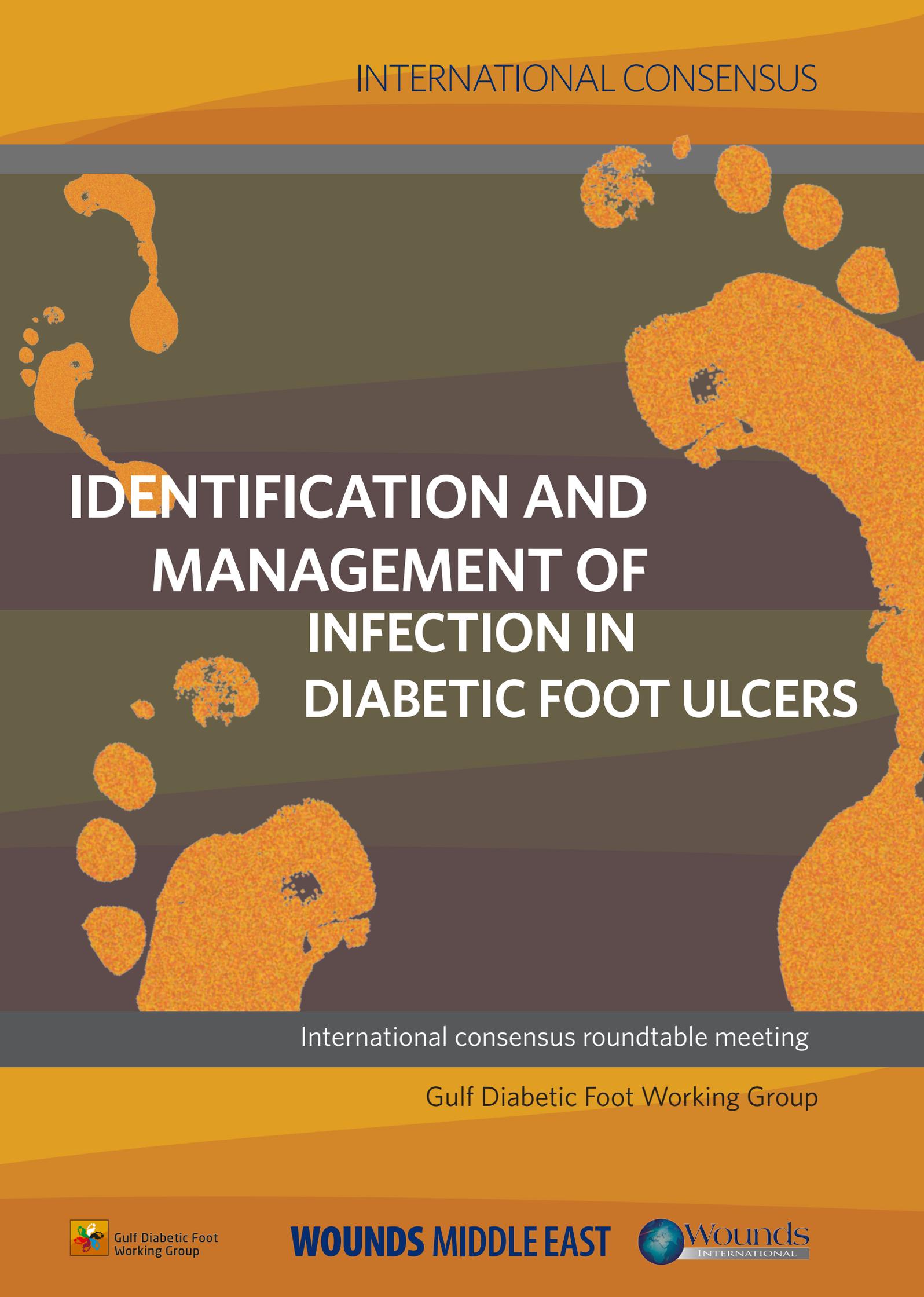


INTERNATIONAL CONSENSUS



IDENTIFICATION AND MANAGEMENT OF INFECTION IN DIABETIC FOOT ULCERS

International consensus roundtable meeting

Gulf Diabetic Foot Working Group



Gulf Diabetic Foot
Working Group

WOUNDS MIDDLE EAST



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**Gulf Diabetic Foot
Working Group**

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FOREWORD

In recent years there has been growing awareness that diabetic foot ulcers (DFUs) are rising in prevalence globally, and particularly in the Gulf region (Ahmed et al, 2011). Of the issues that continue to be challenging in DFU management, infection remains a common and often serious complication.

Infection leads to delays in wound healing and increases the risk of loss of limb and life (IWII, 2016). It is vital to implement effective strategies in order to identify and manage infection in DFUs, in order to improve mortality and morbidity rates.

A group of international experts met in March 2017, organised by the Gulf Diabetic Foot Working Group, to discuss the issue of infection in DFUs and set out to:

- Identify the key challenges of treating DFU infection in the Gulf region
- Provide the first ever guidance for management of DFU infection tailored specifically for care in the region
- Provide clinicians with a practical educational tool that can be easily absorbed into their practice and facilities.

The goal is to provide both specialist and non-specialist practitioners with the information they need and practical guidance on identifying and managing infection in DFUs, which can be directly applied to local practice. A need was identified for local guidelines that considered cultural and religious practices in the region, as well as clinical issues. With all of these elements in mind, this document aims to raise awareness of the prevention of diabetic foot problems, as well as provide guidance that can be used in clinical practice.

Setting the scene: DFUs in the Gulf region

Key learning points

1. Prevalence of diabetes and associated complications is increasing worldwide, causing a significant issue that must be addressed - education and the establishment of guidelines and pathways are essential.
2. DFUs are common in the Gulf region and require specialist considerations for management.

Global incidence of diabetes has almost quadrupled in the last 30 years, with 422 million adults worldwide now diagnosed with the disease, increasing global prevalence from 4.7% to 8.5% (WHO, 2016). Within the diabetic population, the incidence of DFUs has been reported to be between 4% and 10%, with a one-in-four risk of developing a DFU over a patient's lifetime (WUWHS, 2016; Armstrong et al, 2017).

