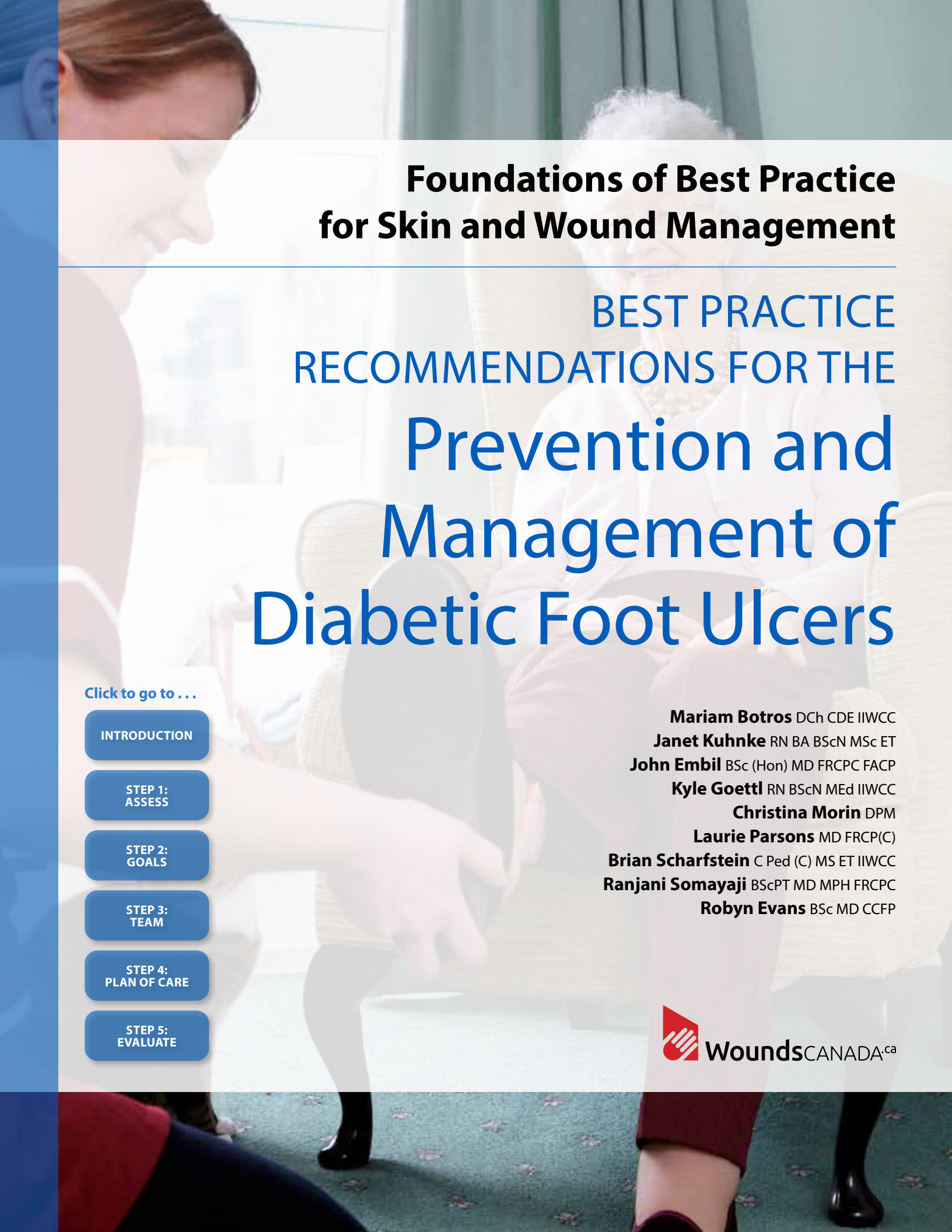


## Foundations of Best Practice for Skin and Wound Management

# BEST PRACTICE RECOMMENDATIONS FOR THE Prevention and Management of Diabetic Foot Ulcers

Click to go to . . .




**Mariam Botros** DCh CDE IIWCC
**Janet Kuhnke** RN BA BScN MSc ET
**John Embil** BSc (Hon) MD FRCPC FACP
**Kyle Goettl** RN BScN MEd IIWCC
**Christina Morin** DPM
**Laurie Parsons** MD FRCP(C)
**Brian Scharfstein** C Ped (C) MS ET IIWCC
**Ranjani Somayaji** BScPT MD MPH FRCPC
**Robyn Evans** BSc MD CCFP



WoundsCANADA.ca

The best practice recommendation articles are special publications of *Wound Care Canada*. Together they form the Foundations of Best Practice for Skin and Wound Management, an online resource available for free download from the Wounds Canada website (woundscanada.ca).

These 2017 updates build on the work of previous author teams and incorporate the latest research and expert opinion.

We would like to thank everyone involved in the production of past and present versions of these articles for their hard work, diligence and rigour in researching, writing and producing these valuable resources.

Executive Editor: Sue Rosenthal
Project Editor: Heather L. Orsted
Editorial Assistant: Katie Bassett
Copy Editor: Allyson Latta

Art Direction and Layout: Robert Ketchen
Photo Researcher: Joanne Crone

This paper was produced by the Canadian Association of Wound Care (Wounds Canada).

**How to cite this document:**
Botros M, Kuhnke J, Embil J, Goettl K, Morin C, Parsons L, et al. Best practice recommendations for the prevention and management of diabetic foot ulcers. In: Foundations of Best Practice for Skin and Wound Management. A supplement of Wound Care Canada; 2017. 68 pp. Retrieved from: www.woundscanada.ca/docman/public/health-care-professional/bpr-workshop/895-wc-bpr-prevention-and-management-of-diabetic-foot-ulcers-1573r1e-final/file.

woundscanada.ca
info@woundscanada.ca



Last updated 2021 02 11.

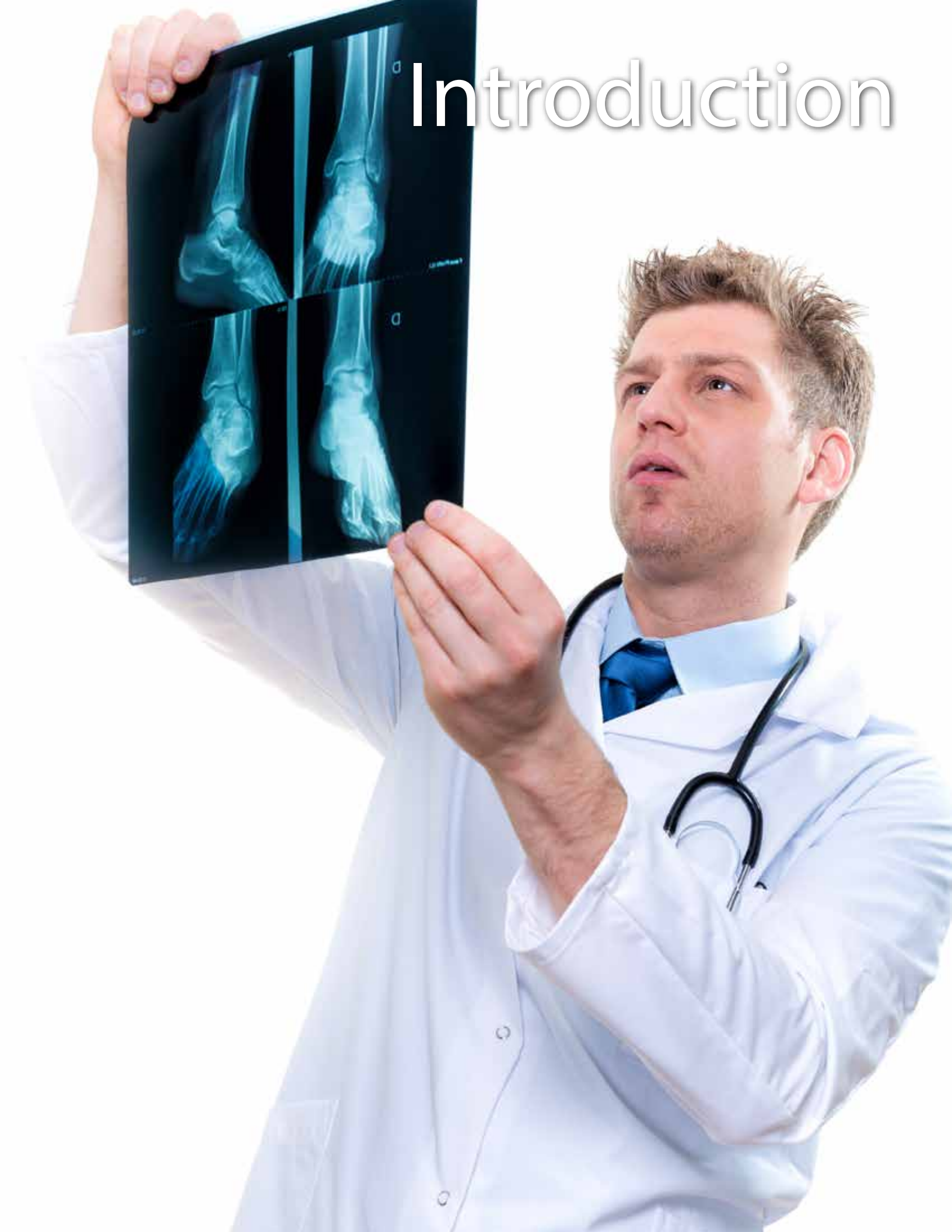
**Foundations of Best Practice for Skin and Wound Management**

# BEST PRACTICE RECOMMENDATIONS FOR THE Prevention and Management of Diabetic Foot Ulcers

**Mariam Botros** DCh CDE IIWCC
**Janet Kuhnke** RN BA BScN MSc ET
**John Embil** BSc (Hon) MD FRCPC FACP
**Kyle Goettl** RN BScN MEd IIWCC
**Christina Morin** DPM
**Laurie Parsons** MD FRCP(C)
**Brian Scharfstein** C Ped (C) MS ET IIWCC
**Ranjani Somayaji** BScPT MD MPH FRCPC
**Robyn Evans** BSc MD CCFP

WoundsCANADA.ca

# Introduction



# Introduction

Diabetes mellitus (DM) is a metabolic disorder characterized by hyperglycemia that leads to microvascular, macrovascular and neuropathic complications. In 2016, there were 11 million Canadians living with type 1, type 2 or pre-diabetes, and every three minutes another Canadian is diagnosed. Certain populations are at higher risk for developing type 2 DM, including those of Asian, African, Hispanic and Indigenous decent. The rates of DM are three to five times higher in Indigenous populations, an issue compounded by unique barriers to care including, but not limited to, a lack of cultural competency among health-care providers, jurisdictional confusion, limited access to care, geographical location and language barriers.[1,2]

Foot health should be a major consideration for people with diabetes and for those who care for them. Foot complications in this high-risk population can lead to a cascade of negative complications, potentially resulting in loss of limb and life.

