beneficial.
8. Emphasis on efforts to reduce the very high cardiovascular risk associated with PAD in the individual with diabetes (cessation of smoking, control of hypertension and dyslipidaemia, use of antiplatelet drugs, SGLT2-inhibitor or GLP1-agonist).

4.2.3 | Pressure offloading and ulcer protection

Offloading is a cornerstone in the treatment of foot ulcers that are caused by increased mechanical stress. Based on the IWGDF Offloading guidelines,[5] the following recommendations for treatment can be made:

1. The preferred offloading treatment for a neuropathic plantar ulcer is a non-removable knee-high offloading device, i.e. either a total contact cast (TCC) or removable walker rendered (by the provider fitting it) irremovable.
2. When a non-removable knee-high offloading device is contra-indicated or not tolerated by the patient, consider using a removable knee-high or ankle-high offloading device. Always provide information on the benefits of adherence to wearing the removable device.
3. If other forms of biomechanical relief are not available, consider using felted foam, but only in combination with appropriate footwear.
4. If the ulcer is on digits 2–5 secondary to a flexible toe deformity, perform digital flexor tenotomy if not contra-indicated (e.g. severe ischaemia, infection).
5. When infection or ischaemia is present, offloading is still important, but be more cautious, as discussed in the IWGDF Offloading guidelines.[5]
6. For non-plantar ulcers, use a removable offloading device, footwear modifications, toe spacers, orthoses, or digital flexor tenotomy, depending on the type and location of the foot ulcer.
7. If the ulcer fails to heal with non-surgical offloading treatment, for a metatarsal head ulcer consider Achilles tendon lengthening, metatarsal head resection, or metatarsal osteotomy, and for a

hallux ulcer, joint arthroplasty, all in combination with an off-loading device.

4.2.4 | Local ulcer care

Local ulcer care is important to create an environment that increases the likelihood of ulcer healing. However, even optimum local wound care cannot compensate for inadequately treated infection or ischaemia or continuing trauma to the wound bed, as described in the sections above. Based on the IWGDF Wound Healing Guidelines,[6] the following recommendations for local ulcer care can be made:

1. Regular inspection of the ulcer by a trained health care provider is essential; its frequency depends on the severity of the ulcer and underlying pathology, the presence of infection, the amount of exudation and wound treatment provided.
2. Debride the ulcer and remove the surrounding callus (preferably with sharp surgical instruments), and repeat as needed.
3. Select dressings to control excess exudation and maintain a moist environment.
4. Wash but do not soak the feet as this may induce skin maceration.
5. Consider negative pressure wound therapy to help heal post-operative wounds.

Consider any of the following adjunctive treatments in non-infected ulcers that fail to heal after 4–6 weeks despite optimal clinical care and where resources exist to support these interventions:

1. A sucrose octasulfate impregnated dressing in neuro-ischaemic ulcers (without severe ischaemia).
2. A multi-layered patch of autologous leucocytes, platelets and fibrin in ulcers with or without moderate ischaemia.
3. Placental membrane allografts in ulcers with or without moderate ischaemia.
4. Topical oxygen therapy.
5. Systemic hyperbaric oxygen therapy as an adjunctive treatment for ischaemic ulcers.

The following treatments are not well-supported for routine ulcer management:

1. Biologically active products (collagen, growth factors, bio- engineered tissue) in neuropathic ulcers;
2. Topical antiseptics and antimicrobial dressings or applications.

4.2.5 | Person-centred care

In addition to the aforementioned recommendations, the person-related factors as assessed in Section 4.1.3 should be treated where possible. This includes:

1. Optimise glycaemic control, if necessary, with insulin.
2. Treat oedema or malnutrition if present.
3. Treat cardiovascular risk factors.
4. Treat depression or other psycho-social difficulties.

5 | ACTIVE CHARCOT NEURO-OSTEOARTHROPATHY

In any person with diabetes mellitus and with a red, hot, swollen foot, the diagnosis of active CNO should be considered. As described in our Charcot guidelines, CNO is a sterile inflammatory process in persons with neuropathy that results in injury to bones, joints and soft tissues.[7] If not treated adequately, it can result in progressive fracturing and dislocations, resulting in a deformed foot. The diagnosis is based on the aforementioned clinical findings of inflammation after the exclusion of other causes and abnormalities on imaging. If these abnormalities are not seen on plain X-rays, an MRI should be performed; if an MRI is not possible, perform a CT-scan and/or a radionucleotide scan. When such advanced imaging is not possible, the person should be treated as having a probable active CNO.

