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International Diabetes Federation



Prevention and management of foot problems in diabetes: A Summary Guidance for Daily Practice 2015, based on the IWGDF guidance documents ☆

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ARTICLE INFO

Article history:
Accepted 26 April 2016
Available online 18 December 2016

Keywords:
Diabetic foot
Guidelines
Guidance
IWGDF
Daily Practice
Implementation

ABSTRACT

Foot problems complicating diabetes are a source of major patient suffering and societal costs. To prevent, or at least reduce, the adverse effects of foot problems in diabetes, the International Working Group on the Diabetic Foot (IWGDF; www.iwgdf.org) was founded in 1996, consisting of experts from almost all the disciplines involved in the care of patients with diabetes and foot problems. An important output of the IWGDF is the international consensus guidance, continuously updated since 1999. To date, the publications have been translated into 26 languages, and more than 100,000 copies have been distributed globally.

The "Summary Guidance for Daily Practice" summarises the essentials of prevention and management of foot problems in persons with diabetes for clinicians who work with these patients on a daily basis. This guidance is the result of a long and careful process that started with the empaneling in 2013 of five working groups consisting of 49 international experts. These experts performed seven targeted systematic reviews to provide the evidence supporting the five chapters of the IWGDF Guidance on prevention; footwear and offloading; diagnosis, prognosis and management of peripheral artery disease; diagnosis and management of foot infections; interventions to enhance healing. In total almost 80,000 studies were detected by our literature review. After review of the title and abstract the reviewers of the different working groups selected only studies that fulfilled a minimal set of quality criteria and ended up with 429 articles for complete quality analysis. The GRADE system was used to translate the evidence from the studies into recommendations for daily clinical practice. The rating of each recommendation takes into account both the strength and the quality of the evidence. The IWGDF Guidance 2015 makes a total of 77 recommendations on prevention and management of foot

☆ This is a reprint of the Summary Guidance that was originally published in Diabetes Metabolism/Research and Reviews, 2016, Jan;32 (Suppl. 1):7–15.

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http://dx.doi.org/10.1016/j.diabres.2016.12.007

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problems in diabetes. These recommendations were condensed by the editorial board into this "Summary Guidance".

Encouraging and aiding clinicians to follow the evidence-based recommendations of the IWGDF Guidance 2015, and in particular the principles outlined in the "Summary Guidance", will likely result in a worldwide reduction in, and better outcomes of, foot problems in persons with diabetes, helping to reduce the morbidity and mortality associated with this major health problem.

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1. Introduction

In this 'Summary Guidance for Daily Practice' we describe the basic principles of prevention and management of foot problems in persons with diabetes. This summary is based on the International Working Group on the Diabetic Foot (IWGDF) Guidance 2015, consisting of evidence-based international consensus guidance documents on:

- Prevention of foot ulcers in at-risk patients with diabetes [1]
- Footwear and offloading to prevent and heal foot ulcers in diabetes [2]
- Diagnosis, prognosis and management of peripheral artery disease in patients with foot ulcers in diabetes [3]
- Diagnosis and management of foot infections in persons with diabetes [4]
- Interventions to enhance healing of chronic ulcers of the foot in diabetes [5]

In addition, the authors, as members of the Editorial Board of the IWGDF, provide some advice in this summary that is based on expert opinion, in areas for which the guidance documents were not able to provide evidence-based recommendations.

Depending on local circumstances, the principles outlined in this summary will have to be adapted or modified, taking into account regional differences in the socio-economic situation, accessibility to and sophistication of healthcare and various cultural factors. This summary is aimed at healthcare providers throughout the world who are involved in the care of people with diabetes. For more details and information on treatment by specialists in foot care, we refer the reader to the five evidence-based global consensus Guidance documents [1–5].

2. Foot problems in diabetes

Foot problems in diabetes are among the most serious complications of diabetes mellitus. Foot problems are a source of major suffering and costs for the patient, and they also place a considerable financial burden on healthcare and society in general. A strategy that includes prevention, patient and staff education, multi-disciplinary treatment of foot ulcers, and close monitoring of people's feet as described in this document can reduce foot problems and their sequelae.