The lifetime risk for foot ulceration in people with diabetes is 15 to 25%. According to the International Diabetes Federation, persons with diabetes are 15 to 40 times more likely to require lower-leg amputation compared to the general population. Approximately 85% of amputations are preceded by the development of a neuropathic foot ulcer.[3] Following a lower-limb amputation, people with diabetes not only suffer the clinical and psychological consequences of limb loss, but also have a five-year mortality rate of 50%. This is a higher mortality rate than is seen in breast cancer in females, prostate cancer in males or lymphoma.[4]

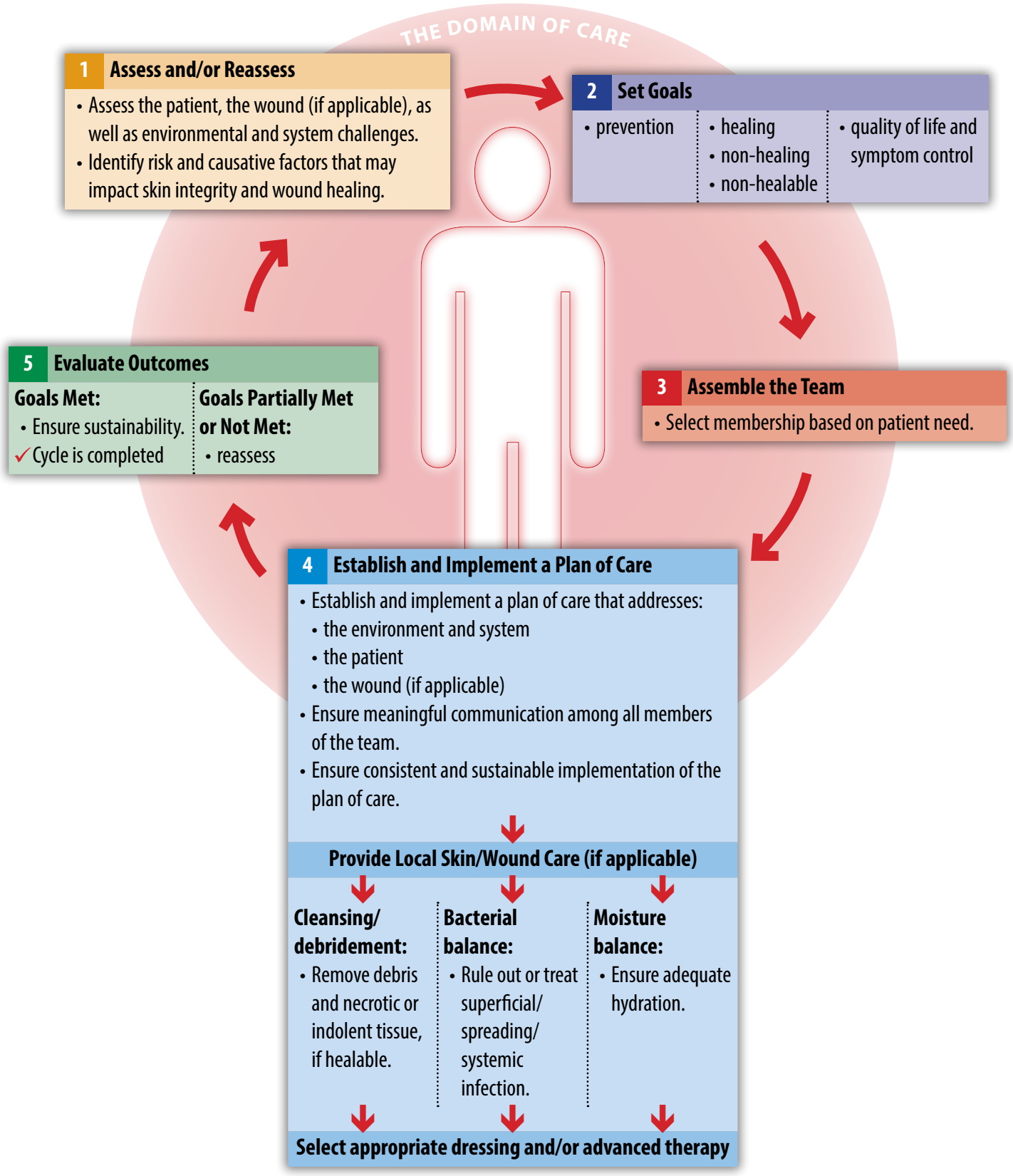
Identifying the high-risk foot has been both cost saving to the health-care system and highly feasible, even in low-and middle-income countries.[5] Unfortunately, Canada has the lowest rate of high-risk diabetic foot screening among the UK, U.S., New Zealand, Australia and Germany.[6]

The negative cascade of diabetic foot complications persists despite the many treatment modalities available for foot care of the persons with diabetes and its related conditions. In addition, public and professional awareness of optimal care is poor.[7]

## The Wound Prevention and Management Cycle

This paper offers a practical, easy-to-follow guide that incorporates the best available evidence. It outlines a process, or series of consecutive steps, that supports patient-centred care. This process, called the Wound Prevention and Management Cycle (see Figure 1) guides the clinician through a logical and systematic method for developing a customized plan for the prevention and management of wounds from the initial assessment to a sustainable plan targeting self-management for the patient.

**Figure 1:** The Wound Prevention and Management Cycle




The recommendations in this document are based on the best available evidence and are intended to support the clinician, the patient, his/her family and the health-care team in planning and delivering the best clinical practice. Two foundational papers supplement this document with additional evidence-informed information and

recommendations that are general to all wound types: "Skin: Anatomy, Physiology and Wound Healing,"[8] and "Best Practice Recommendations for the Prevention and Management of Wounds."[9]

There are three guiding principles within the best practice recommendation papers (BPRs) that support effective prevention and management of skin breakdown:

1. the use of the Wound Prevention and Management Cycle regardless of the specifics to prevent and manage skin breakdown
2. the constant, accurate and multidirectional flow of meaningful information within the team and across all care settings
3. the patient as the core of all decision making

## Quick Reference Guide

The quick reference guide (QRG) (see Table 1) provides the recommendations associated with the five steps in the Wound Prevention and Management Cycle (see Figure 1). These recommendations are discussed with the supporting evidence.

**Table 1:** Wound Prevention and Management Quick Reference Guide

| Step | | Recommendation | Evidence |
|---|---|---|---|
| 1 | **Assess and/or Reassess** | 1.1 Select and use validated patient assessment tools.<br>1.2 Identify risk and causative factors that may impact skin integrity and wound healing.<br>1.2.1 Patient: Physical, emotional and lifestyle<br>1.2.2 Environmental: Socio-economic, care setting, potential for self-management<br>1.2.3 Systems: Health-care support and communication<br>1.3 Complete a wound assessment, if applicable. | Ia<br>Ia–IV<br><br><br><br>IV |
| 2 | **Set Goals** | 2.1 Set goals for prevention, healing, non-healing and non-healable wounds.<br>2.1.1 Identify goals based on prevention or healability of wounds.<br>2.1.2 Identify quality-of-life and symptom-control goals. | IV |
| 3 | **Assemble the Team** | 3.1 Identify appropriate health-care professionals and service providers.<br>3.2 Enlist the patient and their family and caregivers as part of the team.<br>3.3 Ensure organizational and system support. | IV<br>IV<br>IV |
| 4 | **Establish and Implement a Plan of Care** | 4.1 Identify and implement an evidence-informed plan to correct the causes or co-factors that affect skin integrity, including patient needs (physical, emotional and social), the wound (if applicable) and environmental/system challenges.<br>4.2 Optimize the local wound environment aided through<br>4.2.1 Cleansing<br>4.2.2 Debriding<br>4.2.3 Managing bacterial balance<br>4.2.4 Managing moisture balance<br>4.3 Select the appropriate dressings and/or advanced therapy.<br>4.4 Engage the team to ensure consistent implementation of the plan of care. | IV<br><br>Ia–III<br><br><br><br><br>III–IV<br>IV |
| 5 | **Evaluate Outcomes** | 5.1 Determine if the outcomes have met the goals of care.<br>5.2 Reassess patient, wound, environment and system if goals are partially met or unmet.<br>5.3 Ensure sustainability to support prevention and reduce risk of recurrence. | IV<br>Ib–IV<br><br>IV |

Each recommendation above is supported by the level of evidence employed by Registered Nurses' Association of Ontario (RNAO) guideline development panels (see Table 2). For more detailed information refer to the designated references.

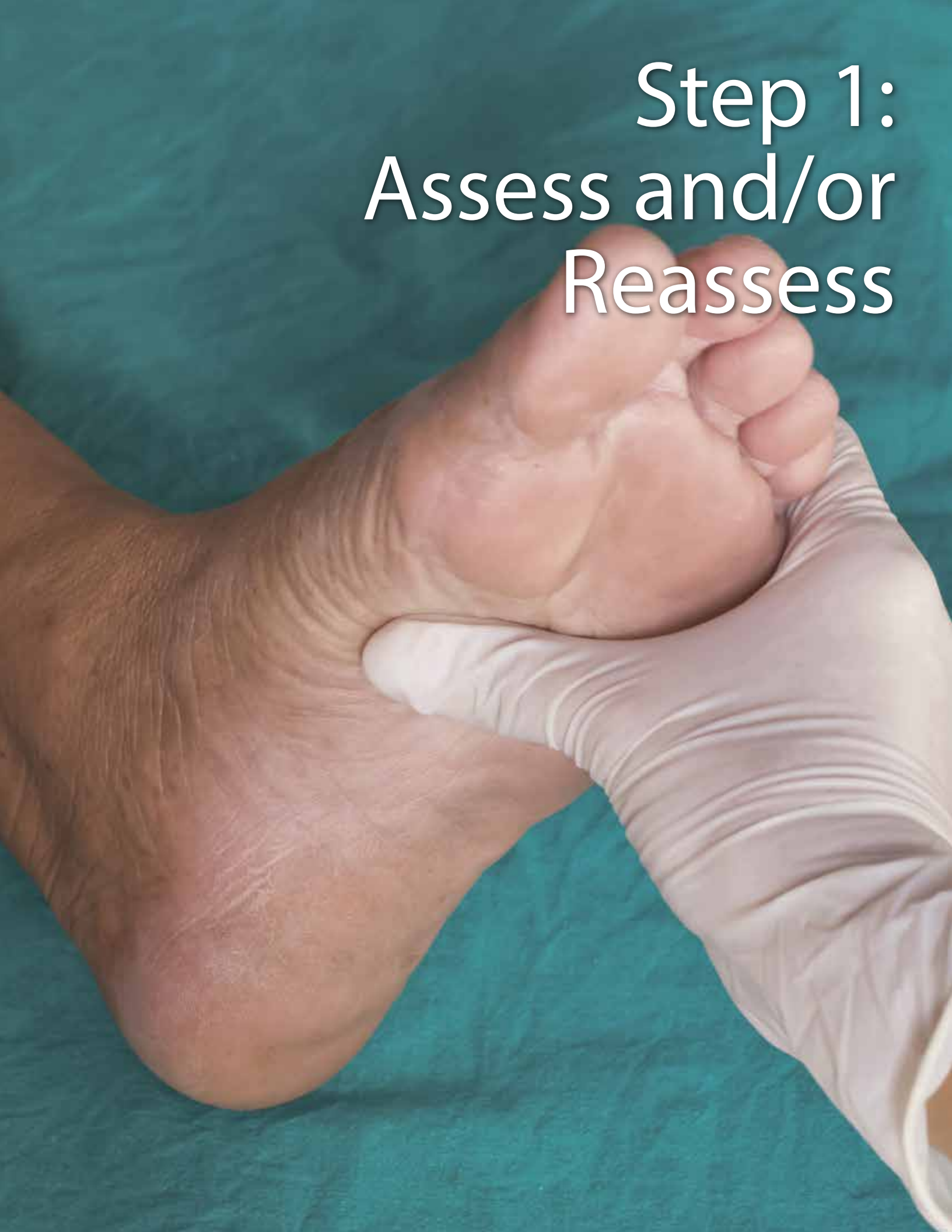
**Table 2:** Levels of Evidence[11]

| | |
|---|---|
| **Ia** | ▪ Evidence obtained from meta-analysis or systematic review of randomized controlled trials |
| **Ib** | ▪ Evidence obtained from at least one randomized controlled trial |
| **IIa** | ▪ Evidence obtained from at least one well-designed controlled study without randomization |
| **IIb** | ▪ Evidence obtained from at least one other type of well-designed quasi-experimental study |
| **III** | ▪ Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies |
| **IV** | ▪ Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities |

*Used with kind permission from the Registered Nurses' Association of Ontario.*

The guidelines included in this in this BPR document are as follows:

- 2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections: www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient_Care/PDF_ Library/2012%20Diabetic%20Foot%20Infections%20Guideline.pdf.
- Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada: http://guidelines.diabetes.ca/browse/Chapter32
- International Working Group on the Diabetic Foot: www.iwgdf.org
- The Management of Diabetic Foot: A Clinical Practice Guideline by the Society for Vascular Surgery in Collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine: www.jvascsurg.org/article/S0741-5214(15)02025-X/abstract www.jvascsurg.org/article/S0741-5214(15)02025-X/abstract#article-footnote-
- NICE guidelines: www.nice.org.uk/guidance/ng19
- International Best Practice Recommendation: www.woundsinternational.com/media/best-practices/_/673/files/dfubestpracticeforweb.pdf
- Assessment and Management of Foot Ulcers for People with Diabetes, Second Edition: http://rnao.ca/bpg/guidelines/assessment-and-management-foot-ulcers-people-diabetes-second-edition
- A Quick Reference Guide for Lower-extremity Wounds: Venous, Arterial and Neuropathic: http://c.ymcdn.com/sites/www.wocn.org/resource/resmgr/Publications/A_Quick_Reference_Guide_for_.pdfn



# Step 1: Assess and/or Reassess

# Step 1: Assess and/or Reassess

**Discussion:** A comprehensive patient assessment to identify factors that may impact skin integrity and wound healing should include history and current health status (physical and emotional), head-to-toe skin assessment, wound assessment (if applicable), investigation of environmental factors such as socio-economic, cultural, care setting and access to services, and system factors such as government policies, support and programs.