DFUs are complex, chronic wounds, which have a major long-term impact on the morbidity, mortality and quality of patients' lives (Wounds International, 2013; NICE, 2011). Developing a DFU is a pivotal event in the life of a patient with diabetes and a marker of serious disease and comorbidities; patients who develop a DFU are at greater risk of premature death, myocardial infarction and fatal stroke (Brownrigg et al, 2012). Diabetic foot ulcers are also associated with a risk for hospitalisation and resource utilisation that is at least equivalent to other major chronic diseases such as heart disease, stroke, and cancer (Skrepnek et al, 2017).

Unlike other chronic wounds, a DFU is often complicated by wide-ranging diabetic changes, such as neuropathy and vascular disease (Wounds International, 2013).

In most patients, peripheral neuropathy or peripheral arterial disease play a central role; therefore, DFUs are commonly classified as:

- Neuropathic
- Ischaemic
- Neuroischaemic.

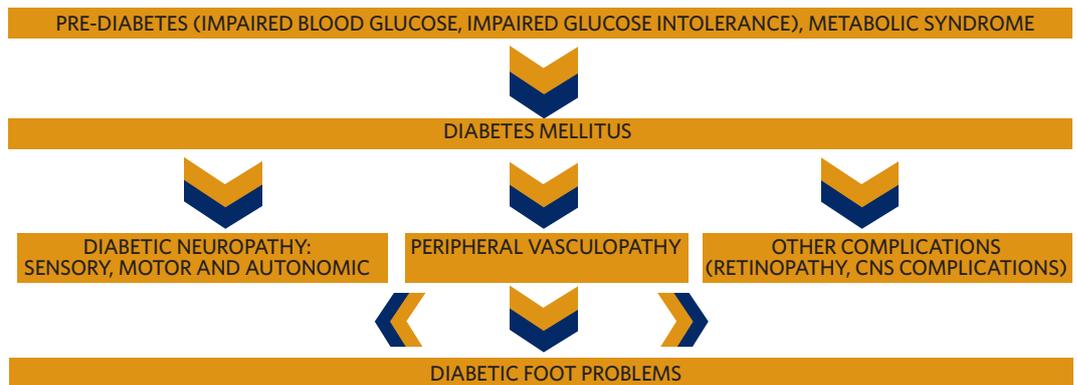
See Table 1 for more information on the typical features of DFUs according to aetiology.

Peripheral neuropathy increases the risk of DFU development through loss of protective sensation, foot deformities and its common association with dry skin, which may in turn cause cracking, fissures and callus. Loss of protective sensation is a major component of nearly all DFUs; it is associated with a seven-fold increase in ulceration (Singh et al, 2005).

Table 1. Typical features of diabetic foot ulcers (DFUs) according to aetiology (adapted from Wounds International Best Practice Guidelines, 2013)

Feature	Neuropathic DFU	Ischaemic DFU	Neuroischaemic DFU
Sensation	Sensory loss	Painful	Degree of sensory loss
Callus/necrosis	Callus present and often thick	Necrosis common	Minimal callus
Wound bed	Pink and granulating, surrounded by callus	Pale and sloughy with poor granulation	Poor granulation
Foot temperature and pulses	Warm with bounding pulses	Cool with absent pulses	Cool with absent pulses
Other	Dry skin and fissuring	Delayed healing	High risk of infection
Typical location	Weight-bearing areas of the foot, such as metatarsal heads, the heel and over the dorsum of clawed toes	Tips of toes, nail edges and between the toes and lateral borders of the foot	Margins of the foot and toes
Estimated prevalence	35%	15%	50%

FIGURE 1 | Diabetic foot continuum (adapted from Ahmed et al, 2011)



PRACTICAL ISSUES AFFECTING PATIENTS IN THE GULF REGION

Diabetes represents a huge global challenge, and this is a particularly significant issue in the Middle East and particularly the Gulf region (Alzahrani, 2012). It is estimated that over 37 million people in the Middle East have diabetes, with this figure expected to rise to over 72 million by 2040 if no action is taken (IDF, 2015); it is further estimated that two out of five adults with diabetes remain undiagnosed. Among Middle Eastern countries, the highest prevalence of diabetes is seen in Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates (IDF, 2015).

Although in recent years awareness and education around diabetes has improved – for example, training and education through the Gulf Diabetic Foot Working Group – there remains a need for targeted guidelines and treatment pathways, tailored specifically for the area, which can be used in everyday practice.

DFUs in particular represent a significant challenge, with specific risk factors and potential complications that need to be taken into account for the patient population in the Gulf region (see Box 1). The majority of lower limb amputations are related to diabetes, with 85% of all diabetes-related amputations preceded by a DFU (IDF, 2015).

BOX 1 | Risk factors and complications specific to diabetic foot ulcers in the Gulf region

- **Climate** – the predominantly hot, dry climate in the Gulf region means that it is common in practice to see dry, cracked skin with fissures in the feet; the hot climate and associated footwear (see below) also exacerbates the issue of infection
- **Footwear** – due to the climate and local tradition, the most common footwear worn in the region is open sandals, and it is also common to walk barefoot (particularly inside the home), which means that the feet are not protected from potential trauma
- **Cultural/religious practice** – as foot washing is culturally more common in the region, this may present a risk factor. While this may afford an opportunity to inspect the feet as well as clean them, patients with diabetes may sustain unnoticed harm to their feet, as well as potential infection issues if the feet are not dried and protected sufficiently
- **Traditional medicine** – in some Gulf countries, traditional herbal medicine is commonly used; anecdotal evidence suggests that DFUs are seen that have been complicated by using traditional herbal methods and medicines
- **Awareness and concordance** – although this varies across the region, there is still a lack of awareness about diabetic foot problems and their prevention in some areas, and patient concordance is a significant issue
- **Health care provision** – resources available vary considerably across the region and management does not generally utilise a multidisciplinary team (MDT) approach, which has been found to be the most effective way of dealing with DFUs and associated issues and complications.

DFU assessment: why a standard approach matters

Key learning points

1. Assessment should take a holistic approach, taking into account any underlying issues and patient lifestyle factors.
2. A multidisciplinary team (MDT) approach is vital and patients should be referred when necessary – assessment should always lead directly to treatment or referral.
3. The 3-minute diabetic foot examination should be used as a structured assessment tool.

Proper, standardised assessment of DFUs is vital. Assessment should trigger appropriate treatment (or referral), which will improve overall outcomes. A multidisciplinary team (MDT) approach is also key to improving outcomes in DFUs, and early referral to an expert MDT is likely to effect clinical improvement (WUWHS, 2016).