In order to promote the remission of the disease and to prevent (progressive) deformity, the affected extremity should be offloaded and immobilised. The first choice is a non-removable knee-high TCC and the second choice a knee-high walker rendered non-removable. A removable knee-high device worn at all times is a third choice, but probably less effective. Below-the-ankle offloading devices are not recommended. Assistive devices (e.g. crutches) can help to reduce weight-bearing on the affected limb. Treatment should start once the diagnosis is considered and continue until clinical remission with consolidation of fractures is achieved. As long as there are clinical signs of inflammation, offloading should be continued. This can take many months. Such long-term treatment is associated with the risk of complications (e.g. ulceration) and adverse effects (e.g. muscle atrophy or excessive loading of the contra-lateral limb), and treated persons must be followed closely. Currently, there is no medical therapy that can shorten the duration of disease or prevent deformities; therefore such interventions are not recommended. Vitamin D and calcium should be supplemented according to local guidelines for persons with an elevated risk of inadequate vitamin D levels.

Measuring skin temperature with infrared thermometry in both feet according to a standardised protocol is an easy and objective technique to monitor disease activity. In unilateral disease, the left-right temperature difference can be calculated at each visit. Unfortunately, there is currently no absolute cut-off value to define the remission of CNO. Therefore, temperature, oedema, and imaging should all be considered when concluding that active CNO is in remission. The knee-high cast can be stopped when there are no clinical signs of inflammation with radiographic consolidation of fractures (if present) on plain X-ray. The person should have custom made footwear and/or orthoses that best accommodate and support the shape of the foot and ankle to help prevent re-activation of the

TABLE 2 Levels of care for diabetes-related foot disease.

Level 1	General practitioner, podiatrist, and diabetes nurse
Level 2	Diabetologist, surgeon (general, orthopaedic, or foot/podiatric), vascular specialist (endovascular and open revascularisation), infectious disease specialist or clinical microbiologist, podiatrist and diabetes nurse, in collaboration with a pedorthist, orthotist or prosthetist
Level 3	A level 2 foot centre that is specialised in care for diabetes-related foot disease, with multiple experts from several disciplines each specialised in this area working together, and that acts as a tertiary reference centre

CNO and to help optimise plantar pressure distribution. When deformity and/or joint instability is present, below-the-knee customised devices should be considered for additional protection. After remission is achieved, ambulation and loading of the foot should be gradually increased because of the risk of reactivation. If signs of recurrence do arise, a member of the team should be contacted promptly.

6 | ORGANISATION OF CARE FOR DIABETES-RELATED FOOT DISEASE

Successful efforts to prevent and treat diabetes-related foot disease depend upon a well-organised team that uses a holistic approach in which a foot ulcer is seen as a sign of multi-organ disease, and that integrates the various disciplines involved. Effective organisation requires systems and guidelines for all aspects of standard care as outlined in these practical guidelines. Local variations in resources and staffing often dictate how to provide care, but ideally organised diabetes-related foot care should provide the following:

1. Education for persons with diabetes and their carers, for healthcare staff in hospitals, and for primary healthcare professionals;
2. Systems to detect all people who are at risk, including annual foot examination of all persons with diabetes;
3. Access to measures for reducing the risk of foot ulceration, such as podiatric care and provision of appropriate footwear and insoles;
4. Ready access to prompt and effective treatment of any foot ulcer or infection;
5. Rapid access to, or expertise in, endovascular and surgical bypass revascularisation procedures;
6. Access to modalities to off-load the ulcer as described in this guideline;
7. Access to wound care that includes, as a minimum, regular inspection, debridement, non-adherent dressings and, if indicated, dressings to control excess exudation;
8. Auditing of all aspects of services to identify and address problems and ensure that local practice meets accepted standards of care;
9. An overall structure designed to meet the needs of persons requiring chronic care rather than simply responding to acute problems when they occur.

In all countries, there should optimally be at least three levels of foot-care management with interdisciplinary specialists like those listed in Table 2.