3. Pathophysiology

Although the prevalence and spectrum of foot problems varies in different regions of the world, the pathways to ulceration are probably very similar in most patients. Diabetic foot lesions frequently result from a patient simultaneously having two or more risk factors, with diabetic peripheral neuropathy playing a central role. This neuropathy leads to an insensitive and sometimes deformed foot, often causing an abnormal walking pattern. In people with neuropathy, minor trauma (e.g., from ill-fitting shoes, walking barefoot or an acute injury) can precipitate ulceration of the foot. Loss of sensation, foot deformities, and limited joint mobility can result in abnormal biomechanical loading of the foot. This produces high pressure in some areas, to which the body responds with thickened skin (callus). This leads to a further increase of the abnormal loading, often with subcutaneous haemorrhage and eventually ulceration. Whatever the primary cause, if the patient continues walking on the insensitive foot it impairs wound healing (see Fig. 1).

Peripheral artery disease (PAD), generally caused by accelerated atherosclerosis, is present in up to 50% of patients with a diabetic foot ulcer. PAD is an important risk factor for impaired wound healing and lower extremity amputation. A minority of foot ulcers are purely ischemic; these are usually painful and caused by minor trauma. The majority of foot ulcers are neuro-ischemic, i.e., caused by combined neuropathy and ischemia. In these patients symptoms may be absent because of the neuropathy, despite severe pedal ischemia. Diabetic microangiopathy (so-called "small vessel disease") is not likely to be the primary cause of an ulcer or poor wound healing.

4. Cornerstones of prevention

There are five key elements that underpin prevention of foot problems:

1. Identification of the at-risk foot
2. Regular inspection and examination of the at-risk foot
3. Education of patient, family and healthcare providers
4. Routine wearing of appropriate footwear
5. Treatment of pre-ulcerative signs

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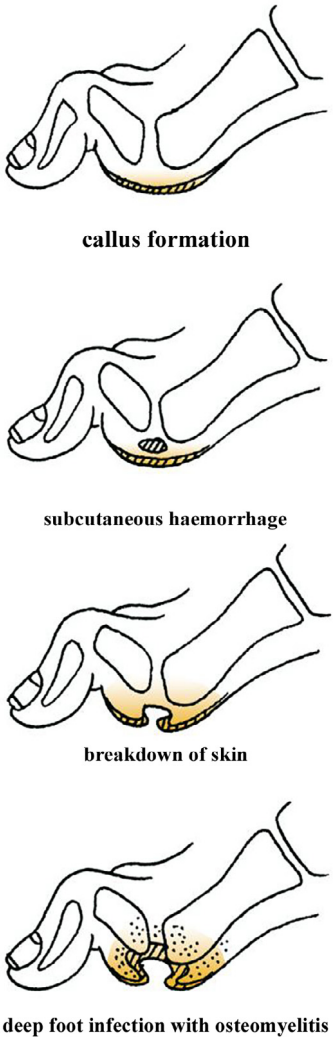


Fig. 1 – Illustration of ulcer due to repetitive stress.

4.1. *Identification of the at-risk foot*

To identify a person with diabetes who is at risk for foot ulceration, examine the feet annually to seek evidence of signs or symptoms of peripheral neuropathy or peripheral artery disease. If a patient with diabetes has peripheral neuropathy, screen for: a history of foot ulceration or lower-extremity amputation; foot deformity; pre-ulcerative signs on the foot; poor foot hygiene; and, ill-fitting or inadequate footwear.

Following examination of the foot, each patient can be assigned to a risk category that should guide subsequent preventative management. The IWGDF risk classification categories 2015 can be found in Table 1. Areas most at-risk are shown in Fig. 2.

4.2. *Regular inspection and examination*

All people with diabetes should have their feet examined at least once a year to identify those at risk for foot ulceration. Patients found to have a risk factor should be examined more often, based on their IWGDF risk category (Table 1).