As DFUs are a manifestation of complex, chronic systemic disease, it is particularly important that a holistic assessment is undertaken, which involves the patient and their overall health, and any underlying issues, as well as the wound itself.

Initial assessment should include evaluation of (WUWHS, 2016):

- Diabetes management and blood glucose control
- Previous history of foot ulceration and surgery
- Smoking status
- Symptoms and signs of peripheral arterial or venous disease
- Symptoms and signs of peripheral neuropathy
- Musculoskeletal evaluation, e.g. for overall flexibility, range of movement in the ankle, foot shape
- Systemic signs of infection
- Pain, e.g. neuropathic pain, wound-related pain
- Socioeconomic circumstances, dexterity, visual acuity and insight.

THE IMPORTANCE OF A HOLISTIC APPROACH

If a thorough holistic assessment is not made, problems will occur from the start of treatment – it is vital to assess the wound properly in order for appropriate and effective treatment to begin. 'Holistic' assessment means that the wound should not be treated in isolation but in the context of the patient's overall wellbeing (Wounds International, 2012).

Therefore, an MDT approach is key – assessment must trigger either effective treatment, or referral, to ensure that all patients are receiving the appropriate care. Recording and monitoring assessment outcome is key to tracking the efficacy of subsequent treatment (Wounds UK, 2017).

Diabetes is a complex disease and the management of DFUs requires input from a wide range of clinical specialties. The MDT approach is required due to the complex links between uncontrolled diabetes, vascular compromise, foot deformity, diabetic foot infection and other comorbidities (WUWHS, 2016). This requires a team of organised and unified specialists, along with a systemic approach towards controlling ischaemia, wound severity and foot infection. This has been shown to improve outcomes and help reduce the risk of amputation.

BOX 2 | How should I assess a diabetic patient presenting with a foot infection?

Recommendations from the 2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections

- Clinicians should evaluate a diabetic patient presenting with a foot wound at 3 levels: the patient as a whole, the affected foot or limb, and the infected wound (strong, low).
- Clinicians should diagnose infection based on the presence of at least 2 classic symptoms or signs of inflammation (erythema, warmth, tenderness, pain, or induration) or purulent secretions
- Clinicians should then document and classify the severity of the infection based on its extent and depth and the presence of any systemic findings of infection (strong, low).
- Clinicians should assess the affected limb and foot for arterial ischemia (strong, moderate), venous insufficiency, presence of protective sensation, and biomechanical problems (strong, low).
- Clinicians should debride any wound that has necrotic tissue or surrounding callus; the required procedure may range from minor to extensive (strong, low).

The International Diabetes Federation recommends that in order to provide comprehensive specialist foot care an MDT should comprise doctors with a particular interest in diabetes, podiatrists, trained nurses, vascular surgeons, orthopaedic surgeons, infection specialists, orthotists, social workers and psychologists. However, despite the guidelines, it is local resources that will govern the skill mix and scope of any foot care team. The key within any team is the ability to access immediately relevant healthcare professionals, e.g. a vascular surgeon. Ideally, one clinician should act as coordinator (or gatekeeper) of multidisciplinary care to ensure that appropriate referrals are made and that care is integrated. The coordinator may be a podiatrist, a surgeon or another type of clinician with a special interest in diabetes (see Table 2 for guidelines on when patients should be referred to a specialist member of the team where possible).

In order to correctly monitor treatment progress, setting realistic goals at the start of treatment – and documenting these goals – is vital. Goals should be patient-centric, as listening to the individual patient and taking their needs into account will result in more effective treatment through improved understanding and compliance (Wounds UK, 2017). While the ultimate aim is healing, wounds impact patients' physical, mental and social wellbeing and these factors must be taken into account (Vowden and Vowden, 2016).

THE 3-MINUTE DIABETIC FOOT EXAMINATION

As it has been found that routine foot examination and risk stratification is often not incorporated efficiently into standard practice, the need was identified for a quick and simple foot examination process. The 3-minute diabetic foot examination (Miller et al, 2014) was developed to provide a standardised approach to practical examination and assessment, enabling the clinician to quickly detect major risks and prompt appropriate and timely referral where necessary.

The examination consists of three components, which should comprise a total of 3 minutes:

- Taking a patient history
- Performing a physical examination
- Providing patient education.

See Figure 2 for full details of these components and how the 3-minute foot examination should be structured

Table 2. Guidelines on referral to specialist members of the multi-disciplinary care team where possible (adapted from WUWHS, 2016)

Priority	Indications	Timeline	Suggested follow up
Urgent (active pathology)	Open wound or ulcerative area with or without signs of infection New neuropathic pain or pain at rest Signs of active Charcot deformity (red, hot, swollen midfoot or ankle) Vascular compromise (sudden absence of DP/PT pulses or gangrene)	Immediate referral/consult	As determined by specialist
High (ADA risk category 3)	Presence of diabetes with a previous history of ulcer or lower extremity amputation Chronic venous insufficiency (skin colour change or temperature difference)	Immediate or 'next available' outpatient referral	Every 1-2 months
Moderate (ADA risk category 2)	Peripheral artery disease +/- LOPS DP/PT pulse diminished or absent Presence of swelling or oedema	Referral within 1-3 weeks (if not already receiving regular care)	Every 2-3 months
Low (ADA risk category 1)	LOPS +/- longstanding, non-changing deformity Patient requires prescriptive or accommodative footwear	Referral within 1 month	Every 4-6 months
Very low (ADA risk category 0)	No LOPS or peripheral artery disease Patient seeks education regarding foot care, athletic training, appropriate footwear, preventing injury, etc	Referral within 1-3 months	Annually as a minimum

*All patients with diabetes should be seen at least once a year by a foot specialist
Key ADA = American Diabetes Association, DP = dorsal peds, LOPS = loss of protective sensation, PT = posterior tibial

FIGURE 2 | Structure of the 3-minute diabetic foot examination

WHAT TO ASK

00:01

Does the patient have a history of:

- Previous leg/foot ulcer or lower limb amputation/surgery?
- Prior angioplasty, stent or leg bypass surgery?
- Foot wound?
- Smoking or nicotine use?
- Diabetes? (If yes, what are the patient's current control measures?)

Does the patient have:

- Burning or tingling in legs/feet?
- Leg or foot pain with activity or rest?
- Changes in skin colour or skin lesions?
- Loss of sensation of lower extremity?

Has the patient established regular podiatric care?