7 | CONCLUDING REMARKS

Studies around the world have shown that setting up an interdisciplinary foot care team and implementing prevention and management of diabetic foot disease according to the principles outlined in these practical guidelines are associated with a decrease in the frequency of diabetes related lower-extremity amputations. If it is not possible to create a full team from the outset, aim to build one step-by-step, introducing as many disciplines as possible. This team must first and foremost act with mutual respect and understanding, work in both primary and secondary care settings, and have at least one member available for consultation or assessment at all times. We hope that these updated practical guidelines and the seven underlying evidence-based guidelines continue to serve as reference documents to reduce the global burden of diabetes-related foot disease.

AUTHOR CONTRIBUTIONS

Nicolaas C. Schaper and Jaap J. van Netten wrote the first draft of this manuscript. All authors have read and commented on this version. All authors agreed on the final version.

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CONFLICT OF INTEREST STATEMENT

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APPENDIX A: CONDUCTING A SENSORY FOOT EXAMINATION

Peripheral neuropathy can be detected using the 10 g (5.07 Semmes-Weinstein) monofilament (detects LOPS) and a tuning fork (128 Hz, detects loss of vibratory sensation).

A.1 | 10g (5.07) Semmes-Weinstein monofilament (Figures A1 and A2)

1. First, apply the monofilament on the patient's hands (or elbow or forehead) to demonstrate what the sensation feels like.
2. Test three different sites on both feet, selecting from those shown in Figure A1.
3. Ensure the patient cannot see whether or where the examiner applies the filament.
4. Apply the monofilament perpendicular to the skin surface (Figure A2A) with sufficient force to cause the filament to bend or buckle (Figure A2B).
5. The total duration of the approach -> skin contact -> and removal of the filament should be approximately 2 s.
6. Do not apply the filament directly on an ulcer, callus, scar, or necrotic tissue.
7. Do not allow the filament to slide across the skin or make repetitive contact at the test site.
8. Press the filament to the skin and ask the patient whether they feel the pressure applied ('yes'/'no') and next where they feel the pressure (e.g., 'ball of left foot'/'right heel').
9. Repeat this application twice at the same site, but alternate this with at least one 'mock' application in which no filament is applied (a total of three questions per site).
10. Protective sensation is present at each site if the patient correctly answers two out of three applications or absent with two out of three incorrect answers.
11. Encourage the patients during testing by giving positive feedback.

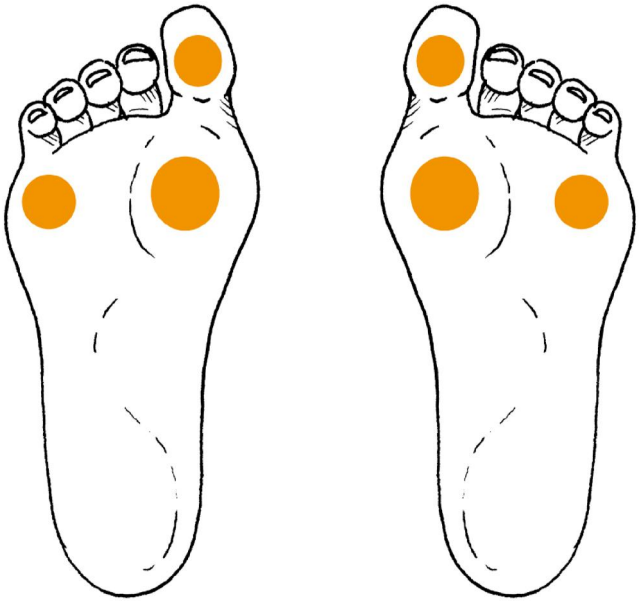

FIGURE A1 Sites that should be tested for Loss of protective sensation (LOPS) with the 10 g Semmes-Weinstein monofilament.

Monofilaments tend to lose buckling force temporarily after being used several times on the same day or permanently after long duration use. Depending on the type of monofilament, we suggest not using the monofilament for the next 24 h after assessing 10–15 patients and replacing it after using it on 70–90 patients.

A.2 | 128 Hz Tuning fork (Figure A3)

1. First, apply the tuning fork on the patient's wrist (or elbow or clavicle) to demonstrate what the sensation feels like.
2. Ensure the patient cannot see whether or where the examiner applies the tuning fork.
3. Apply the tuning fork to a bony part on the dorsal side of the distal phalanx of the first toe (or another toe if the hallux is absent).
4. Apply the tuning fork perpendicularly with constant pressure (Figure A4).
5. Repeat this application twice, but alternate this with at least one 'mock' application in which the tuning fork is not vibrating.