## Recommendations

### 1.1 Select and use validated patient assessment tools.

**Discussion:**

Foot screening tools

Clinicians are encouraged to use a validated foot screen in clinical practice. Foot screening tools provide a uniform approach that helps ensure that a comprehensive foot exam is completed. There are many validated diabetic foot-screening tools available, but a tool can only be effective if clinician education and organizational and system supports are in place, and if the tool is "evidence-informed and relevant to the characteristics of the target population."[12] There are multiple tools for the clinician to consider, including the the Inlow 60-second Diabetic Foot Screen, which includes three parts: assessment, risk stratification and care recommendations, and the Simplified 60 Second Diabetic Foot Screening Tool.[13–15]

A comprehensive diabetic foot screening includes assessment of the following:

- sensation
- vascularity
- deformity
- areas of pressure
- footwear (all types)
- skin breakdown
- infection

Quality-of-life tools

The Canadian Diabetes Association (CDA) recommends the use of reliable and valid tools that are diabetes-specific and measure quality of life.[16] Some tools include the following:

- The Problem Areas in Diabetes Scale (PAID): http://care.diabetesjournals.org/content/20/5/760
- The Diabetes Distress Scale: www.diabetesed.net/page/_files/diabetes-distress.pdf

- The World Health Organization – WHO-5 Well-being Index: www.ncbi.nlm.nih.gov/pubmed/11824831
- The Hospital Anxiety and Depression Scale (HADS): www.scalesandmeasures.net/files/files/HADS.pdf
- The Patient Health Questionnaire (PHQ-9): www.ubcmood.ca/sad/PHQ-9.pdf
- The Centre for Epidemiological Studies-Depression Scale (CES-D): www.actonmedical.com/documents/cesd_long.pdf
- The Beck Depression Inventory: www.hr.ucdavis.edu/asap/pdf_files/Beck_Depression_Inventory.pdf

Wound assessment tools

Assessment of any wound and documentation of findings also require a standardized approach.[17] Clinicians should use a comprehensive, validated and reliable wound assessment tool to provide a baseline and to assist with identifying any wound changes. This information helps identify wound healing or deterioration and should guide ongoing treatment decisions.[17]

## 1.2 Identify risk and causative factors that may impact skin integrity and wound healing.

**Discussion:** Individuals with diabetes may have modifiable and/or non-modifiable risk factors that can impact skin integrity and wound healing. Table 3 lists the most common factors the clinician might identify during the patient assessment.

**Table 3:** Factors that may Impact Skin Integrity and Wound Healing[18]

| Factors that may Impact Skin Integrity and Wound Healing |
|---|
| ▪ **Glycemic level:** hyperglycemia results in delayed wound healing and compromised chemotaxis and phagocytosis.<br>▪ **Activity:** patients may participate in activities that are not appropriate for their risk levels (e.g., running) because they can lead to injury and interfere with wound healing.<br>▪ **Smoking:** increases the risk of wounds through compromised blood flow and delays healing.<br>▪ **Trauma:** patients with diabetic neuropathy and loss of protective sensation are prone to injury/re-injury.<br>▪ **Footwear:** ill-fitting and inappropriate footwear increases the risk of skin breakdown and may interfere with healing.<br>▪ **Neuropathy:** manifested in the motor, autonomic and sensory components of the nervous system. Once neuropathy is established, it not reversible and exacerbates the development of ulcerations.<br>▪ **Bony deformity:** can result in areas of high pressure and skin breakdown.<br>▪ **Peripheral arterial disease:** increases the risk for the development of ulcers and impacts wound healing.<br>▪ **History of wounds:** healed wounds are more vulnerable to re-injury due to less resiliency and elasticity.<br>▪ **Amputation:** abnormal mechanics and ill-fitting prosthetics may cause pressure leading to tissue injury and prevent closure of existing wounds.<br>▪ **Age:** age-related changes in the structure and function of the skin can result in skin that may be easily traumatized and delayed wound healing. |

### 1.2.1 Patient: Physical, emotional and lifestyle

**Discussion:**

Physical Health

A complete medical history is important, as it can identify undisclosed medical conditions or potential risks to wound healing. A complete patient history should elicit any active and past medical conditions. The complications of diabetes include retinopathy, nephropathy, neuropathy and vasculopathy. It is important to obtain a smoking history, as this represents a major risk for peripheral arterial disease (PAD). A patient history may also identify barriers to self-managed and clinician-delivered care, such as visual or auditory impairment, which can prevent a patient from conducting effective foot assessments or receiving instructions. By recognizing barriers, patients and their team can better implement appropriate plans of care.

#### Populations at risk for type 2 DM:[16,18]

- individuals with pre-diabetes
- individuals with metabolic syndrome
- women with gestational diabetes
- individuals with mental illness
- individuals of African, Asian, Hispanic, Indigenous or South Asian descent
- individuals with vascular risk factors (e.g., cholesterol, hypertension, obesity)

Risk of foot ulceration in persons with diabetes increases in the presence of peripheral neuropathy, previous ulceration or amputation, structural deformity, limited joint mobility, PAD, onychomycosis and high glycocylated hemoglobin (A1c) levels.[16] Loss of sensation over the distal plantar surface (most often tested using a 10 g Semmes-Weinstein monofilament) is a significant and independent predictor of future foot ulceration and the possibility of lower-extremity amputation.[16]

Assessing glycemic control is critical in persons with diabetes. Table 4 outlines testing parameters to identify glucose levels.

**Table 4:** Glycemic Control: Targets for People with Diabetes[16]

| Test | Normal Range* |
|---|---|
| A1c | 7% or less |
| Fasting blood glucose/blood glucose (mmol/L) | 4.0 – 7.0 mmol/L before eating<br>5.0 – 10 mmol/L 2 hours after eating |

* Persons with diabetes who have multiple co-morbidities may have higher targets.

A focused physical examination for persons with diabetes should include assessment of vascular status, evaluation for neuropathy causing bony/structural abnormalities, sensation and review of footwear.

Vascular status

Clinicians should evaluate persons with diabetes with or without a foot ulcer for the presence of PAD. Arterial insufficiency falls just behind neuropathy in risk for developing a foot ulcer.[11,19]

PAD is four times more common in people with diabetes than in those without diabetes. Up to 50% of patients with diabetic foot ulcers (DFUs) will have significant underlying PAD.[20]

A thorough physical examination along with a focused history of vascular risks and current symptoms can detect arterial compromise. Clinical signs include vascular

dilation/flush (rubor) that blanches with elevation, hair loss, thickened nails and a cold foot with absent or reduced distal leg/foot pulses. Blanching the skin of the foot can give an indication of the quality of the local microcirculation.[21] With removal of the finger from the tissue, a delay in return of skin colour may represent decreased tissue perfusion. Distal gangrene of the toes with a palpable pulse or adequate circulation may indicate micro-emboli from proximal atheromatous plaques. If there is a distally located foot ulcer, a punched-out appearance with a pale base is a potential indicator of vascular compromise.

Clinicians must take into account that persons with diabetes often have factors that may complicate the assessment of blood flow to the feet. In patients with neuropathy, the classic trademarks of advanced arterial disease may not be present. Palpable pulses may be a poor indicator of arterial status. The ankle–brachial pressure indices (ABPI) may be falsely elevated due to vessel calcification. As a result, it is recommended that toe pressures, waveforms or transcutaneous oxygen readings be conducted to assess arterial blood flow.[22]

**Table 5:** Arterial Flow and Perfusion 2018 (combining Arterial, Venous and Diabetic BPR tables)[23]

| Classification | ABPI | Toe Brachial Index | Toe Pressure | Waveforms | $TcPO_2$* (indicating perfusion) |
|---|---|---|---|---|---|
| **Non-compressible** | > 1.40<br>Be aware of possible falsely elevated measures | Preferred when non-compressible vessels are present | Preferred when non-compressible vessels are present | | Preferred when non-compressible vessels are present |
| **Normal Range** | 1.0–1.40 | > 0.7 | > 70 mmHg | triphasic | > 40 mmHg |
| **Borderline** | 0.91–0.99 | > 0.6 | > 70 mmHg | biphasic/mono | > 40 mmHg |
| **Abnormal** | < 0.90 | > 0.6 | < 70 mmHg | biphasic/mono | < 40 mmHg |
| **Mild** | 0.7–0.9 | > 0.4 | > 50 mmHg | biphasic/mono | 30–39 mmHg |
| **Moderate** | 0.4–0.69 | > 0.2 | > 30 mmHg | biphasic/mono | 20–29 mmHg |
| **Severe** | < 0.4<br>Critical limb ischemia | > 0.2 | < 30 mmHg | monophasic | < 20 mmHg |

*Transcutaneous oxygen pressure

The International Working Group on the Diabetic Foot (IWGDF)[25] provides key recommendations for diagnosis, prognosis and management of persons with DM and DFUs. The following are several of the IWGDF key recommendations for diagnosis:[20,26]

- Examine a patient with diabetes annually for the presence of peripheral arterial disease; this should include, at a minimum, taking a history and palpating foot pulses.
- In patients with diabetes who have a foot ulcer and PAD, signs and symptoms alone are unreliable in predicting healing of the ulcer. However, one of the following tests can be helpful: a skin perfusion pressure ≥ 40 mmHg; a toe pressure ≥ 30 mmHg;

or a transcutaneous oxygen level ($TcPO_2$) ≥ 25 mmHg. Note: Other documents use 55 mmHg with prognosis guarded between 30 and 55 mmHg.

A validation study by Alavi et al. identified the utility of an audible hand-held Doppler.[24] Many persons with diabetes (up to 80%) have calcified leg arteries, and the ABPI is often high. This study examined 200 patients with 379 evaluable legs. All patients had ABPIs and toe pressures conducted at certified vascular labs, which is the gold standard. The audible hand-held Doppler signals were sensitive to rule out PAD (98.6% posterior tibial, 97.8% dorsalis pedis) but not specific for the diagnosis of PAD (37.5% posterior tibial, 30.19% dorsalis pedis). This test is a simple, quick screen and an alternative to the ABPI. However, the diagnosis of PAD still requires a sequential lower-leg duplex Doppler in the vascular lab. Results of the audible hand-held Doppler (> 0.9) are identified as biphasic or triphasic. If a monophasic wave or no audible sound is detected, a complete lower-leg duplex Doppler in the vascular lab should be ordered.

The symptom of pain in patients with diabetes may be unreliable due to the presence of neuropathy. Pain with arterial claudication is described in a specific area of the lower limb that is brought on by exercise and relieved by rest. This nociceptive pain signal is often described as gnawing, aching, tender or throbbing (GATT). The location of the discomfort can be anywhere from the buttock to the calf, depending on where the blockage of blood flow occurs. More concerning is pain that occurs at rest, often described by patients as pain in part of the lower extremity when lying down to sleep at night. This is known as critical limb ischemia. Persons with diabetes (even with the loss of protective sensation) may experience spontaneous neuropathic pain often described as burning, stinging, shooting, or stabbing (BSSS). This neuropathic pain often requires treatment.

Vascular assessment may include a surgical consultation prior to determining the healing potential and treatment of the wound.[21]

Bony/structural deformities

Foot deformities in the patient with diabetes can result from neuropathic changes, stiffening of the joints (termed *cheiroarthropathy*),[27] altered biomechanics or previous surgeries. There are three components to neuropathy: sensory, autonomic and motor. Sensory neuropathy is detected through monofilament testing. Autonomic neuropathy is identified by the presence of dry skin on the plantar surface and needs to be distinguished from fungal disease. Motor neuropathy is identified by testing for an absence of reflexes in the ankle and knee.

Motor neuropathy is characterized by intrinsic muscle atrophy and results in contracted digits and a displaced fat pad from the metatarsal heads to just below the toes.[22] Consequently, metatarsal heads become prominent and close to the skin surface,

leading to increased pressure and a potential ulceration site.[22] Abnormal pressure over bony deformities can lead to callus formation and ulceration, particularly in the absence of protective sensation. A body of evidence has shown that elevated plantar pressure is a major risk factor for ulcer development. There is a direct relationship between elevated pressures and deformity.

The ability of the first toe joint to dorsiflex (lift upward) is essential to normal foot function. Limitation in the range of motion of the first metatarsophalangeal joint is

called hallux limitus, or, with complete immobility, hallux rigidus. With impaired joint mobility, gait is altered and pressure increases on the plantar surface of the first toe (hallux), potentially leading to ulceration.[28,29] Gait examination, assessment of the range of motion, X-rays of the deformity and pressure mapping will enable the clinician to determine the extent of plantar pressures and any resulting forces on the foot.