WHAT TO LOOK FOR

00:02

Dermatologic exam:

- Does the patient have discoloured, ingrown or elongated nails?
- Are there signs of fungal infection?
- Does the patient have discoloured and/or hypertrophic skin lesions, calluses or corns?
- Does the patient have open wounds or fissures?
- Does the patient have interdigital maceration?

Neurological exam:

- Is the patient responsive to light touch (protective sensation) on the foot?

Musculoskeletal exam:

- Does the patient have full range of motion of the joints?
- Does the patient have obvious deformities? If so, for how long?
- Is the midfoot hot, red or inflamed?

Vascular exam:

- Is hair growth on the foot dorsum or lower limb decreased?
- Are the dorsalis pedis AND posterior tibial pulses palpable?
- Is there a temperature difference between the calves and feet or between the left and right foot?

WHAT TO TEACH

00:03

Recommendations for daily foot care:

- Visually examine both feet, including the sides and between the toes. If the patient can't do this, have a family member do it
- Keep feet dry by regularly changing shoes; dry feet after baths or exercise
- Report any new lesions, discolourations or swelling to an HCP.

Education regarding shoes:

- Educate the patient on the risks of walking barefoot, even when indoors
- Recommend appropriate footwear and advise against shoes that are too small, tight or rub against a particular area of the foot
- Suggest yearly replacement of shoes - more frequently if they exhibit high wear.

Has the patient established regular podiatric care?

- Recommend smoking cessation (if applicable)
- Recommend appropriate glycaemic control.

Recognition of infection and the role of early intervention

Key learning points

1. Early intervention is key and results in more positive patient outcomes.
2. Infection must be recognised as early as possible and result in appropriate management.
3. Infection should be classified using a structured system, such as using the WIfI system to cover infection.

Individuals with DFUs are demonstrating increased incidence of hospitalisation due to infection, and infection is commonly the driving force towards amputation (WUWHS, 2016). Patients presenting with severe infection often require emergency surgical intervention.

Recognising infection in patients with DFUs can present a challenge in clinical practice, but is one of the most important elements of initial assessment (Wounds International, 2013). The early stage of examination and assessment is crucial to allowing practitioners the potential opportunity to curb what is often the progression from simple/mild infection to a more severe problem, which can lead to necrosis, gangrene and ultimately amputation – therefore early intervention is key.

Around 50% of DFUs become infected, and in approximately 20% of these patients, infection will lead to amputation (Wu et al, 2007).

The classic signs of infection should be assessed for, such as:

- Redness
- Heat
- Pain
- Swelling.

However, arterial insufficiency and loss of sensation means that up to half of patients may not present with these signs, and it is vital to assess for more subtle 'secondary' signs (Edmonds et al, 2004), such as:

- Exudate
- Malodour
- Wound undermining
- Friable granulation tissue.

Therefore, the absence of these signs means that infection in DFUs can be particularly challenging to identify. Swabbing the wound may be useful where available; however, note that swab culture results may be misleading, as clinical microbiology laboratories are not always suitable for culture of anaerobic species and also may not capture bacteria protected within a biofilm (nor will it detect biofilm), so clinical judgement is also required (Swanson et al, 2014). Where a culture is taken, it is vital that the wound has been thoroughly cleansed and debrided first in order to obtain the most accurate results.

Table 3. Diabetic foot infection classification schemes (from Lavery et al, 2007)

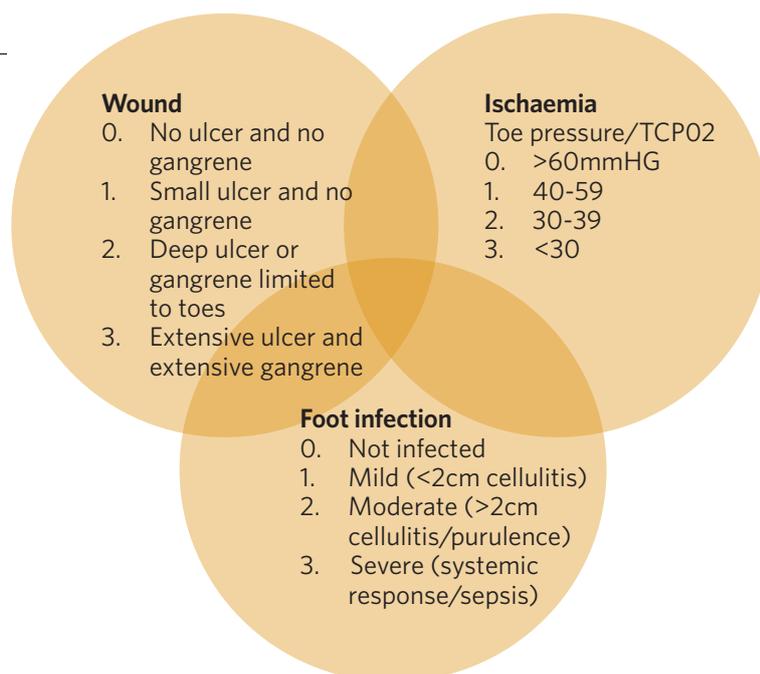
Clinical description	Infectious Diseases Society of America	International Working Group on the Diabetic Foot
Wound without purulence or any manifestations of inflammation	Uninfected	1
>2 manifestations of inflammation (purulence or erythema, pain, tenderness, warmth, or induration; any cellulitis or erythema extends <2cm around ulcer, and infection is limited to skin or superficial subcutaneous tissues; no local complications or systemic illness	Mild	2
Infection in a patient who is systemically well and metabolically stable but has >1 of the following: cellulitis extending >2cm; lymphangitis; spread beneath fascia; deep tissue abscess; gangrene; muscle, tendon, joint or bone movement	Moderate	3
Infection in a patient with systemic toxicity or metabolic instability (e.g. fever, chills, tachycardia, hypotension, confusion, vomiting, leukocytosis, acidosis, hyperglycemia, or azotemia	Severe	4

INFECTION CLASSIFICATION

The classifications used by the International Working Group on the Diabetic Foot and the Infectious Diseases Society of America (2007) both provide a useful means to assess and document infection. The two systems work in the same way: first dividing wounds by whether they are clinically infected on the basis of the presence of purulent secretions or local or systemic signs of inflammation or infection. Infected wounds are further divided into those that are considered to be mild, moderate, or severe, on the basis of the size (especially of any cellulitis) and depth (or level of tissue involved) of the infection and presence of systemic manifestations of infection or metabolic instability (see Table 3).