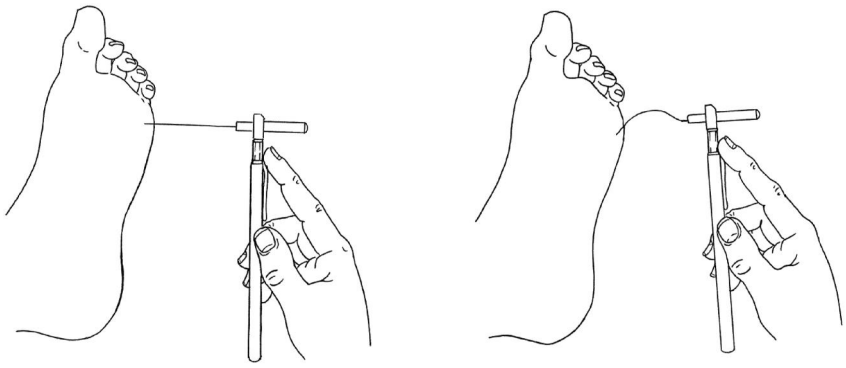

FIGURE A2 Proper method of using the 10 g Semmes-Weinstein monofilament.

6. The test is positive if the patient correctly answers at least two out of three applications, and negative if two out of three answers are incorrect.
7. If the patient is unable to sense the vibrations on the toe, repeat the test more proximally (e.g., malleolus, tibial tuberosity).
8. Encourage the patient during testing by giving positive feedback.

A.3 | Light touch test

This simple test (also called the Ipswich Touch test) can be used to screen for LOPS when the 10 g monofilament or 128 HZ tuning fork is not available. The test has reasonable agreement with these tests to determine LOPS, but its accuracy in predicting foot ulcers has not been established.

1. Explain the procedure and ensure that everything is understood
2. Instruct the subject to close their eyes and to say yes when they feel the touch
3. The examiner lightly sequentially touches with the tip of her/his index finger the tips of the first, third, and fifth toes of both feet for 1–2 s
4. When touching, do not push, tap, or poke
5. LOPS is likely when light touch is not sensed in ≥2 sites

APPENDIX B: MEASUREMENT ANKLE PRESSURES, ASSESSMENT OF DOPPLER WAVEFORMS AND CALCULATION OF ANKLE-BRACHIAL INDEX (ABI)

In persons with diabetes, the diagnostic accuracy of clinical examination for the presence of peripheral arterial disease (PAD) is low. Therefore, in any person with a foot ulcer, objective assessment of the perfusion in the foot is warranted with tests described below.[22,23]

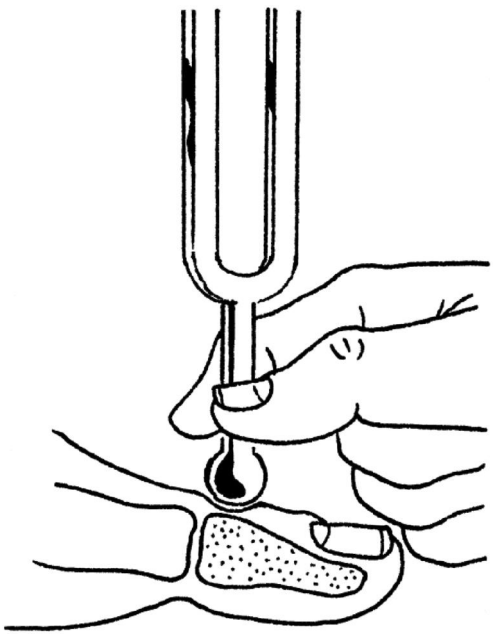

FIGURE A3 Proper method of using a 128 Hz tuning fork to check for vibratory sensation.

These tests are also advised when PAD is suspected in a person without a foot ulcer.

B.1 | Materials required

Hand-held 5–10 mHz Doppler device.

Transducer gel.

Sphygmomanometer.

Select a blood pressure cuff of sufficient size to be placed around the upper arms and calves (approx. 40% extra to wrap around).

B.2 | Measurement conditions

Quiet surroundings in a room with comfortable temperature for the patient, such as 22–24 °C.

Alcohol, exercise and caffeine should be avoided for 2 h prior to testing.

Patient in a supine horizontal position for 10 min prior to the measurement.

Both arms and lower legs should be bare.

No tight sleeves of shirts and trousers.

Always use the same sequence of measurements as described below.