**Charcot osteoarthropathy** (Charcot foot) is one of the major complications of diabetes mellitus. It is a progressive condition characterized by pathological fractures, joint dislocation and destruction of the pedal architecture. Well-recognized predisposing factors for Charcot osteoarthropathy include peripheral neuropathy, increases in local

blood flow, excessive osteoclastic activity, unrecognized injury and continued repetitive stress. There is no singular cause for the development of Charcot foot, but there are factors—such as neuropathy—that predispose an individual to the development of the condition. Once the condition is triggered, the uncontrolled inflammation process leads to osteolysis. This is directly responsible for joint and bone destruction.[30]

The acute Charcot metabolic changes result in bony reabsorption and multiple spontaneous fractures. Charcot joint changes can be classified into stages (see Table 6).[31,32] Charcot-associated fractures (usually multiple) may result from normal activities of daily living—in contrast to those caused by overt trauma.[19]

Increased warmth is the first indicator of inflammation in an insensate foot and may be the first sign of acute Charcot foot.[33] Skin temperature assessment of an acute Charcot joint with infrared thermometry may have an 8- to 15-degree Fahrenheit difference compared with a mirror image.[4] In the early stages of an acute Charcot joint, radiographs may not display any abnormalities. Bone scans will demonstrate increased activity.[32] If available, magnetic resonance imaging will identify micro-fractures. Failure to recognize Charcot foot in the early stages can result in catastrophic deformities with subsequent risk for ulceration and significant functional impairments.

Two randomized control trials (RCTs) have documented that repetitive trauma can result in a lower 4-degree Fahrenheit or higher temperature elevation.[4,33] Patient self-monitoring and reduction of physical activity can decrease the incidence of subsequent foot ulcers. The challenge is in distinguishing repetitive trauma, or an acute Charcot, from deep and surrounding infection, including osteomyelitis, which can have similar clinical presentations.[34]

**Table 6:** Assessment of Charcot Foot[35]

| Stage | Description[34] |
|---|---|
| **0 (prodromal)** | Includes dermal flush/redness and increased skin temperature, with or without local edema and bounding pulses. There is evidence of instability of the foot. X-ray evidence may or may not be seen. |
| **1 (developmental, acute)** | An acute destructive period that is induced by minor trauma resulting in fragmentation of bone and joint dislocation and subluxation. This is the most important stage for clinicians to recognize and where they can make the greatest difference in prevention of significant impairment for the patient.[34] |
| **2 (coalescence, subacute)** | The patient presents with lessening of edema and healing of fractures. |
| **3 (reconstruction, chronic)** | Healing of bone and remodelling on X-ray, plus evidence of deformity. |

Skin assessment

A complete head-to-toe skin assessment needs to occur, with special attention to legs and feet, including the toenails. Clinicians should identify and record any changes in colour, pigmentation, texture, turgor and odour, as well as assess between the toes and on the heels for cracks or fissures that may lead to ulceration. An inspection of skin for calluses, their location, size and colour should take place, along with an inspection of toenails for length, colour, thickness, subungal debris, trauma, separation from the nail bed and pain. The appearance of the toenails can be a good indicator of self-care and foot health.[36]

Footwear assessment

Footwear and orthotic assessments are key components of patient assessment, as ill-fitting footwear is a significant cause of ulcers and amputations.[11] It is important to ensure that footwear and orthotics match the person's function and activity level, address indoor and outdoor needs and are not a source of pressure.

As patients with neuropathy may not feel pain, daily foot and shoe examinations performed by patients or caregivers are essential for preventing complications (pressure-related trauma, ulcers, amputations). The Self-Assessment Footwear Checklist for Patients (see Figure 2) should be taught to all persons with diabetes and incorporated into their normal shoe-buying routine. Every clinician should assess the shoes and orthotics at every visit.

An area of callus build-up indicates that abnormal pressure is present, and if there is a blister, friction or shear is present. All persons with high-risk feet should be referred to a foot specialist (in chiropody, podiatry, orthotics or the equivalent)

if the health-care provider does not have the expertise to provide optimal plantar pressure redistribution.

The clinician should assess the following characteristics of each piece of footwear the patient wears:

- **Fit:** The toe box should be large enough to prevent pressure on toes. The heel should be firm-fitting but not too tight.
- **Structure:** Shoes should have features that support the foot, including midtarsal support and solid heal counters. Shoes should have laces/Velcro. Shoes should not have seams or structures that could result in friction or pressure.
- **Cushioning:** Shoes need enough cushioning to act as shock absorbers.
- **General features:** Shoes should be made of breathable materials such as leather to allow moisture to dissipate.
- **Motion control:** Shoes should limit overpronation (foot rolling inward and arch flattening).
- **Other:** The clinician should check inside the shoe for the presence of foreign objects. This should also be part of the patient's daily exam.

**Figure 2:** The Self-Assessment Footwear Checklist for Patients[37]

- ❑ Are the heels of your shoes less than 2 cm high?
- ❑ Do your shoes have laces, buckles, elastic or other fasteners to hold them onto your feet?
- ❑ Do you have 1 cm (approximately thumbnail length) of space between your longest toe and the end of your shoes when standing?
- ❑ Do your shoes have well-padded soles?
- ❑ Are your shoes made from material that breathes, such as leather?
- ❑ Do your shoes protect your feet from injury, i.e., cover and protect your foot entirely?
- ❑ Are your shoes safe (e.g., no seams)? Ensure they cannot cause injury.
- ❑ Are your shoes the same shape as your feet?
- ❑ Are the heel counters of your shoes firm?
- ❑ Are your shoes appropriate for your activities, e.g., a walking shoe for shopping?

Sensation

Peripheral neuropathy, to which persons with diabetes are prone, affects sensory, motor and autonomic nerves.[19] Diabetic sensory neuropathy classically presents as a distal symmetric sensorimotor neuropathy and is the leading cause of foot ulcers. This is because persons with diabetes are prone to serious injury from minor trauma due to their inability to feel the injury to the foot as it occurs. In addition to single injurious incidents, such as stepping on a needle, repetitive stress simply from walking can lead to tissue breakdown in the absence of protective sensation.

Two simple and effective tests for peripheral neuropathy are commonly used:

- 10 g Semmes-Weinstein monofilament
- standard 128 Hz tuning fork

**Monofilament testing:** Protective sensation can be readily assessed through use of a Semmes-Weinstein monofilament. Inability to perceive the monofilament force is associated with large-fibre neuropathy. Although guidelines suggest varying numbers of testing points, 10 monofilament test sites per foot is suggested to capture the largest proportion of patients with loss of protective sensation.[19,22] Note: monofilaments test one aspect of sensation and should not be used as the sole method for diagnosis of peripheral neuropathy.[38]

Calibrated nylon 10 gram monofilaments are recommended to optimize accuracy for sensation testing. Although other forms, including hand-made monofilaments, are available, they may vary widely in accuracy due to differences in filament diameter and length. Because nylon has memory properties, monofilaments should be rested for two hours following 100 applications (20 points/patient = five visits). The effective length of use of nylon monofilaments before replacement is required remains to be studied.

**Vibration testing:** Neuropathy is also demonstrated by an inability to sense vibration from a standard tuning fork. A biothesiometer or neurothesiometer can also be used for assessing the perception of vibration.

Emotional Health

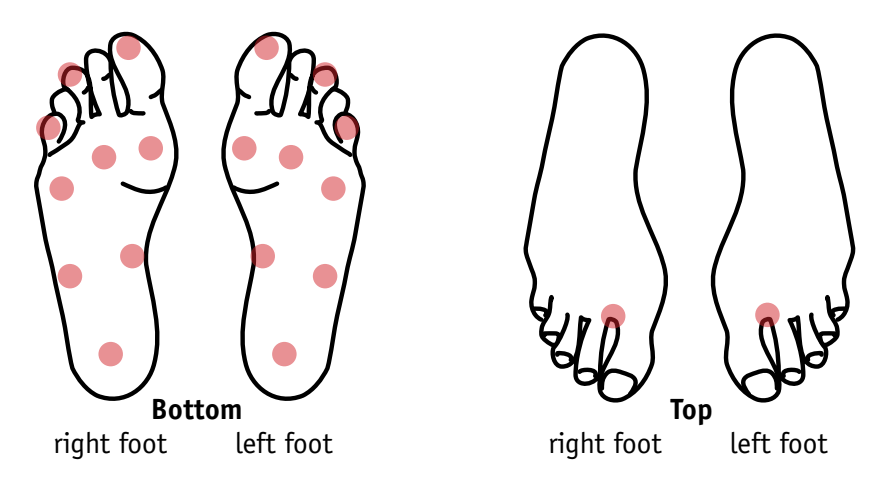
Mental health and diabetes have received growing interest from researchers and clinicians. For persons with diabetes, depression, major depressive disorder, bipolar disorder, generalized anxiety disorder and eating disorders are more prevalent than in

## How to Use a Monofilament

*The Semmes-Weinstein monofilament uses a 5.07 monofilament that exerts 10 grams of force when bowed into a C-shape against the skin for one second.*

1. Touch the monofilament to the patient's arm or hand (avoid the hand if the person with diabetes has glove and stocking neuropathy) so they understand what to expect when monofilament testing is performed on the foot.
2. Before you touch the monofilament to their foot, have the patient close their eyes and instruct them to say "yes" when they feel the sensation of the monofilament on their foot.
3. Hold the monofilament perpendicular to the foot and touch the skin only once, until the monofilament bends into a C-shape. Do not apply over ulcer, callus, scar or necrotic tissue.
4. Test the 10 sites indicated in the diagram (Figure 3).
5. Record the response on the foot screening form with "+" for yes and "–" for no.
6. If the monofilament is not felt in an area on the foot, this indicates loss of protective sensation (LOPS) in that area.

**Figure 3:** Monofilament Testing Sites




the general population.[16] In an 11-year follow-up study, Iverson and colleagues state when assessing clients' depression rates at baseline that these are associated with an increased risk of diabetic foot ulcers.[39] Mental health screening for emotional health is therefore a priority.[16]

### Lifestyle

Patients with diabetes need to be assessed for lifestyle choices that may impact the health of their feet:

- glycemic control
- nutritional status

### Diabetes and Mental Health

The Canadian Diabetes Association determined that "Research is increasingly demonstrating a relationship between mental health disorders and diabetes. Patients with serious mental illnesses, particularly those with depressive symptoms or syndromes, and patients with diabetes share reciprocal susceptibility and a high degree of co-morbidity."[16]

- weight
- smoking
- activity (including occupation and exercise)
- self-management (e.g., daily foot examination and wearing fitted and appropriate footwear)
- mental well-being

### 1.2.2 Environmental: Socio-economic, care setting, potential for self-management

A significant barrier for patients may be the financial cost of managing diabetes. Purchasing offloading (pressure redistributing) devices, boots and footwear, for example, is unachievable for many patients. Therefore, an environmental assessment is important to determine if the patient has socio-economic supports in place to engage in a sustainable plan of care and self-management. Other socio-economic determinants may include education level, adequate housing, access to nutritious food,[40] social network, access to services or equipment as well as family knowledge, comfort or capacity in providing support or care.

### 1.2.3 Systems: Health-care support and communication

**Discussion:** The collective health of Canadians has a significant impact on economic performance and the health-care system. With an aging population and increased chronic disease burden, including diabetes, health-care costs are increasing. Health-care delivery for persons with diabetes is highly variable between regions, leading to significant heterogeneity in outcomes. Due to the high variability of health-care delivery for persons with diabetes between regions, an assessment of regional services is required to determine the availability of services. To address the needs of the growing 11 million Canadians living with type 1 and type 2 diabetes and pre-diabetes, an organized, interprofessional and collaborative approach to care is critical to improve diabetes-associated outcomes.[11,41]

## 1.3 Complete a wound assessment, if applicable.

**Discussion:** The clinician should describe the characteristics of any ulcers using a validated wound assessment tool. Wound assessment can help the clinician determine the ability of the wound to heal, plan treatment, facilitate communication, monitor treatment and predict and verify outcomes.

There are several different classification systems available that may be used in the assessment of diabetic foot ulcers. These include the Wagner, Meggitt–Wagner, University of Texas and SINBAD (site, ischemia, neuropathy, bacterial infection, area and depth) systems. The University of Texas system (see Table 7) is the most predictive and positively correlates to the risk of amputation and other adverse outcomes.[42] Research on the SINBAD system indicates favourable results relating to its accuracy in predicting ulcer outcome.[43] Ulcers should be evaluated for infection at every visit.

**Table 7:** Classification Systems[44]

| System | Characteristics |
|---|---|
| **Wagner** | ▪ assesses ulcer depth along with the presence of gangrene and loss of perfusion using six grades (0 – 5) |
| **Meggitt–Wagner** | ▪ assesses ulcers into three categories: infective, non-infective and mixed |
| **University of Texas** | ▪ assesses ulcer depth, presence of infection and presence of signs of lower extremity ischemia using a matrix of four grades combined with four stages |
| **PEDIS** | ▪ assesses perfusion, extent (size), depth (tissue loss), infection and sensation (neuropathy) using four grades (1 – 4) |
| **SINBAD** | ▪ assesses site, ischemia, neuropathy, bacterial infection and depth; uses a scoring system to help predict outcomes and enable comparisons between different settings and countries |

*Adapted with kind permission from* Wounds International.