More recently, the WIfI system (Mills et al, 2014) has been developed for use in both diabetic and non-diabetic patients, using a classification system of 'the threatened lower limb' and includes infection as one of its elements. Risk stratification is based on three major factors that impact amputation risk and clinical management: WIfI (Wound, Ischaemia, foot, Infection). This system has been validated and adopted by the Society for Vascular Surgery (see Figure 3).

FIGURE 3 | Structure of the WIfI (Wound, Ischaemia, foot, Infection) system (adapted from WUWHS, 2016)



WIfI outlines three areas that need to be addressed and helps to identify which, at any one time, is the most 'dominant' risk:

1. Tissue loss
2. Ischaemia
3. Infection.

Assessment should be completed and should trigger appropriate action as soon as possible. An audit in the UK found that early intervention plays a key role in achieving successful outcomes: patients who were assessed by experts within two weeks were more likely to be free of foot ulcers at 12 weeks than patients who had to wait longer to be seen (NHS, 2016). Various worldwide studies have also shown that early intervention (and an MDT approach) improve amputation rates (WUWHS, 2016).

Prevention and management of infection

Key learning points

1. A standardised approach to management should be used in all DFUs, including offloading in all patients.
2. Management of infected DFUs should be based around cleansing and debridement.
3. Dressing selection should incorporate standard DFU care and dealing with infection.

Where possible, prevention of infection before it starts should be the first consideration, so at-risk patients should be closely monitored. Initially, practitioners should assess the patient for risk factors that increase the likelihood of infection and closely monitor those patients deemed to be at-risk. Particular risk factors for DFUs that may become infected include (Lipsky et al, 2012):

- A positive probe-to-bone test
- DFU present for more than 30 days
- A history of recurrent DFUs
- A traumatic foot wound
- The presence of peripheral arterial disease in the affected limb
- A previous lower extremity amputation
- Loss of protective sensation
- The presence of renal insufficiency
- A history of walking barefoot.

The risk of complications in diabetes and developing ulceration is high, so it is vital to provide patient-centric care that focuses on patient education and engagement (WUWHS, 2016).

In at-risk patients, pressure-relief strategies and use of inflammation-identifying tools such as thermometry to identify and reduce risk of re-ulceration have been proven to be effective (WUWHS, 2016). Educating patients in strategies on avoiding infection is key.

THE IMPORTANCE OF OFFLOADING

Offloading should be considered a key first-line treatment in suitable patients. If a person with diabetes has a lesion on the sole of their foot, offloading body weight is of vital importance; all therapeutic efforts are bound to fail if he or she continues to walk on an ulcer (Shankhdhar et al, 2009).

Methods to offload the foot include bed rest, the use of a wheelchair, crutch-assisted walking, total-contact casts, felted-foam half-shoes, therapeutic shoes, custom splints, and removable cast walkers. However, economic constraints or lack of availability can mean these methods are not practical to use. Moreover, offloading methods like total-contact casts need technical expertise for application (Shankhdhar et al, 2009).

The Samadhan System was specifically developed as a solution to this problem, based on the principles of simplicity and ease of application, which requires no specialist training, providing an offloading solution that is both effective and practical to use. The Samadhan System can be adopted by anyone with an understanding of the basic principles of offloading. All that is required to manufacture the Samadhan device is a piece of foam, some adhesive, and a piece of an elastocrepe bandage, which are economical and freely available in most settings. See Box 3 for practical information on how to use the Samadhan System.

Patient non-adherence is commonly the most significant barrier to the success of offloading, therefore employing strategies to promote patient engagement and increased concordance is key to treatment (Wu and Armstrong, 2006). Patient education in caring for their feet and avoiding infection is paramount.

BOX 3 | Using the Samadhan System in practice (adapted from Shankhdhar et al, 2015)

- The Samadhan System is very simple to use and we recommend that healthcare providers have a Samadhan manufacturing unit in their own clinic. One only needs a small space to accommodate a small table with a shelf to keep the necessary materials and prepared Samadhan units.
- Items required for manufacturing a Samadhan Unit include a sheet of rubberised foam with a thickness of 1cm and a density of 40kg/m³, a saw blade, liquid adhesive, sealing wax and a pair of scissors.
- Cut a piece of foam measuring 6 x 4 inches from the big sheet. Apply liquid adhesive on one side of the foam piece with a metallic applicator since the adhesive is corrosive. We apply with a saw blade. Then we carefully roll up the foam piece into a cylinder, saving the skin of fingertips, and put some weight on this cylinder to allow the adhesive to dry. One can use any weight, such as a brick.
- After about two hours, remove the weight and the Samadhan unit is ready for use. We recommend keeping several Samadhan units ready beforehand. One can cut the cylinder to the size of the plantar surface of the patient with the saw blade. After rendering proper wound care, including the dressing, the clinician can decide where to place the Samadhan Unit for adequate offloading. For example, if there is a DFU under the big toe, place a Samadhan Unit along the metatarsal heads and wrap the retainer. Then apply fasteners at the edge of the retainer.
- The position of the Samadhan unit should change as per the location of the DFU. If a DFU is present over the plantar surface of the heel, apply the Samadhan unit before the ulcer. In the case of a midfoot ulcer, one might use two Samadhan units, one before and the other after the ulcer. Both the Samadhan unit and retainer are washable with soap and water. We provide two sets to every patient so they can change these items as necessary (e.g. they may become soaked in exudate from an infected ulcer).
- The frequency of dressing change depends upon the mobility and weight of the patient. Mostly, they need no change for 10-15 days. We ask patients while walking to use commonly used sandals with Velcro and felt to be fastened over the dorsal surface of the foot.

PRINCIPLES OF LOCAL MANAGEMENT

The first step in wound treatment for all DFUs should be thorough, routine cleansing (WUWHS, 2016). This includes removing all surface debris, slough and infected tissue. DFUs are generally cleansed with water or saline; however, in infected DFUs a cleansing solution containing an antiseptic agent may be used. If slough is present, a gentle rubbing action during cleansing may aid detachment.

Regular debridement is an important aspect of DFU management and aims to remove slough, non-viable tissue and hyperkeratotic wound margins (callus). Sharp debridement carried out by experienced clinicians with specialist training is widely used in treatment of DFUs, but should be used with caution in a patient with an ischaemic foot (WUWHS, 2016). In cases of ischaemia, it is vital that the patient is referred to a vascular surgeon before extensive tissue loss occurs; in these cases, referral in a timely manner is essential.