The absence of symptoms in a person with diabetes does not exclude foot disorders; they may have asymptomatic neuropathy, peripheral artery disease, pre-ulcerative signs or even an ulcer. The clinician should examine the feet with the patient both lying down and standing up, and should also inspect their shoes and socks. Inspection and examination should minimally consist of:

History and foot examination:

- History: Previous ulcer/amputation, end stage renal disease, previous foot education, social isolation, poor access to healthcare, bare-foot walking
- Vascular status: History of claudication, rest pain, palpation of pedal pulses
- Skin: Callus, colour, temperature, oedema
- Bone/joint: Deformities (e.g., claw toes, hammer toes) or bony prominences, limited joint mobility
- Footwear/socks (worn when at home and when outside): Assessment of both their inside and outside

Assessment of neuropathy, using the following techniques:

- Symptoms, such as tingling or pain in the lower limb, especially at night
- Pressure perception: Semmes–Weinstein monofilaments (see addendum)
- Vibration perception: 128 Hz tuning fork (see addendum)
- Discrimination: Pin prick (dorsum of foot, without penetrating the skin)
- Tactile sensation: Cotton wool (dorsum of foot), or by lightly touching the tips of the toes of the patient with the tip of the index finger of the examiner for 1–2 s
- Reflexes: Achilles tendon reflexes

4.3. *Education of patients, family and healthcare providers about foot care*

Education, presented in a structured, organized and repeated manner, plays an important role in the prevention of foot problems. The aim is to improve patients' foot care knowledge, awareness, and self-protective behaviour, and to enhance motivation and skills in order to facilitate adherence to this behaviour. People with diabetes should learn how to recognize potential foot problems and be aware of the steps they need to take when problems arise. The educator must demonstrate the skills, such as how to cut nails appropriately. A member of the health care team should provide education (see examples of instructions below) in several sessions over time, and preferably using a mixture of methods. It is essential to evaluate 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 skills in care for patients at high-risk for foot ulceration.

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Table 1 – The IWGDF Risk Classification System 2015 and preventative screening frequency

Category	Characteristics	Frequency
0	No peripheral neuropathy	Once a year
1	Peripheral neuropathy	Once every 6 months
2	Peripheral neuropathy with peripheral artery disease and/or a foot deformity	Once every 3–6 months
3	Peripheral neuropathy and a history of foot ulcer or lower-extremity amputation	Once every 1–3 months