One aspect of assessment of diabetic foot ulcers is etiology. To create an optimal plan of care, the wound needs to be assessed and categorized as neuropathic, ischemic or neuroischemic.

**Table 8:** Categories of Diabetic Foot Ulcers[44]

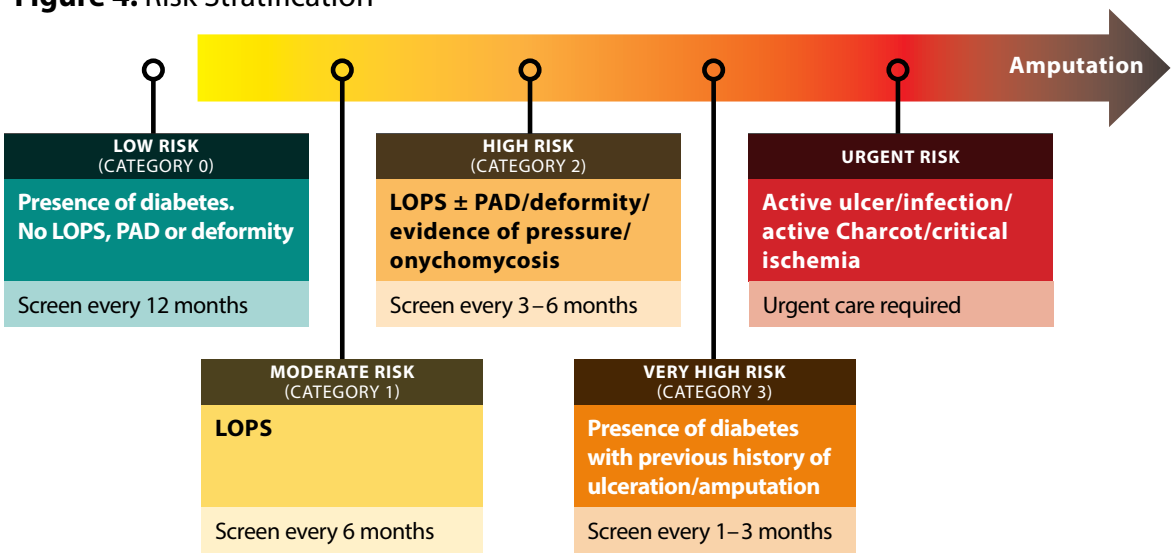
| Feature | Neuropathic | Ischemic | Neuroischemic |
|---|---|---|---|
| **Sensation** | sensory loss | pain | degree of sensory loss |
| **Callus/necrosis** | callus present and often thick | necrosis common | minimal callus; prone to necrosis |
| **Wound bed** | pink and granulating, surrounded by 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 |
| **Prevalence[45]** | 35% | 15% | 50% |

*Used with kind permission from* Wounds International.

Once the assessment is completed, risk of diabetic foot complications can be determined by referring to Step 2 of the Inlow 60-second Diabetic Foot Screen.[14] A risk classification system was developed by the IWGDF, which allows for efficient classification of persons with diabetic foot ulcers and guides clinicians in selecting appropriate therapeutic interventions, activity recommendations and follow-up for re-screening (see Figure 4).[46] This classification system was subsequently modified to include history of amputation and peripheral arterial disease. It was demonstrated to be more

effective at predicting diabetic foot complications than the original tool developed by the IWGDF.[47]

**Figure 4:** Risk Stratification[14]




Diabetic foot infections remain the most frequent complication of diabetes requiring hospitalization and are the most common precipitating events for lower leg amputation. Any form of trauma to the insensate foot (sharp blow, thermal injury, pressure or friction) can result in disruption of the skin barrier and penetration of bacteria. The underlying immune disturbance and perfusion issues that are common in persons with diabetes allow for the inflammatory reaction to progress to infection.

The factors that increase the risk for diabetic foot infections include:[50]

- Positive probe to bone test.
- Ulceration is present > 30 days.
- Recurrent foot ulcers.
- Peripheral arterial disease.
- Previous lower-extremity amputation.
- Peripheral neuropathy.
- Renal insufficiency.
- History of walking barefoot.

### The Pathway to Diabetic Foot Ulcers

For a great visual representation of the pathway to diabetic foot ulcers, please visit the following link: http://pda.rnao.ca/content/pathway-diabetic-foot-ulcers-0.

Clinical Signs and Symptoms of Infection in a Person with a Diabetic Foot Ulcer

The Infectious Disease Society of America (IDSA) and the IWGDF state that the diagnosis and classification of infection is based on clinical signs and symptoms.[50,51] The inflammatory response (erythema, warmth, tenderness, pain and induration) may be blunted in people with diabetes due to peripheral neuropathy, peripheral vascular disease and hyperglycemia. Secondary signs of infection, which may be useful in diagnosing infection, include the presence of necrotic tissue, friable granulation tissue, the type and amount of exudate and increased pain and odour. The severity of the infection should be defined based on the extent, depth and presence of systemic findings.[50,52]

The classification systems mentioned above all stratify infection into degree of severity. Table 9 shows the University of Texas ulcer classification system,[51] which grades infection based on the extent of the wound, presence of infection and degree of vascular compromise.

**Table 9:** University of Texas Diabetic Wound Classification System

| Stage | Grade 0 | Grade 1 | Grade 2 | Grade 3 |
|---|---|---|---|---|
| **A** | pre- or post-ulcerative lesion completely epithelialized | superficial wound not involving tendon, capsule or bone | wound penetrating to tendon or capsule | wound penetrating to bone or joint |
| **B** | infection | infection | infection | infection |
| **C** | ischemia | ischemia | ischemia | ischemia |
| **D** | infection and ischemia | infection and ischemia | infection and ischemia | infection and ischemia |

Hand-held infrared skin temperature devices can be used to detect early signs of inflammation and tissue injury and have been validated in clinical wound assessment.[53–55] It has been reported that high temperature gradients between feet may predict the onset of neuropathic ulceration and that self-monitoring may reduce the risk of ulceration.[45] With further studies, an infrared skin-temperature-measuring device may become part of routine patient education and self-monitoring advice.

Diabetic foot osteomyelitis

Osteomyelitis in the diabetic foot is a highly challenging diagnosis that can occur in up to 60% of hospitalized patients with diabetic foot infections and in up to 20% in outpatients with less severe infections.[51,56] Clinical presentations may vary greatly based on the involved site, extent of infection, perfusion, presence of surrounding infection and causative organism(s).[51]

Osteomyelitis should be suspected when ulcers lie over a bony prominence and fail to heal in spite of offloading or have associated soft tissue induration ("sausage toe" appearance).[57,58] Diabetic foot osteomyelitis commonly involves the forefoot and occurs by contiguous spread of infection from overlying soft tissues through to the underlying bone. A definitive diagnosis of diabetic foot osteomyelitis requires both histologic evidence of bone infection and isolation of a bacterial pathogen from a bone sample.[59]

As bone biopsies are not routine in all clinical settings, diagnosis is made on the basis of clinical, laboratory and radiographic features. Diagnostic accuracy is critical to guide management.

The probe to bone (PTB) test is a useful clinical tool when employed correctly for the diagnosis of osteomyelitis. A sterile blunt metal probe is inserted through a wound, and if bone is struck (hard, gritty end-feel), the likelihood of osteomyelitis is greatly increased in populations with high prevalence of osteomyelitis, such as persons with diabetes.[60–62] Conversely, in low-risk populations (< 20%), a negative PTB test is very useful, as it essentially excludes the possibility of osteomyelitis.[60,63,64]

## Foot Screening

A uniform approach to diabetic foot screening ensures that all elements of the examination are completed. Risk factor recognition is vital in helping clinicians predict and prevent the occurrence of diabetic foot ulcers.[48] The most effective method for amputation prevention may simply be to have all health-care professionals remove the shoes and socks of persons with diabetes and examine their feet.[49]

When considering radiographic evaluation, clinicians should be aware that plain X-rays are often adequate to evaluate the bone for established osteomyelitis. They are also useful for assessing for foot deformities, fractures, the presence of gas in the soft tissue and radiopaque foreign bodies. Bony changes seen on plain X-rays can be slower to develop, but X-rays are low-cost and readily available. Plain X-rays have sensitivity and specificity of 0.54 and 0.68 respectively,[51] demonstrating that they should not be used in isolation, as they are not highly predictive of osteomyelitis regardless of the result. X-rays have poor positive predictive value even when they are positive, unless subsequent radiographic evidence is positive.

Blood tests for inflammatory markers such as C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) are often used but are not specific to the type of infection. An ESR elevated to more than 70 mm/hr increases the likelihood of osteomyelitis. Lower levels can decrease the likelihood. An ESR may be a useful biochemical adjunctive test.[51,65–67] Fewer studies have suggested that other tests, including CRP, leukocyte counts and procalcitonin, may also be useful. There is insufficient evidence, however, for routine use of these biochemical tests for diagnosis of diabetic foot osteomyelitis. Of these, as ESR drops more slowly with treatment, it may serve as a marker for treatment response.[51,68]

Magnetic resonance imaging (MRI) is considered the gold standard for diagnosing osteomyelitis. When MRI is contraindicated, or not available, a white-blood-cell labelled radionuclide scan, computed tomography or positron emission tomography may be considered.[51]

# Step 2: Set Goals

# Step 2: Set Goals

**Discussion:** Based on identified risk factors and complete patient, wound and environmental assessments, goals need to be set in collaboration with the patient, family and/or caregiver. Identify the available options so that informed decisions can be made. Health-care providers must respect the individual's right to choose the interventions they prefer.[11]

## Recommendations

### 2.1 Set goals for prevention, healing, non-healing and non-healable wounds.

**Discussion:** From a long-term health perspective, a primary goal for those with diabetes should involve the prevention of diabetic foot ulcers. Therefore, factors that can cause skin breakdown or influence healing need to be identified.[11,69] Reducing the risk of neuropathy and peripheral arterial disease should also be considered.

#### 2.1.1 Identify goals based on prevention or healability of wounds.

**Discussion:** Prevention of an initial wound or additional wounds on the contralateral limb or other parts of the foot is a goal that should be given paramount consideration. Ultimately, preservation of limb and life may depend on it.

In the presence of wounds, the health-care professional must identify whether the wound is healing, non-healing or non-healable. This decision is made based on the patient's modifiable and non-modifiable risk factors and is the only way to ensure that the goals are made in conjunction with, and are appropriate to, the patient.[9,11]

#### 2.1.2 Identify quality-of-life and symptom-control goals.

**Discussion:** Health-care professionals must always remember that the end goal may or may not be the healing of a wound, and it may not necessarily be the only goal. Clinicians must also consider other goals of care, such as wound stabilization, pain reduction, controlled bacterial load and a reduced frequency of dressing changes.[70] Once legitimate goals are identified, they should become part of the plan of care.

A special note on pain: Reducing painful diabetic neuropathy can be a key goal for patients living with diabetic foot complications. According to the Canadian Diabetes Association (CDA) guidelines, few patients have complete relief of painful symptoms with any treatment, and reduction of 30 to 50% in pain levels is clinically meaningful.[16]

Many clinicians struggle with the decisions surrounding limb preservation and need support when exploring all goals of care with the team. It is important to note that some patients may elect to undergo amputation, as the wound may be interfering with their occupation, attitude, social support system, access to care and financial resources.

### ABCDEFS Scheme for Goal Setting[16]

- **A – A1c** – Aim for a glucose control target of 7% or less.
- **B – Blood pressure** – Aim for a blood pressure control target of less than 130/80 mmHg.
- **C – Cholesterol** – Aim for an LDL target of 2.0 mmol/L or less.
- **D – Drugs** – Protect against heart attack and stroke with appropriate medication.
- **E – Exercise** – Participate in regular physical activity.
- **F – Footcare** – Perform a daily examination.
- **S – Smoking and stress** – Stop smoking and manage stress effectively.