B.3 | Brachial & ankle pressures and Doppler waveforms

B.3.1 | Brachial pressure

Place the cuff around the upper arm.

Apply the gel over the area of the brachial artery (can be palpated first). Ensure that a clear audible signal is detected.

Inflate the cuff to supra-systolic values, that is, about 30 mmHg above the pressure when the signal disappears completely.

Slowly deflate the cuff at a rate of 2–3 mmHg per second until an audible signal re-appears; the cuff pressure at that moment equals the systolic pressure in the artery. Record the result.

Repeat this procedure in the other arm.

B.3.2 | Ankle pressure and assessment of the Doppler waveform

Place the calf cuff approximately 2 cm above the malleolus, with the tubes pointing upwards.

Apply the gel in the areas of the dorsalis pedis and posterior tibial arteries (see figure below).

Place the Doppler probe with an angle of 40–60° pointing upstream in the area of each artery.

Slowly move the probe to select the area with the best signal.

Ideally print/review waveform on the screen of the Doppler machine. If the waveform is not displayed by the machine used, audibly assess the Doppler waveform and sound.

An absent signal or a monophasic signal is abnormal (see Figure A4) and is indicative of the presence of PAD (Figure A4).

Inflate the cuff to 30 mmHg above the pressure where the pulsatile sound is lost/the visual waveform disappears.

Slowly deflate the cuff at a rate of 2–3 mmHg per second; the systolic pressure should be taken as soon as an audible waveform returns or there is a small regular upstroke of a visual waveform (which occurs before the full waveform returns). Record the result.

After a minute rest, perform the measurement on the other artery of the same foot or if the signal was lost during the first measurement (do not reinflate the cuff during the procedure).

Repeat these measurements on the other leg.

B.4 | Calculation of ABI in persons with diabetes

To diagnose PAD, calculate the ABI for each limb by dividing the **lower** value of the dorsalis pedis or posterior tibial pressures of that foot by the highest of the left or right brachial pressures. This is particularly in those people with diabetes who have below knee arterial disease, which may affect only one of the tibial arteries.

The ABI has traditionally been calculated using the **higher** of the dorsalis pedis or posterior tibial pressures. This gives a best-case scenario of blood flow to the foot.

An ABI above 1.3 or below 0.9 is abnormal, that is, indicative of PAD.[4,12]

B.5 | Toe pressure and Toe-Brachial Index (TBI) measurement using photoplethysmography (PPG)

B.5.1 | Equipment

Several different types of equipment can be used, such as mercury strain gauge, laser Doppler, and continuous wave Doppler. PPG is commonly used; with an infra-red probe. Changes in opacity and blood volume are measured in the toe, resulting in a waveform. Here, we describe the use of PPG.

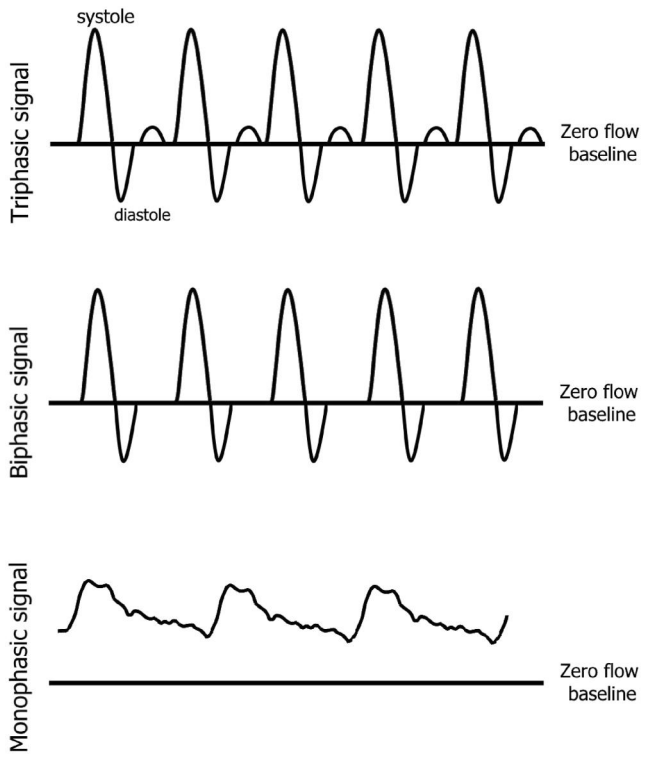

FIGURE A4 Triphasic (A), biphasic (B) and monophasic Doppler (C) signals. Based on Ref. 24.