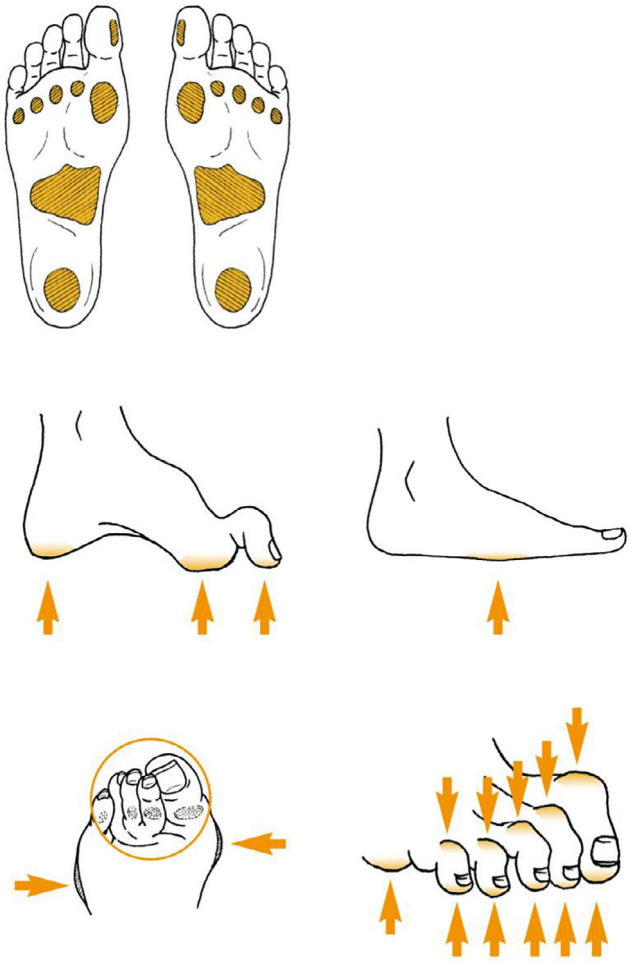


Fig. 2 – Areas at risk for foot ulceration.

Items that should be covered when instructing the patient at-risk for foot ulceration:

- Determine if the person with diabetes is able to perform a daily foot inspection. If not, discuss who can assist the person in this task. A substantially visually impaired person cannot adequately do the inspection
- Perform daily foot inspection, including areas between the toes
- Notify the appropriate healthcare provider at once if foot temperature is markedly increased, or if a blister, cut, scratch or ulcer has developed
- Avoid walking barefoot, in socks without footwear, or in thin-soled standard slippers, whether at home or outside
- Do not wear shoes that are too tight, have rough edges or uneven seams
- Inspect and feel inside all shoes before you put them on
- Wear socks/stocking without seams (or with the seams inside out), do not wear tight or knee-high socks, and change socks daily
- Wash feet daily (with water temperature always below 37 °C), and dry them carefully, especially between the toes
- Do not use any kind of heater or a hot-water bottle to warm feet
- Do not use chemical agents or plasters to remove corns and calluses; see the appropriate healthcare provider for these problems
- Use emollients to lubricate dry skin, but not between the toes
- Cut toenails straight across (see Fig. 3)
- Have your feet examined regularly by a healthcare provider

4.4. *Routine wearing of appropriate footwear*

Inappropriate footwear and walking barefoot with insensitive feet are major causes of foot ulceration. Patients with loss of protective sensation should have access to appropriate footwear without financial restraints and should be encouraged to wear this footwear at all times, both indoors and outdoors. All footwear should be adapted to conform to altered biomechanics and deformities affecting the patient's foot. Patients without peripheral neuropathy (IWGDF risk classification 0) can select off-the-shelf footwear, but should ensure that they fit properly. Patients with neuropathy (IWGDF risk classification 1) must take extra care when selecting or being fitted with footwear; this is most important when they also have foot deformities (IWGDF risk classification 2) or have had a previous ulcer/amputation history (IWGDF risk classification 3).

The shoe should not be either too tight or too loose (see Fig. 4). The inside of the shoe should be 1–2 cm longer than the foot. 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

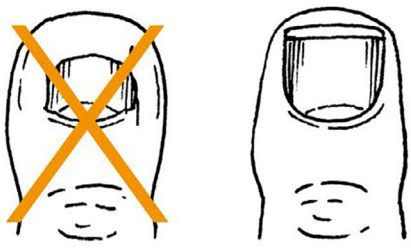


Fig. 3 – How to cut toe nails.

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toes. Evaluate the fit with the patient in the standing position, preferably at the end of the day. If the fit is poor due to foot deformities, or if there are signs of abnormal loading of the foot (e.g., hyperaemia, callus, ulceration), refer the patient for special footwear (advice and/or construction), including insoles and orthoses. If possible, demonstrate that there is reduced plantar pressure of this special footwear to prevent a recurrent plantar foot ulcer.

4.5. *Treatment of pre-ulcerative signs*

In a patient with diabetes treat any pre-ulcerative sign on the foot. This includes: removing abundant callus; protecting blisters, or draining them if necessary; treating ingrown or thickened nails; and, prescribing antifungal treatment for fungal infections. This treatment should be repeated until the pre-ulcerative sign resolves and does not recur over time, and should preferably be performed by a trained foot care specialist. If possible, treat foot deformities non-surgically (e.g., with an orthosis).