*Modified with kind permission from the Canadian Diabetes Association.*

# Step 3: Assemble the Team

# Step 3: Assemble the Team

**Discussion:** Assessment, prevention and management of diabetic foot problems require the collaboration of an integrated team in the hospital and community settings. The team must work closely and collaboratively to address the complex lifestyle, self-care and emotional and social impacts of living with diabetes and being at risk for foot complications. Clinicians require clear protocols and clinical pathways that reflect the continued and integrated care needs of patients across all settings and that can be communicated among all team members.[71]

## Recommendations

### 3.1 Identify appropriate health-care professionals and service providers.

**Discussion:** The professional members of the team need to be trained and empowered to work with patients with diabetes since the knowledge and skills necessary to assess and treat a person with a diabetic foot ulcer are not usually taught in an entry-level health-care-professional curriculum. Caring for individuals with diabetes at risk of developing foot complications or those who already have foot ulceration requires that clinicians have the skills to address glycemic control, infection, offloading of high-pressure areas, lower-extremity vascular status and local wound care while supporting a self-management approach to care.[16]

Ideally the professional members of the team will all be in one location. If not, strategies must be established to ensure that fluid, effective collaboration and communication ensue.[72] Patients with disabilities, including visual impairment and mental health issues, or those who are housebound or living in specialized care settings, may need further support.[72]

Additional considerations for assembling the appropriate team are as follows:

- Specialized assessment equipment and training are required to assess the vasculature of a person with diabetes.[11,69] Appropriate referral for any patient diagnosed with or suspected of arterial insufficiency is essential for the prevention and treatment of diabetic neuropathic foot ulcers.
- If a person with diabetes is admitted to acute care where a diabetic foot problem is the dominant clinical factor for admission, acute care protocols and care pathways should be in place to support care delivery.[69] In the acute care setting, the patient needs to be assigned to a lead clinician who can ensure that timely care is provided.[69] In the United Kingdom, patients with diabetic foot complications access the multidisciplinary foot care team to enforce limb preservation strategies. This effective model needs to be considered in the Canadian health-care system.

#### Patients First

The first team members should be the patient and their family or caregivers. The next team member is usually the primary care provider, depending on the needs of the patient and allocation of resources within the community. A diabetologist, specialist in internal medicine, diabetes nursing specialist, podiatrist/chiropodist (biomechanics), orthotist, pedorthist, nursing and rehabilitation professionals and an enterostomal therapist might round out the list. In some cases, there should be contact with specialists in endocrinology, dermatology, vascular surgery, microbiology, orthopedics (casting, bone debridement) and infectious disease, as well as social workers, cultural/ethnic health liaisons, registered dietitians, spiritual care providers and mental health workers (psychologists).[71]

- Clinicians and other professional team members involved in the assessment and treatment of diabetic feet should receive competency-based education and training.[73] Guidelines from the UK's National Institute for Health and Clinical Excellence (NICE) refer to "trained personnel."[69] Since early detection and intervention may be the key to more successful outcomes, access to individuals with knowledge and training specific to diabetes and diabetic foot care will improve patient outcomes. In addition, professionals need to recognize the impact of living with neuropathy, which can reduce motivation to heal or prevent injury.[11]

### Professional Team Members Guidelines (adapted from IWGDF)[74]

**Low Risk (Category 0):** family physician, diabetic nurse

**Moderate Risk (Category 1):** general practitioner, podiatrist/chiropodist, diabetic nurse, professional shoe fitter

**High Risk (Category 2):** endocrinologist, surgeon (vascular and/or orthopedic), podiatrist/chiropodist, diabetic nurse, professional shoe fitter

**Very High Risk (Category 3) or Urgent Risk:** foot centre with multiple disciplines specialized in diabetic foot care and linked to a surgical facility

## 3.2 Enlist the patient and their family and caregivers as part of the team.

**Discussion:** Patients with or at risk for diabetic foot ulcers need to become part of a specialized, integrated diabetes team that is proactive, incorporates elements of the chronic care model (CCM) and is organized around them.[16] For pediatric patients, parents or legal guardians need to be part of the care-planning team.[69]

Ideally, the patient and caregivers are willing and able to set goals and participate in the plan of care. Every attempt should be made to have meaningful communication with the patient and family regarding lifestyle choices that will result in the best possible long-term outcomes.[11,69]

To help ensure active participation, individuals with diabetes and their families should be offered timely diabetes information that is tailored to enhance self-care/management practices and behaviours. According to the CDA, self-management education (SME) is defined "as a systematic intervention that involves active patient participation in self-monitoring (physiological processes)

and/or decision-making (managing). It recognizes that patient-provider collaboration and the enablement of problem-solving skills are crucial to the individual's ability for succeed at sustained self-care."[16]

A self-assessment tool is available to assist in patient education. A Wounds Canada expert advisory group, in collaboration with a patient focus group, has developed a self-assessment brochure and an interactive website in many languages to help patients in recognizing risk factors and identifying foot issues that they may have been unaware of. The brochure and interactive website are available at www.woundscanada.ca. A more informed patient is likely to be a more engaged team member.

Peer or lay educators may also increase diabetes-related knowledge and self-care behaviours.[16] The PEP Talk: Diabetes, Healthy Feet and You program, from Wounds Canada, is an example of a peer-led, patient-focused program that provides supportive educational sessions on diabetic foot care. It is delivered to people with diabetes and their family members by facilitators living with diabetes, alongside clinical experts. This approach gives patients the opportunity to ask clinical questions while also learning from the lived experience of a peer educator.[75]

## Terminology

*Multidisciplinary team* refers to a team of health-care workers from a variety of disciplines. *Integrated team* is the preferred term because it describes a team that includes the patient, family and a mixture of professional and paraprofessional providers.

## 3.3 Ensure organizational and system support.

**Discussion:** Successful diabetic foot care programs are designed and evaluated in collaboration with clinical practice leaders, educators and administrators at the institutional, regional and provincial/territorial levels.[11] It is critical that care is co-ordinated between health-care agencies and the community and promotes a standardized approach to wound prevention and care to improve patient outcomes and efficiency. Successful programs involve formalized collaboration between the patient and acute, long-term, primary and community care to align best practices across the board. Teamwork and integration of services help to alleviate confusion and duplication of services.[11,69]

Organizations and leaders are encouraged to do the following, all of which are reinforced by the CDA:[11,69]

- Develop policies (federal, provincial/territorial, regional and local/institutional) that acknowledge and designate human, material and financial resources to support the team in diabetic foot assessment, prevention and management.

### Self-managed Care

Support your patient in self-managing their care to prevent foot complications by having them do the following:

- Manage their blood glucose levels.
- Stop smoking if they are a smoker.
- Perform a daily foot exam.
- Select professionally measured shoes, if they have neuropathy.
- Perform high-quality foot care and hygiene.
- Seek professional foot care.
- Seek help with urgent foot complications.
- Ensure they receive an annual foot screening.

- Establish a pathway for referral of people with diabetes that supports risk stratification, from immediate to 48 hours, to a multidisciplinary foot-care service.
- Work with community and other partners to develop a process to facilitate patient referral and access to local diabetes resources and health-care professionals with specialized knowledge in diabetes management (e.g., glycemic control).
- Work with community and other partners to advocate for strategies and funding for all aspects of preventative foot care, preventative and treatment footwear, and glycemic control.
- Ensure foot care services exist for the assessment, surveillance and treatment of preventative care.
- Establish and support a multidisciplinary team composed of interested, skilled and knowledgeable persons to address and monitor quality improvements in the prevention and management of diabetes-related foot complications.
- Use globally recognized risk classifications to help allocate resources such as therapeutic shoes, patient education and clinical visits.
- Establish and sustain a communication network among the person with diabetes, health-care professionals and community systems.
- Audit all aspects of the service to ensure that local practice meets accepted national and international standards of care.
- Engage patients with diabetes to check their feet daily for cuts, cracks, bruises, blisters, sores, infection and unusual markings.[16]

See more at: www.diabetes.ca/about-cda/public-policy-position-statements/amputation-prevention#sthash.kK3V3rLF.3fqVAA2k.dpuf

www.diabetes.ca/about-cda/public-policy-position-statements/amputation-prevention#sthash.kK3V3rLF.dpuf

Diabetes and Foot Care: The Problem and Solutions www.woundscanada.ca/docman/public/wound-care-canada-magazine/2016-14-no1/89-working-for-change-the-cawc-s-advocacy-campaign-for-the-prevention-of-diabetic-foot-complications/file

# Step 4: Establish and Implement a Plan of Care

# Step 4: Establish and Implement a Plan of Care

**Discussion:** Diabetic foot ulcer prevention and wound healing is challenging, as DM presents many complex management issues. The plan of care should incorporate factors identified during the assessment process.

## Recommendations

### 4.1 Identify and implement an evidence-informed plan to correct the causes or co-factors that affect skin integrity, including patient needs (physical, emotional and social), the wound and offloading (if applicable) and environmental/system challenges.

**Discussion:** Prevention of diabetic foot complications is key. All individuals with diabetes need to receive an annual foot screen to identify whether they are at low, moderate, high, very high or urgent risk for the development of foot complications. Management strategies can then be developed that revolve around the prevention and/or management of diabetic foot ulcers as seen in Step 3 of the Inlow 60-second Diabetic Foot Screen.[14]

Whether or not the person with diabetes has an ulcer, the patient and health professional team should work together to monitor and manage the factors that affect the patient's health and well-being, including smoking, glycemic control, weight-management, use of medications,[16] level of physical activity, exercise and occupation, professional foot care and offloading and behavioural choices,[11,69] such as daily foot self-examination, recognizing and managing foot injury, accessing care and acquiring and wearing appropriate footwear.

Employment may be impacted, and the patient may need employment modification or time off work to support wound healing.[76]

Skin and nail care

Ensure that the person with diabetes has a skin- and nail-care routine that supports the maintenance of healthy feet. Skin should be assessed frequently for signs of impending injury. Callused areas require debridement and footwear adaption/offloading as needed to prevent injury or recurrence of a wound. Heel cracks or fissures should be treated with debridement and appropriate dressings as well as appropriate footwear selection to reduce pressure and shear. Foot odour may indicate poor hygiene or a fungal infection, also known as athlete's foot, that requires treatment with antifungal therapy as well as attention to footwear to ensure it is breathable and hygienic. Ragged and unkempt nails may require professional and routine follow-up.[36]

Smoking

The effects of smoking on health are well documented. Every effort should be made to encourage and support smoking cessation in individuals with diabetes. Clinicians should consider appropriate referrals to smoking cessation programs to facilitate this crucial modifiable risk factor.[1,77]

Glycemic control

Appropriate glycemic control is essential for delaying complications of diabetes. A glycated hemoglobin (HbA1c) test shows

blood glucose levels over the previous three months. Although glycemic targets must be individualized, most people with diabetes should aim for an HbA1c level of less than 7% to reduce the risk of micro- and macro-vascular complications.[16]

Although it is clear from the literature that tight glycemic control prevents or delays the complications of diabetes, the relationship between HbA1c and ulcer healing time is less well understood. Various studies have, however, demonstrated significantly decreased healing times in individuals with lower HbA1c.[78] Decreased healing time results in a lower financial burden for both the patient and the health-care system and increased quality of life for the patient.[79,80]

If poor glycemic control is suspected, the clinician should refer the patient to their primary care provider, diabetes educator or other specialist as appropriate for consideration of services, technologies or devices that could support glycemic control.[81]

### Medications

During the assessment phase, the clinician should have obtained a medication list and identified medications that may interfere with skin health or wound healing. The clinician may need to arrange a consult with the pharmacist to determine if the medication interferes or delays healing. A query to the prescribing physician, nurse practitioner or psychiatrist may elicit a medication option that does not interfere with skin health or healing.[82,83] In addition, for individuals with DM-related depression, nonadherence may contribute to care-planning challenges.[84]

All patients with diabetes and an ischemic foot ulcer should receive aggressive cardiovascular risk management that may include support for cessation of smoking, treatment of hypertension and prescription of a statin as well as low-dose acetylsalicylic acid or clopidogrel.[20]

### Nutrition

Nutrition recommendations for people with diabetes and foot ulcers should be individualized, taking into consideration co-morbidities, any previously documented abnormal laboratory test results, patient age, preference and medications. Patients should be counselled by a registered dietitian in a group or individually. It has been demonstrated that when dietitians collaborate with the patient in a meaningful exchange of information, HbA1c, quality of life and medication adherence is improved. Clinicians can refer patients to credible online resources to assist in decision-making regarding nutritional choices.[85]

### Physical activity

Appropriate levels of physical activity should be a cornerstone for any prevention and wound management program.

Most people with diabetes or those at risk for diabetes do not meet the CDA's guidelines for aerobic and resistance exercise, despite the following:

- Patients have the power to improve their blood glucose control by actively exercising five days a week and engaging in resistance training.
- Regular physical activity, in conjunction with healthy eating and weight control, can reduce diabetes incidence by 60%.[86]

Therefore, it is essential that physical activity be built into the plan of care for most patients.