Surgical debridement should also be considered where necessary (e.g. large areas where rapid removal is required), although this must be carried out by a surgeon skilled and experienced in the management of foot infections (Gray et al, 2011).

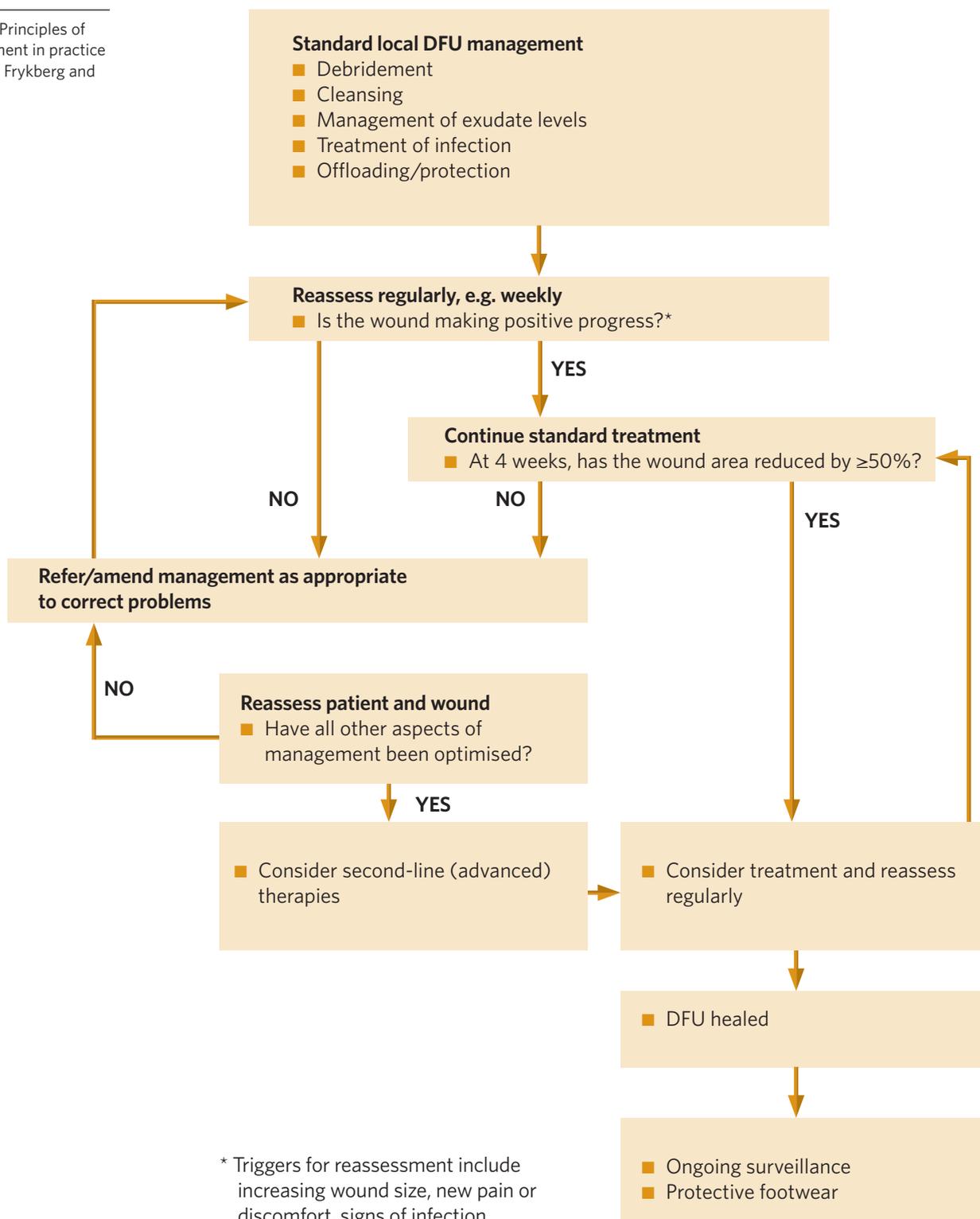
In deep/cavity wounds where infection is present, negative pressure wound therapy (NPWT) or NPWT with instillation may be considered. NPWT with instillation can be used with saline or antimicrobial agents that have been assessed for device compatibility to reduce the potential for wound infection. The decision as to whether to use standard NPWT or NPWT with the addition of instillation therapy should be based on the need for wound cleansing or treatment with topical antiseptics (Wounds Middle East, 2016). Where appropriate to use, NPWT with instillation can help to deal with deep and hard-to-heal wounds, contributing to healing time and reduced tissue damage. Where necessary (e.g. in instances of severe and systemic infection) antibiotic use should be considered.

Documentation and continued monitoring of the patient as treatment continues is key. If the wound is not improving, treatment should be reassessed and other strategies considered. Monitoring the wound's size is crucial, as this is an indicator of progress and will also help to identify any other potential problems that may lead to chronicity (see Table 4).

Table 4. Wound size monitoring as a predictor of healing in diabetic foot ulcers	
Study	Outcome(s)
Sheehan et al, 2003	<ul style="list-style-type: none"> ■ 53% area reduction at 4 weeks was associated with a significantly higher probability of healing at 12 weeks ($p<0.01$)
Lavery et al, 2008	<ul style="list-style-type: none"> ■ $\geq 15\%$ area reduction at one week or $\geq 60\%$ at 4 weeks was associated with a higher probability of healing at 16 weeks
Coerper et al, 2009	<ul style="list-style-type: none"> ■ $\geq 50\%$ area reduction at 4 weeks was associated with a significantly higher probability of healing at 12 weeks, 16 weeks and 1 year (all $p<0.01$)
Snyder et al, 2010	<ul style="list-style-type: none"> ■ $\geq 50\%$ area of reduction at 4 weeks was associated with a significantly higher probability of healing by 12 weeks ($p<0.01$) ■ DFUs that healed by week 12 had significantly greater % area reduction at weeks 1, 2 and 3 than DFUs that did not heal ($p<0.01$)

For more information on how the principles of local management can be translated into everyday practice and form the basis of a structured treatment plan, see Figure 4.