5. Foot ulcers

Health care providers should follow a standardized and consistent strategy for evaluating a foot wound, as this will guide further evaluation and therapy. The following items must be addressed:

5.1. *Type*

By history and clinical examination, classify the ulcer as neuropathic, neuro-ischemic or 'purely' ischemic. Evaluate all patients for the presence of PAD by taking a symptom-directed history and palpating foot pulses. If possible, examine the arterial pedal wave forms and measure the ankle pressure and ankle brachial index (ABI), using a Doppler instrument. The presence of an ABI 0.9–1.3 and a triphasic pedal pulse waveform largely excludes PAD, as does a toe brachial index (TBI) $\geqslant$ 0.75. However, ankle pressure and ABI can be falsely elevated due to calcification of the arteries. In selected cases other tests, such as measurements of toe pressure or transcutaneous pressure of oxygen ($TcpO_2$), are useful. No specific symptoms or signs of PAD reliably predict healing of the ulcer.

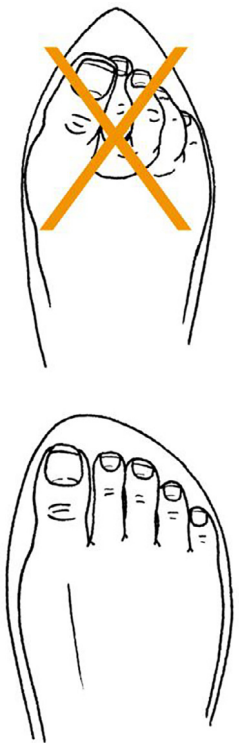


Fig. 4 – Internal width of the shoe.

5.2. *Cause*

Ill-fitting shoes and walking barefoot with insensitive feet are the most frequent causes of ulceration, even in patients with purely ischemic ulcers. Therefore, meticulously examine shoes and footwear behaviour in all patients.

5.3. *Site and depth*

Neuropathic ulcers frequently occur on the plantar surface of the foot, or in areas overlying a bony deformity. Ischemic and neuro-ischemic ulcers are more common on the tips of the toes or the lateral borders of the foot.

The depth of an ulcer can be difficult to determine, especially in the presence of overlying callus or necrotic tissue. To enable an adequate assessment of the ulcer debride neuropathic ulcers with callus and necrosis as soon as possible. This debridement should not be performed in non-infected ulcers with signs of severe ischemia. In neuropathic ulcers, debridement can usually be performed without any local anaesthetic.

5.4. *Signs of infection*

Infection of the foot in a person with diabetes presents a serious threat to the affected limb, and must be evaluated and treated promptly. Because all open wounds are colonised with potential pathogens, we diagnose infection by the presence of at least two signs or symptoms of inflammation (redness, warmth, induration, pain/tenderness) or purulent secretions. Unfortunately, these signs may be blunted by neuropathy or ischemia, and systemic findings (e.g., fever, increased white blood count) are often absent. Infections should be classified as mild (superficial with minimal cellulitis), moderate (deeper or more extensive) or severe (accompanied by systemic signs of sepsis).

If not properly treated, infection can spread contiguously to underlying tissues, including bone (osteomyelitis). Assess patients with a diabetic foot infection for the presence of osteomyelitis, especially if there is a longstanding or deep wound, a wound overlying bone, or if it is possible to touch bone with a sterile metal probe. In addition to the clinical evaluation, plain radiographs suffice for screening for osteomyelitis in most patients. Consider magnetic resonance imaging when more advanced imaging is needed.

For clinically infected wounds obtain a tissue specimen for culture (and Gram-stained smear, if available); avoid culturing superficial swab specimens. Mild (superficial and limited) infection is usually caused by aerobic gram-positive cocci,

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especially Staphylococcus aureus. Chronic and more severe infections are often polymicrobial, with aerobic gram-negative rods and anaerobes accompanying the gram-positive cocci.