### Revascularization

IWGDF advises that patients with diabetes that have PAD and a foot infection are at a higher risk for major limb amputation and require emergency treatment. All patients with diabetes and an ischemic foot ulcer should receive aggressive cardiovascular risk management, including support for cessation of smoking, treatment of hypertension and prescription of a statin as well as low-dose acetylsalicylic acid.[20]

### Exercise and Diabetes

Physical activity can be as powerful as glucose-lowering medication, with fewer side effects.

Physical activity levels of Canadians have fallen dramatically over the last 40 years.

Fitness level is one of the strongest predictors of all-cause mortality in people with diabetes.

Poor physical fitness is as strong a risk factor for mortality as smoking.

### Pain control

For neuropathic pain management, anticonvulsants and antidepressants are considered first-line treatments. Opioids are used mostly when other treatments fail. Other effective therapeutic options include topical nitrate sprays, topical capsaicin, and transcutaneous electrical nerve stimulation.[16]

### Psychosocial factors

Once psychological issues, such as depression, are identified, appropriate interventions, referrals and education need to occur. Treatment and intervention options may include the following: support to facilitate adaptation to diabetes, reduction of diabetes-related distress to improve outcomes, motivational interventions, stress-management strategies, coping skills training, family therapy and collaborative case management. Cognitive behaviour therapy and/or antidepressant medications may also be used.[16]

Individuals taking psychiatric medications, particularly atypical antipsychotics, benefit from regular screening of metabolic parameters.[16]

Self-management issues can be addressed in a one-on-one session or during diabetes self-management workshops given by peer leaders with diabetes.

### Management of Charcot arthropathy

Once a diagnosis of Charcot arthropathy has been made, interventions must be initiated immediately to prevent the progression of deformity and subsequent risk for ulcers and amputation. Treatment revolves around *immediate* plantar pressure management; in the chronic phase, it may require surgical intervention.

| Stage | Management[87] |
|---|---|
| **0 (prodromal)** | ▪ non-weight-bearing cast<br>▪ minimum immobilization: 8 – 12 weeks |
| **1 (developmental, acute)** | ▪ non-weight-bearing cast<br>▪ immobilization or graduation to removable cast walker |
| **2 (coalescence, subacute)** | ▪ patellar tendon-bearing brace (PTB)<br>▪ Charcot restraint orthotic walker (CROW walker) |
| **3 (reconstruction, chronic)** | ▪ custom-made shoes with or without a brace |

Lower-limb amputation

The decision to preserve or amputate a diabetic limb is one of the most difficult that patients, families and clinicians face. Determining whether to amputate or not must be made on a case-by-case basis. It requires an in-depth evaluation of each individual patient's physical, mental and socio-economic status. While amputation is often the last resort and can elicit a sense of failure for both the patient and the clinician, for some it can be life giving as well as a welcome relief from intractable ischemic pain. Support of the individual pre and post amputation is important.

## Lower-limb Amputation

The criteria to amputate can be[88]

- **clinical**: peripheral arterial disease and progressing infection
- **patient-focused:** lifestyle, occupation, age, wishes, attitude, reliability, social support system, access to care and financial resources
- **system**: regional/institutional policies may be in place to support or inhibit limb preservation versus amputation

Amputations can be divided into two broad categories:

**Minor amputations:**

- amputation of digits
- partial foot amputation
- ankle disarticulation

**Major amputations:**

- below-knee amputation, abbreviated as BKA
- knee disarticulation
- above-knee amputation, abbreviated as AKA (transfemoral)
- Van Nes rotation/rotationplasty (foot turned around and reattached to allow the ankle joint to be used as a knee)
- hip disarticulation
- hemipelvectomy/hindquarter amputation

Post-amputation care is essential for health, function and mobility. With all lower-limb amputations, the use of compression in the form of a proper wrapping technique is important for residual limb ("stump") shaping, wound healing, control of edema and preparation for a possible prosthesis. Consideration needs to be given to limb, skin and prosthetic care for the prevention of further breakdown. The following website provides tips to identify and correct minor problems: www.amputee-coalition.org/inmotion/may_jun_08/taking_care_your_limb.html.[89]

Although not everyone will benefit from the provision of a lower-limb prosthesis or will master their device, patients should be offered this option.[90] Individuals living with diabetes and lower-limb amputation should be encouraged to take ownership of their health and be introduced or reintroduced to foot-care strategies if there is a remaining limb. In one study, it was found that almost half of those living with diabetes who were admitted to an inpatient amputee rehab program had never received information on preventative foot care.[91] Hopping on the remaining limb post operatively will increase plantar pressures and should be done cautiously and consider the presence and severity of neuropathy. It should never be done in the presence of an actual or suspected Charcot deformity. Where there is significant loss of protective sensation and/or Charcot foot, safe transfers should be the main goal until prosthetic training is provided.

Offloading for prevention

Prevention of ulceration or re-ulceration in the feet of individuals with diabetes is possible when pressure is taken off vulnerable plantar areas and friction is eliminated. This

is achieved through proper fitting, use and inspection of insoles and footwear. Those with compromised sensation need the assistance of regular visual and hand inspection by themselves and their support team. As well, their footwear should always be professionally fitted.

It is important that the entire team be aware of the following footwear selection and wearing protocols for prevention of foot complications in persons with diabetes:

- Therapeutic footwear or orthotics must be worn at all times, both indoors and outdoors.
- Inappropriate footwear such as high-heeled or narrow-toed shoes should be avoided, as these can cause damage even if worn for only a few hours.[92]

In creating the plan of care, the ability of the patient to put on and remove shoes and socks must be considered and assistive devices prescribed as appropriate (e.g., sock aid, long-handled shoe horn).

Improved pressure management can be facilitated through patient participation in appropriate activities. Low-impact activities such as swimming, aqua-fit classes and bicycling are preferable to high-impact activities such as walking, jogging and aerobics.

### Offloading for wound healing

Pressure is a factor in 90% of diabetic plantar ulcers; therefore, inappropriate pressure must be modified or removed.[19]

Elevated foot pressure that may result in ulceration can be caused by several factors, either individually or in combination, including the following:

- genetic or structural factors that result in pressure-induced ischemia, which occurs in tissues over bony, weight-bearing areas during ambulation and standing
- poor-fitting or inappropriate footwear
- poor walking pattern caused by neuropathy or other factors
- traumatic accident
- surgery

These factors must be the primary drivers of the development and implementation of any plan of care. Unfortunately, failure to adequately offload the neuropathic foot is common and may result from the clinician's lack of knowledge regarding the concept of an insensate foot or pressure, lack of resources to acquire proper footwear or orthotics, improper fit or inconsistent use of the offloading device.[93]

Clinicians should remember that considerations when offloading the foot are not limited to the device itself, but also include patient characteristics, environmental factors, appropriate use of the device, reduction of activity, reduction of walking speed and alteration of gait (see Table 10).[94]

While offloading is of paramount importance, there are significant challenges, including availability and cost of devices and the impact on the patient's ability to work. In some cases, job modification will need to be considered for the patient to progress to full recovery, and sometimes the modification will be permanent. Clinicians may support clients by writing letters with recommendations for employment modification.

Selection of offloading devices

Offloading options for the prevention and treatment of forefoot ulcers can be selected according to the risk and severity of complication status and patient acceptability (see Table 11).

First line of treatment:[26]

- devices that cross the ankle joint, such as removable contact casts and total contact casts
  - irremovable devices are a better option than removable devices
  - patients must have adequate balance to use these devices

Second line of treatment:[26]

- devices that do not cross the ankle joint, such as surgical shoes and customized or custom-made footwear and orthotics

Third line of treatment:[26]

- shoes and orthotics, which are mainly used for prevention

The best device is a mechanically supportive device the patient will use inside and outside the house.

**Table 10:** Factors to Consider When Offloading Diabetic Foot

| Factors | Description |
|---|---|
| **Disease** | ▪ neuropathy<br>▪ PAD<br>▪ inflammatory disorder |
| **Pressure** | Type of pressure:<br>▪ shear pressure<br>▪ vertical pressure<br>Intrinsic<br>▪ structural modifications (deformity/limited range of motion/tissue quality loss)<br>▪ infection<br>▪ malignancy<br>Extrinsic<br>▪ biomechanics<br>▪ deformity<br>▪ footwear |
| **Foot ulcer** | ▪ presence of ulcer<br>▪ type of ulcer<br>▪ location<br>▪ dressing selection |
| **Physical activity** | ▪ occupation<br>▪ home lifestyle<br>▪ sports/recreational activity<br>▪ balance |
| **Funding** | ▪ ability to pay for device<br>▪ third-party insurance |
| **Patient behaviour** | ▪ ability to adhere to treatment plan<br>▪ occupation and lifestyle<br>▪ mental capabilities |

Surgical offloading

Surgery can be an effective method of addressing diabetic foot complications.

Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection, or osteotomy can support healing and prevent a recurrent foot ulcer when conservative treatment fails. These interventions are contraindicated in the presence of ischemia or uncontrolled infection.[44]

Digital flexor tenotomy is a method to prevent or support healing of a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammertoes and either a pre-ulcerative sign or an ulcer on the toe.[92] These interventions are contraindicated in the presence of ischemia or uncontrolled infection.[44]

Surgical treatment is beneficial for patients with Charcot foot in cases where offloading and immobilization have failed or where there are non-healing foot ulcers.[30]

Procedures such as exostectomy in combination with tendon lengthening are useful to relieve bony pressure by reducing forefoot pressure and improving the alignment of the ankle and rear foot to the midfoot and forefoot.

**Table 11:** Offloading Options[35]

| Offloading Device | Photo | Wound Location | | | | Advantages | Disadvantages |
|---|---|---|---|---|---|---|---|
| | | Toes | Forefoot | Midfoot | Heel (Rearfoot) | | |
| **Total contact cast (TCC)** |  | ✓✓ | ✓✓✓ | ✓✓✓ | ✓✓ | ▪ gold standard<br>▪ reduces pressure under ulcer site between 84 and 92%<br>▪ custom moulded to shape of foot<br>▪ most studies indicate the shortest healing time as 8 to 12 weeks<br>▪ forced patient adherence to device | ▪ requires a trained professional to apply on a weekly basis<br>▪ can result in secondary ulceration with improper application<br>▪ contraindicated for infected or ischemic wounds; use with caution for heel ulcers<br>▪ difficult to sleep with<br>▪ may prevent patient's ability to work<br>▪ patient may not tolerate device |
| **Removable cast walker (RCW)** |  | ✓✓✓ | ✓✓✓ | ✓✓ | ✗ | ▪ effective at reducing plantar pressure at ulcer site with close peak pressures similar to TCC<br>▪ can be used for infected wounds<br>▪ all clinicians can be trained to apply<br>▪ same device can be used for the full the duration of treatment<br>▪ can be made irremovable with the application of a cohesive bandage to become an Instant Total Contact Cast (iTCC) (see below) | ▪ generic fit to the foot<br>▪ complicated by patients not wearing the device as prescribed because it is removable<br>▪ use of removable device results in longer healing times<br>▪ patient needs time to learn how to use device<br>▪ may prevent patient's ability to work<br>▪ contraindicated for those with heel ulcers and poor balance |
| **Instant total contact cast (iTCC)** |  <br>  | ✓✓✓ | ✓✓✓ | ✓✓ | ✗ | ▪ removable cast walker made irremovable to become an iTCC<br>▪ same advantages as RCW<br>▪ same device can be used throughout the duration of treatment – and will require a change of the irremovable component | ▪ generic fit to the foot<br>▪ may prevent patient's ability to work<br>▪ patient may not tolerate device |

*cont'd.*

| Offloading Device | Photo | Wound Location | | | | Advantages | Disadvantages |
|---|---|---|---|---|---|---|---|
| | | Toes | Forefoot | Midfoot | Heel (Rearfoot) | | |
| **Half shoe (forefoot)** |  | ✓✓ | ✓✓ | ✗ | ✗ | ▪ transfers pressure to mid-foot and rearfoot by eliminating propulsion<br>▪ low cost | ▪ very unstable<br>▪ contraindicated for patients with gait instability<br>▪ high risk of falls |
| **Half shoe (rearfoot)** |  | ✗ | ✗ | ✗ | ✓ | ▪ low cost | ▪ very unstable |
| **Surgical shoe** |  | ❣ | ✓✓ | ❣ | ❣ | ▪ low cost<br>▪ accommodates edema<br>▪ good for short-term management | ▪ offloading property limited<br>▪ use with orthotic or insert devices<br>▪ not ideal for activity |
| **Over-the-counter walking footwear** |  | ✓ | ✓✓ | ✓ | ✓ | ▪ affordable<br>▪ easy to access<br>▪ for preventative care | ▪ offloading property limited<br>▪ use with orthotic or insert devices |
| **Footwear modifications (rocker toe)** |  | ✓✓ | ✓✓ | ✓ | ✗ | ▪ moves pressure from forefoot to rearfoot | ▪ requires trained professional to apply<br>▪ expensive |
| **Custom-made footwear** |  | ✓✓ | ✓✓ | ✓✓ | ✓✓ | ▪ distributes pressure under foot evenly<br>▪ ideal for foot deformity | ▪ requires trained professional to apply<br>▪ very expensive |
| **Custom-made orthotics** |  | ✓ | ✓✓ | ✓✓ | ✓ | ▪ distributes pressure underfoot evenly<br>▪ may be used with over-the-counter footwear | ▪ requires trained professional to apply<br>▪ expensive |
| **Total contact inserts** |  | ✓ | ✓✓ | ✓✓ | ✓ | ▪ distributes pressure under foot evenly<br>▪ may be used with over-the-counter footwear | ▪ requires trained professional to apply |
| **Padding** |  | ✓ | ✓ | ✓ | ✓ | ▪ low cost | ▪ offloading property limited<br>▪ can cause "edge effect" |
| **Crutches/ cane** |  | ✓ | ✓ | ✓ | ✓ | ▪ low cost | ▪ offloading property limited<br>▪ can cause shoulder dislocation |

✓ = indicated; ✗ = contraindicated; ❣ = can be used

Arthrodesis can be useful in patients with instability, pain or recurrent ulcerations that fail to heal.[30]

## 4.2 Optimize the local wound environment.

**Discussion:** Local wound care needs to be based on healing potential and the goals that have been set by the team. The wound environment should be optimized. This involves cleansing, irrigation, debridement, ensuring bacterial balance and controlling moisture.