FIGURE 4 | Principles of local management in practice (adapted from Frykberg and Banks, 2016)



DRESSING SELECTION

Dressing selection in DFUs requires a multifactorial approach that takes all aspect of the wound into account (WUWHS, 2016). Using the appropriate dressing in DFUs should address the necessary requirements, including infection. It is important to bear in mind that dressing selection should be led by evidence-based medical practice: treatment and products with high-level proven clinical evidence (RCT or meta) must be given prime consideration.

The factors that must be taken into account when selecting a dressing include:

- Moisture/exudate management: the dressing needs to be able to handle high levels of exudate if necessary, taking into account both volume and type/viscosity of the exudate (which may particularly be an issue in infected wounds, as they may have a high level of exudate); equally, in dry wounds, it is important to encourage a moist wound environment for optimum healing.
- Depth: in deep DFUs, packing may be required to eliminate dead space; in deep wounds, negative pressure wound therapy (NPWT) may be considered.
- Protection: the dressing needs to be appropriate for use with offloading devices/footwear solutions as required.

Dressings incorporating antimicrobial agents may be used in infected DFUs. Frequently used topical antimicrobial agents include iodine or silver-impregnated dressings, or dressings incorporating PHMB or octenidine. Charcoal dressings may be considered to deal with malodour. The principle of the two-week challenge is recommended, i.e. if after 2 weeks no improvement is seen, the antimicrobial agent in use should be discontinued and an alternative considered.

There is a correlation between delayed healing (and therefore infection risk) and an imbalance of matrix metalloproteinases (MMPs). MMP modulation is a key area that should be considered in dealing with DFUs, particularly in situations where suspected biofilm is an issue. MMP imbalance can create a vicious cycle of delayed healing and infection, which needs to be addressed (Gibson et al, 2009). In such instances, an MMP-modulating dressing should be considered.

For further information on the management of biofilm, see the World Union of World Healing Societies position document (WUWHS, 2016).

TIPS AND CONSIDERATIONS FOR DRESSING USE

In order to prevent maceration, skin contact with exudate should be avoided, so it is key to select a dressing that can handle exudate levels. Using a skin protectant cream or barrier film on the periwound skin may reduce the risk of skin damage. Dressing fixation is also an important consideration, to avoid skin damage and reduce the risk of constriction, which can trigger ischaemia. To avoid constriction, dressings and fixatives used on toes should not encircle the digit. Tape fixatives should be avoided where possible; tubular gauze may be useful for keeping dressings in place.

Dressing change frequency should be minimised as much as possible to reduce the potential for external contamination; however, clinicians should be aware that DFUs can deteriorate quickly and should be closely monitored. Where infection is present, the wound should be monitored frequently (as often as every 1-2 days). This is particularly important if there are signs of systemic infection.

Despite the frequency of sensory neuropathy, many patients experience pain on dressing change. Pain can be minimised by paying close attention to technique and using non-adherent, easy-to-remove dressings. It is important to remember that newly occurring pain may be due to infection.