6. Ulcer treatment

Foot ulcers will heal in the majority of patients if the clinician bases treatment on the principles outlined below. However, even optimum wound care cannot compensate for continuing trauma to the wound bed, or for inadequately treated ischemia or infection. Patients with an ulcer deeper than the subcutaneous tissues often require intensive treatment, and, depending on their social situation, local resources and infrastructure, they may need to be hospitalised.

7. Principles of ulcer treatment

7.1. *Relief of pressure and protection of the ulcer*

This is a cornerstone in treating an ulcer associated with increased biomechanical stress:

- The preferred treatment for a neuropathic plantar ulcer is a non-removable knee-high offloading device, either total contact cast (TCC) or removable walker rendered irremovable
- When a non-removable TCC or walker is contra-indicated, use a removable device
- When these devices are contra-indicated, use footwear that best offloads the ulcer
- In non-plantar ulcers, consider offloading with shoe-modifications, temporary footwear, toe-spacers or orthoses
- If other forms of biomechanical relief are not available, consider felted foam, in combination with appropriate footwear
- Instruct the patient to limit standing and walking, and to use crutches if necessary

7.2. *Restoration of foot perfusion*

- In patients with either an ankle pressure < 50 mm Hg or ABI < 0.5 consider urgent vascular imaging and, when appropriate, revascularisation. If the toe pressure is <30 mmHg or $TcpO_2$ is <25 mmHg a revascularisation should also be considered
- When an ulcer is not showing signs of healing within 6 weeks, despite optimal management, consider revascularisation, irrespective of the results of the tests described above
- If contemplating a major (i.e. above the ankle) amputation, first consider the option of revascularisation
- The aim of revascularisation is to restore direct flow to at least one of the foot arteries, preferably the artery that supplies the anatomical region of the wound
- Select a revascularisation technique based on both individual factors (such as morphological distribution of PAD, availability of autogenous vein, patient co-morbidities) and local expertise
- Pharmacological treatments to improve perfusion have not been proven to be beneficial
- Emphasise efforts to reduce cardiovascular risk (cessation of smoking, control of hypertension and dyslipidemia, use of aspirin or clopidogrel)

7.3. *Treatment of infection*

Superficial ulcer with skin infection (mild infection):

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

Deep (potentially limb-threatening) infection (moderate or severe infection):

- Urgently evaluate for need for surgical intervention to remove necrotic tissue, including infected bone, and drain abscesses
- Assess for PAD; if present consider urgent treatment, including revascularisation
- Initiate empiric, parenteral, broad-spectrum antibiotic therapy, aimed at common gram-positive and gram-negative bacteria, including anaerobes
- Adjust (constrain, if possible) the antibiotic regimen based on clinical response and culture and sensitivity results

7.4. *Metabolic control and treatment of co-morbidity*

- Optimise glycemic control, if necessary with insulin
- Treat oedema or malnutrition, if present

7.5. *Local wound care*

- Inspect the ulcer frequently
- Debride the ulcer (with scalpel), and repeat as needed
- Select dressings to control excess exudation and maintain moist environment
- Consider using negative pressure therapy to help heal post-operative wounds
- Consider systemic hyperbaric oxygen treatment in poorly healing wounds; this treatment may hasten wound healing

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

- Biologically active products (collagen, growth factors, bio- engineered tissue) in neuropathic ulcers
- Silver, or other anti-microbial agent, containing dressings

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Note: Do not use footbaths in which the feet are soaked, as they induce skin maceration.