B.5.2 | Preparation

Sphygmomanometer.

Cuff for digital pressure measurements; cuff size approximately 1.5 times the diameter of the digit.

PPG probe.

PPG unit or hand-held Doppler that can be connected to the PPG probe.

B.5.3 | Measurement conditions

As in ABI measurements, see above.

B.5.4 | Toe-pressure measurement

Place the digital cuff at the base of the hallux and the PPG probe against the distal toe pulp, sufficiently firmly to keep it in place but ensure there is no excess pressure on the digit whilst not inflated.

Where the hallux cannot be used, the second digit can be used (if a smaller cuff can be placed around the base of the toe).

Fixate the probe with tape ensuring contact of its entire flat surface against the skin (no external light should enter the underside of the probe) and preventing small movements which will disrupt the waveform.

Wait until a cyclical signal of the probe appears on the unit's screen.

Once a consistent waveform is seen, inflate the cuff to approximately 30 mmHg higher than the point at which the waveform flatlines.

Deflate the cuff slowly at a rate of 2–3 mmHg per second.

The cuff pressure at the first sign of reappearance of a regular upstroke is equal to the systolic pressure in the artery. Record the result.

In case of a suboptimal measurement, repeat the measurement after a 3 min waiting period.

Note: when the resting toe pressure is low (indicating reduced peripheral blood flow), the returning waveform is typically smaller and less clearly distinguishable from the baseline.

B.5.5 | Brachial artery systolic pressure

Measure the brachial artery systolic pressure in both arms as per ABI (above).

B.5.6 | Calculation of TBI

The TBI is calculated for each limb by dividing the toe pressure by the highest of the left and right brachial pressures.

A TBI below 0.7 is considered to be abnormal, that is, indicative for PAD.[4,12]

APPENDIX C: TERMS TO COVER WHEN PROVIDING EDUCATION FOR A PERSON AT-RISK FOR FOOT ULCERATION (IWGDF RISK 1 OR HIGHER)

1. Determine if the person is able to perform a foot inspection. If not, discuss who can assist the person in this task. Persons who have substantial visual impairment or physical inability to visualise their feet cannot adequately do the inspection
2. Explain the need to perform daily foot inspection of the entire surface of both feet, including areas between the toes
3. Ensure the patient knows how to notify the appropriate healthcare professional if measured foot temperature is perceptibly increased or if a blister, cut, scratch, or ulcer has developed
4. Review the following practices with the patient:
   - 4.1 Avoid walking barefoot, in socks without footwear, or in thin-soled slippers, whether at home or outside
   - 4.2 Do not wear shoes that are too tight or have rough edges or uneven seams
   - 4.3 Visually inspect and manually feel inside all shoes before you put them on
   - 4.4 Wear socks/stocking without seams (or with the seams inside out), do not wear tight or knee-high socks (compressive stocking should only be prescribed in collaboration with the foot care team), and change socks daily
   - 4.5 Wash feet daily (with water temperature always below 37° C), and dry them carefully, especially between the toes
   - 4.6 Do not use any kind of heater or a hot-water bottle to warm feet
   - 4.7 Do not use chemical agents or plasters to remove corns and calluses; consult the appropriate healthcare professional for these problems
   - 4.8 Use emollients to lubricate dry skin but not between the toes
   - 4.9 Cut toenails straight across (see Figure A5)
   - 4.10 Have your feet examined regularly by a healthcare professional

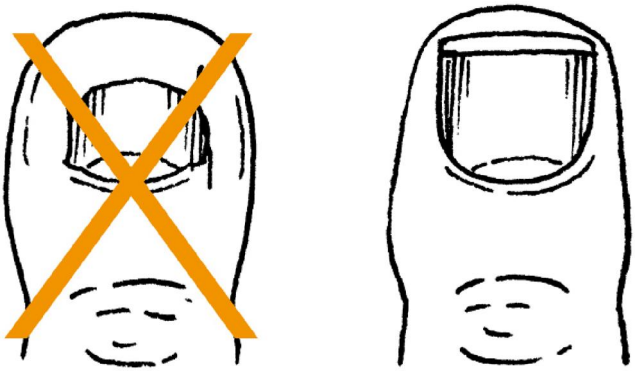

FIGURE A5 The proper way to cut toe nails.