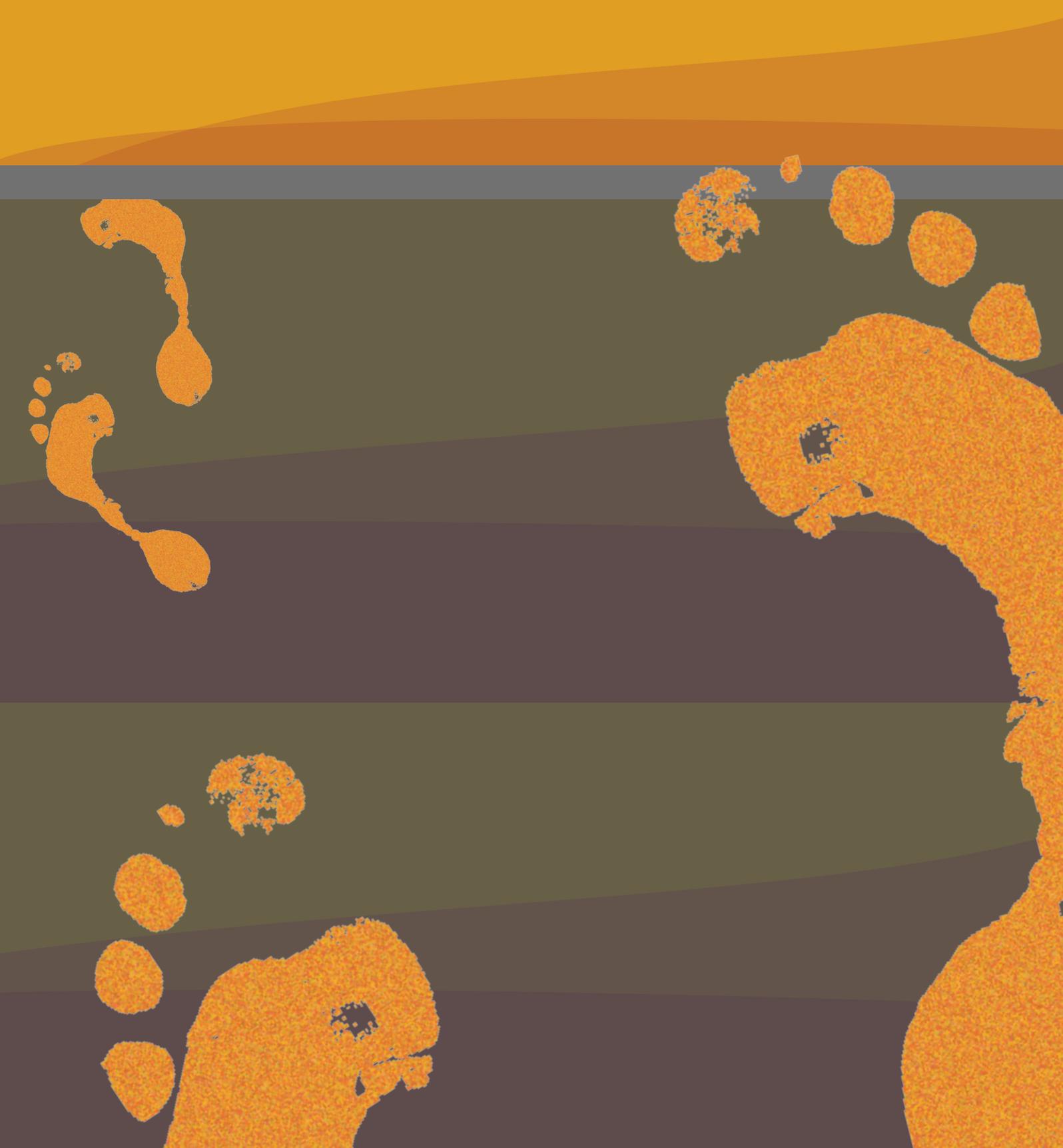
References

1. Ahmed AA, Elsharief E, Alsharief, A (2011) The diabetic foot in the Arab world. *The Journal of Diabetic Foot Complications* 3(3): 55-61
2. Alzahrani HA (2012) Diabetes-related lower extremities amputations in Saudi Arabia: The magnitude of the problem. *Ann Vasc Dis* 5(2): 151-6
3. Armstrong D, Boulton AJM, Bus SA (2017) Diabetic foot ulcers and their recurrence. *New Eng J Med* 376: 2367-75
4. Bakker K, Apelqvist J, Schaper NC on behalf of the International Working Group on the Diabetic Foot Editorial Board. Practical guidelines on the management and prevention of the diabetic foot 2011. *Diabetes Metab Res Rev* 2012; 28(Suppl 1): 225-31
5. Brownrigg JR, Davey J, Holt PJ et al. The association of ulceration of the foot with cardio vascular and all-cause mortality in patients with diabetes: a meta-analysis. *Diabetologia* 2012; 55(11): 2906-12
6. Edmonds M, Foster AVM, Vowden P. Wound bed preparation for diabetic foot ulcers. In: EWMA Position Document. *Wound bed preparation in practice*. London: MEP Ltd, 2004. Available at: http://www.woundsinternational.com/media/issues/87/files/content_49.pdf (accessed 25.04.2017)
7. Gibson D, Cullen B, Legerstee R et al (2009) MMPs Made Easy. *Wounds International*. Available at: http://www.woundsinternational.com/media/issues/61/files/content_21.pdf (accessed 13.07.2017)
8. Gray D, Acton C, Chadwick P et al (2011) Consensus guidance for the use of debridement techniques in the UK. *Wounds UK* 7(1): 77-84
9. International Diabetes Federation (IDF). Diabetes Atlas (7th edition): Middle East and North Africa at Glance, 2015. Available at: <http://www.diabetesatlas.org/resources/2015-atlas.html> (accessed 16.03.2017)
10. International Wound Infection Institute (IWII) Wound infection in clinical practice. *Wounds International* 2016. Available at: http://www.wounds-uk.com/pdf/content_11897.pdf (accessed 9.03.2017)
11. Lavery LA, Armstrong DG, Murdoch DP (2007) Validation of the infectious classification system. *CID* 44: 562-5
12. Lipsky BA, Berendt AR, Comia PB (2012) Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections. *CID* 54: e132-73
13. Miller JD, Carter E, Shih J (2014) How to do a 3-minute diabetic foot exam. *J Fam Pract* 63(11): 646-9, 653-6
14. Mills JL, Conte MS, Armstrong DG et al (2014) The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI). *Journal of Vascular Surgery* 59(1); 220-34
15. National Institute for Health and Clinical Excellence. Diabetic foot problems: prevention and management. NICE guideline NG19. London: NICE, 2015. Available at: <https://www.nice.org.uk/guidance/ng19> (accessed 9.03.2017)
16. NHS (2016) National Diabetes Foot Care Audit. March, 2016
17. Shankhdhar LK, Shankhdhar K, Shankhdhar U, Shankhdhar S (2009) Offloading the diabetic foot in the developing world. *Diabetes Voice* 54(3): 27-9
18. Shankhdhar LK, Shankhdhar K, Shankhdhar U, Shankhdhar S (2015) Offloading a diabetic foot ulcer in the developing world. *Podiatry Today* 28(10). Available online at: <http://www.podiatrytoday.com/offloading-diabetic-foot-ulcer-developing-world> (accessed 26.04.2017)
19. Singh N, Armstrong DA, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005; 293: 217-28
20. Skrepnek GH, Mills JL, Lavery LA, Armstrong DJ (2017) Health care service and outcomes among an estimated 6.7 million ambulatory care diabetic foot cases in the US. *Diabetes Care* 40(7): 936-42
21. Spichler A, Hurwitz BL, Armstrong DG, Lipsky BA (2015) Microbiology of diabetic foot infections: from Louis Pasteur to 'crime scene investigation'. *BMC Medicine* 13(2): DOI 10.1186/s12916-014-0232-0
22. Swanson T, Grothier L, Schultz G (2014). Wound infection Made Easy. *Wounds International*. Available at: http://www.woundsinternational.com/media/other-resources/_/1152/files/wi-made-easy.pdf (12.07.2017)
23. Vowden P, Vowden K (2016) The impact of hard-to-heal wounds: promoting practice change to address passivity in wound management. *Wounds International* 7(2): 10-5

24. World Health Organization (2016) Global report on diabetes. Available at: http://apps.who.int/iris/bitstream/10665/204871/1/9789241565257_eng.pdf (accessed 9.03.2017)
25. World Union of Wound Healing Societies. Position document: Local management of diabetic foot ulcers, 2016. Available at: <http://www.woundsinternational.com/wuwhs/view/position-document-local-management-of-diabetic-foot-ulcers> (accessed 9.03.2017)
26. Wounds International. International Best Practice Guidelines: Wound Management in Diabetic Foot Ulcers, 2013. Available at: http://www.woundsinternational.com/media/best-practices/_/673/files/dfubestpracticeforweb.pdf (accessed 8.03.2017)
27. Wounds Middle East (2016) International consensus proceedings of the Middle East Expert Forum on NPWT in infected wounds. Available at: <http://www.woundsme.com/journal-content/view/middle-east-expert-forum-on-npwt-in-infected-wounds-an-overview> (accessed 12.07.2017)
28. Wounds UK (2017) How to guide: Meeting CQUIN targets: Improving the assessment of wounds
29. World Union of Wound Healing Societies (2016) Position document: Management of biofilm. Available at: <http://www.woundsinternational.com/wuwhs/view/position-document-management-of-biofilm> (accessed 31.07.2017)
30. Wu SC, Armstrong DG (2006) The role of activity, adherence, and offloading on the healing of diabetic foot wounds. *Plas Recon Surg* 117 (7s) 248-53
31. Wu S, Driver VR, Wrobel JS et al. Foot ulcers in the diabetic patient, prevention and treatment. *Vasc Health Risk Manag* 2007; 3(1): 65-76

Notes





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