7.6. *Education for patient and relatives*

- Instruct patients (and relatives or carers) on appropriate self-care and how to recognize and report signs and symptoms of new or worsening infection (e.g., onset of fever, changes in local wound conditions, worsening hyperglycaemia)
- During a period of enforced bed rest, instruct on how to prevent an ulcer on the contra-lateral foot

7.7. *Prevention of recurrence*

- Once the ulcer is healed, include the patient in an integrated foot-care programme with life-long observation, professional foot treatment, adequate footwear, and education
- The foot should never return in the same shoe that caused the ulcer

8. Organization

Successful efforts to prevent and treat foot complications depend upon a well-organised team, that uses a holistic approach in which the ulcer is seen as a sign of multi organ disease, and that integrates the various disciplines involved. Effective organisation requires systems and guidelines for education, screening, risk reduction, treatment, and auditing. Local variations in resources and staffing often dictate how care is provided, but ideally a foot care programme should provide the following:

- Education for people with diabetes and their carers, for healthcare staff in hospitals and for primary healthcare providers
- A system to detect all people who are at risk, with annual foot examination of all persons with diabetes
- Measures to reduce risk of foot ulceration, such as podiatric maintenance care and appropriate footwear
- Prompt and effective treatment of any foot complication
- Auditing of all aspects of the service to identify problems and ensure that local practice meets accepted standards of care
- An overall structure designed to meet the needs of patients requiring chronic care, rather than simply responding to acute problems when they occur.

In all countries, there should be at least three levels of foot-care management:

Level 1 General practitioner, podiatrist, and diabetic nurse.

Level 2 Diabetologist, surgeon (general, orthopaedic, or foot), vascular surgeon, endovascular interventionist, podiatrist and diabetic nurse, in collaboration with a shoe-maker, orthotist or prosthetist.

Level 3 A level 2 foot centre that is specialized in diabetic foot care, with multiple experts from several disciplines each specialised in this area working together, and that acts as a tertiary reference centre.

Many studies around the world have shown that setting up a multidisciplinary foot care team is associated with a drop in the number 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 the various disciplines as possible. This team must first and foremost be a team that acts with mutual respect and understanding, that works in both primary and secondary care settings, and that has at least a member available for consultation or patient assessment at all times.

Conflict of interest

No conflicts of interest for this manuscript.

Addendum

Sensory foot examination

Neuropathy can be detected using the 10 g (5.07 Semmes–Weinstein) monofilament, tuning fork (128 Hz), and/or cotton wisp.

Semmes–Weinstein monofilament (Figs. 5 and 6)

- Sensory examination should be carried out in a quiet and relaxed setting. First apply the monofilament on the patient's hands (or elbow or forehead) so that he or she knows what to expect.
- The patient must not be able to see whether or where the examiner applies the filament. The three sites to be tested on both feet are indicated in Fig. 5.
- Apply the monofilament perpendicular to the skin surface (Fig. 6).
- Apply sufficient force to cause the filament to bend or buckle (Fig. 6).
- The total duration of the approach – skin contact and removal of the filament – should be approximately 2 s.
- Apply the filament along the perimeter of, not on, an ulcer site, callus, scar or necrotic tissue.
- Do not allow the filament to slide across the skin or make repetitive contact at the test site.
- 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 ('left foot'/'right foot').
- Repeat this application twice at the same site, but alternate this with at least one 'mock' application in which no filament is applied (total three questions per site).

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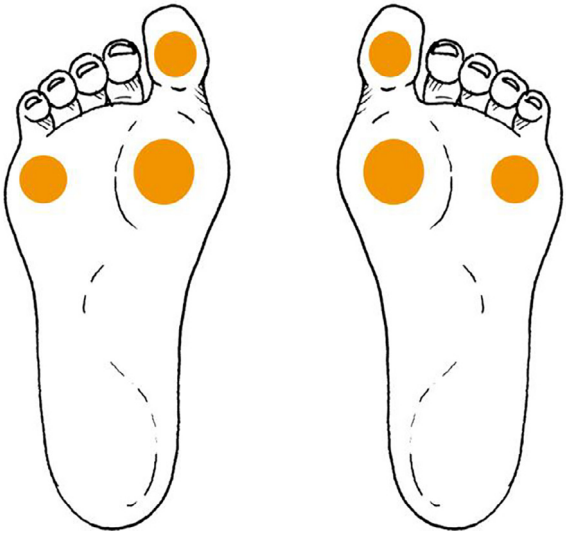
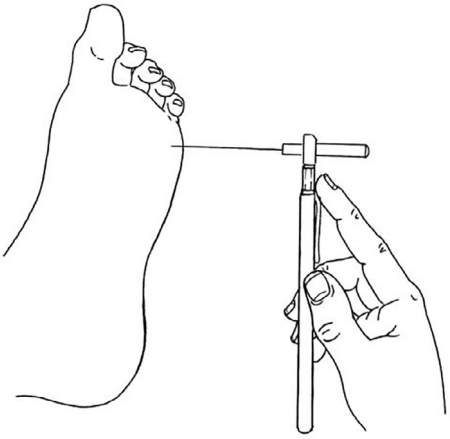


Fig. 5 – Sites to be tested with the monofilament.



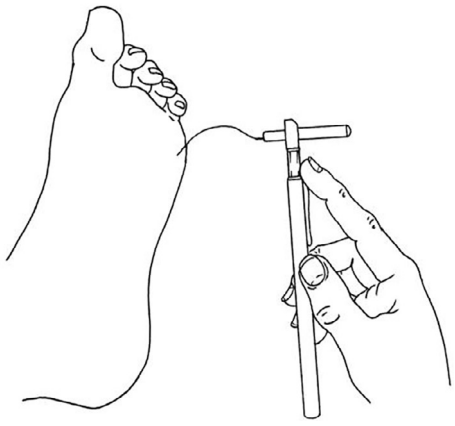


Fig. 6 – Application of the monofilament.

- Protective sensation is present at each site if the patient correctly answers two out of three applications. Protective sensation is absent with two out of three incorrect answers – the patient is then considered to be at risk of ulceration.
- Encourage the patients during testing by giving positive feedback.
- The healthcare provider should be aware of the possible loss of buckling force of the monofilament if used for too long a period of time.

Tuning fork (Fig. 7)

- The sensory exam should be carried out in a quiet and relaxed setting. First, apply the tuning fork on the patient's wrists (or elbow or clavicle) so that he or she knows what to expect.
- The patient must not be able to see whether or where the examiner applies the tuning fork. The tuning fork is applied on a bony part on the dorsal side of the distal phalanx of the first toe.
- The tuning fork should be applied perpendicularly with constant pressure (Fig. 7).
- Repeat this application twice, but alternate this with at least one 'mock' application in which the tuning fork is not vibrating.
- The test is positive if the patient correctly answers at least two out of three applications, and negative ('at risk for ulceration') with two out of three incorrect answers.
- If the patient is unable to sense the vibrations on the big toe, the test is repeated more proximally (malleolus, tibial tuberositas).
- Encourage the patient during testing by giving positive feedback.

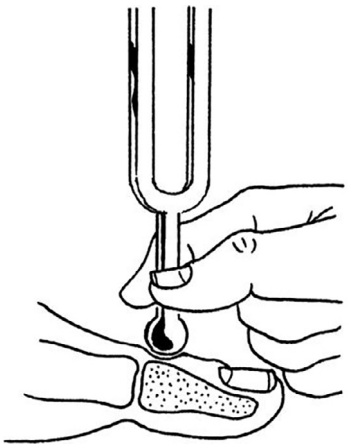


Fig. 7 – How to use a tuning fork.

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Easy to use foot screening assessment sheet for clinical examination

Foot ulcer	
Presence of a full thickness ulcer	Yes/No
Risk factors for foot ulceration	
Neuropathy	
Monofilament undetectable	Yes/No
Tuning fork undetectable	Yes/No
Cotton wool undetectable	Yes/No
Foot pulses	
Tibial posterior artery absent	Yes/No
Dorsal pedal artery absent	Yes/No
Other	
Foot deformity or bony prominences	Yes/No
Loss of joint mobility	Yes/No
Signs of abnormal pressure such as callus	Yes/No
Discoloration on dependency	Yes/No
Poor foot hygiene	Yes/No
Inappropriate footwear	Yes/No
Previous ulcer	Yes/No
Amputation	Yes/No

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