### 4.2.1 Cleansing

**Discussion:** Wound cleansing solutions vary and should be used at body temperature. Cleansing solutions should be nontoxic, hypoallergenic, readily available, cost-effective and easy to use. Wound cleansing solutions commonly used in wound management include sterile normal saline, sterile water, potable tap water and liquid antiseptics.[9]

The Cochrane review on wound cleansing concluded that there is no evidence for the beneficial effects of cleansing.[95] Expert opinion does support this practice, but clinicians need to avoid causing local pain and discomfort with cleansing procedures.

Wound irrigation involves debridement of necrotic tissue using 4 to 15 pounds per square inch (psi) of pressure to support removing debris from the wound bed. Wound irrigation uses a 19-gauge angiocatheter with a 35 mL syringe (not a bulb syringe). Wound-care professionals need to exercise caution that all irrigation fluid is recovered from the wound and that excess pressure is not exerted on the wound surface.

### 4.2.2 Debriding

**Discussion:** Debridement involves removing debris (biofilm), eschar and surrounding callus to promote wound healing. Debridement methods include sharp/surgical, mechanical, autolytic and biologic (larval).[9] Persons with diabetic ulcers are prone to heavy peri-ulcer callus development. Sharp surgical debridement is considered the gold standard for DFUs.[44]

Debridement allows the clinician to do the following:[51]

- remove tissue that serves as a reservoir for bacteria
- disrupt surface biofilm
- appreciate the depth and evaluate for possible bony involvement
- reduce peak plantar pressure caused by calluses
- facilitate the collection of specimens for culture

**Sharp debridement** using a scalpel or curette is considered the optimum method for rapidly debriding the wound.[51] However, only health-care professionals with the appropriate level of training should perform sharp or surgical debridement.[51,96] If there is inadequate blood supply to the wound, sharp debridement is contraindicated. Due to the presence of peripheral neuropathy, this is usually a painless procedure; however, pain may limit debridement in some patients. Evidence exists to support regular serial debridement of diabetic foot ulcers to improve healing rates.[51,96] The frequency of debridement depends on the needs of the individual patient.

**Autolytic debridement** relies on dressings to create a moist environment that allows the body's natural enzymes to break down necrotic tissue. Occlusive or semi-occlusive dressings such as hydrocolloids, hydrogels and films may be suitable for this function. Evidence suggests that these dressings are better than gauze or standard care to promote debridement and healing in diabetic foot ulcers.[50]

**Mechanical debridement** includes wet-to-dry gauze dressings, wound irrigation and pulsative lavage of necrotic tissue. Wet-to-dry gauze dressings are painful and not recommended.

### 4.2.3 Managing bacterial balance

**Discussion:** Diabetic foot infections are very common, and a comprehensive approach is required for the diagnosis, management and prevention of future events. Diagnosis is made on the basis of clinical symptoms and signs, with adjunctive microbiologic testing to guide therapeutic decisions. Once identified, the infection should be classified by severity (see Figure 5).

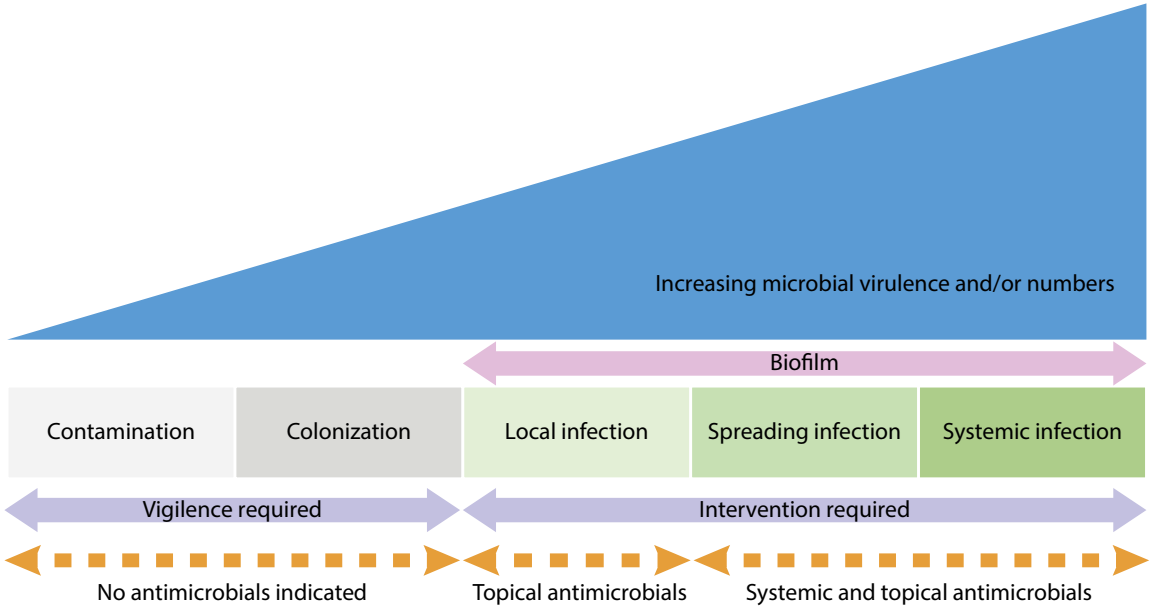
To manage diabetic foot infections, clinicians are advised to follow these steps:

1. Evaluate signs and symptoms.
2. Obtain appropriate specimens for culture.
3. Select appropriate antibiotics (based on local epidemiology and antibiotic susceptibility patterns).
4. Determine effectiveness of antibiotics.
5. Facilitate further testing.
6. Refer to other specialties.

#### Wound culture specimens

If clinical infection is not suspected based on the clinical assessment, cultures are not recommended and antibiotic treatment is not required.[50] Obtaining specimens for culture is recommended only for clinically infected wounds prior to initiation of antibiotic therapy.[50,96] The specimen for culture should be obtained following wound cleansing and debridement. Surface swabs most often do not reflect the microbiology of deeper tissues.[96] If bone is involved, the recommendation is to obtain a bone biopsy for culture based on the presentation and local resources.[50]

**Figure 5:** Severity of Infection[50,51]




## Antibiotic selection

Antibiotic selection should be empiric and initially related to patient factors and the severity of the infection. In general, acute diabetic foot infections without prior antibiotic treatment are caused by aerobic Gram-positive organisms and most commonly by *Staphylococcus aureus* (including methicillin-resistant strains).[16] With time, the microbiology of the wound becomes polymicrobial and includes anaerobes. For more severe infections, the recommendation is to use antibiotics with broad-spectum coverage until culture results and clinical response can be evaluated. Coverage for methicillin-resistant organisms (MRSA) should be considered based on local epidemiology and risk factors. The duration of therapy depends on the severity of infection, the involvement of bone and the patient's response to treatment.

In general, for mild soft tissue infections, two weeks of oral treatment is recommended.[51,97] For more severe soft-tissue infection or for larger necrotic wounds, a longer course may be required.[97]

For osteomyelitis, usually four to six weeks of intravenous treatment is recommended (this may be followed by oral antibiotic course), although the duration varies based on severity, chronicity of infection, need for surgical intervention and clinical response.[98] Osteomyelitis can also be treated orally, but treatments may be prolonged.[97]

Antibiotics should be discontinued with resolution of infection, which may be on the basis of clinical, biochemical and/or radiographic features, and are not required to continue until wound closure.[50]

Empiric antibiotic options used to treat diabetic foot infections are listed in Table 10. This serves as a guide only, and antibiotic decisions must be based on the type and severity of infection, culture result if available and patient factors such as co-morbidities, allergies, drug interactions along with local epidemiology and resistance patterns. Consultation with an infectious disease specialist may be considered.

**Table 12:** Empiric Antibiotic Choices for Diabetic Foot Infections[16]

| Infection Severity | Antimicrobial Agent (see notes 1 – 4) |
|---|---|
| Localized infections:<br>▪ neither limb- nor life-threatening<br>▪ usually associated with cellulitis surrounding an ulcer<br>▪ purulent debris may be present at the base of the ulcer<br>▪ usual organisms: aerobic Gram-positive cocci (*S. aureus*) and beta-hemolytic streptococci<br>▪ frequently treated with outpatient oral antimicrobial therapy | ▪ cloxacillin<br>▪ cephalexin<br>▪ TMP/SMX<br>▪ clindamycin<br>▪ amoxicillin–clavulanic acid<br>▪ linezolid<br>▪ doxycycline |
| More extensive infections:<br>▪ includes more severe infections than those classified as localized infections, including more extensive cellulitis, plantar abscess, and deep-space infections<br>▪ The choice of oral or parenteral therapy should be guided by the extent of the infection and the patient's overall clinical status.<br>▪ initial antimicrobial therapy against staphylococci, streptococci, anaerobes, and common *Enterobacteriaceae* species<br>▪ Patients who are not toxic may be treated with debridement and oral antimicrobial therapy.<br>▪ Patients who are ill or toxic despite moderate local signs are treated as having a severe infection.<br>♦ limb- or life-threatening<br>♦ Patients may be critically ill or toxic and usually are treated with initial parenteral therapy until stable, then oral therapy.<br>♦ frequently polymicrobial<br>♦ immediate hospitalization, early surgical debridement and parenteral antimicrobial therapy<br>♦ If MRSA is present or suspected, the addition of vancomycin or linezolid may be considered. | Oral options:<br>▪ TMP/SMX plus metronidazole or clindamycin<br>▪ ciproflaxin (or levofloxacin) plus clindamycin or metronidazole<br>▪ amoxicillin–clavulanic acid<br>▪ moxifloxacin<br>▪ linezolid<br>Parenteral options:<br>▪ cefoxitin<br>▪ first-generation (cefazolin), second-generation (cefuroxime) or third-generation (ceftriaxone or cefotaxine) cephalosporin plus metronidazole<br>▪ combination of beta-lactam antibiotic and beta-lactamase inhibitor (piperacillin/tazobactam)<br>▪ clindamycin plus third-generation cephalosporin (cefotaxime, ceftriaxone or ceftazidime)<br>▪ carbapenem (imipenem/cilastatin, meropenem or ertapenem) |
| Osteomyelitis:<br>▪ Treat with parenteral therapy or long-term oral antimicrobial therapy with agents that are well-absorbed from the gastrointestinal tract and have good distribution to bone and tissue.<br>▪ Surgical debridement is indicated to remove necrotic debris, abscess or sequestrum.<br>▪ Therapy should be based on culture results whenever possible.<br>▪ If MRSA is present or suspected, addition of vancomycin or linezolid may be considered. | Oral options:<br>▪ cloxacillin<br>▪ cephalexin<br>▪ TMP/SMX<br>▪ clindamycin<br>▪ amoxicillin–clavulanic acid<br>▪ linezolid<br>▪ doxycycline<br>▪ TMP/SMX plus metronidazole or clindamycin<br>▪ levofloxacin or ciprofloxacin plus metronidazole or clindamycin<br>Parenteral options:<br>▪ combination of beta-lactam antibiotic and beta-lactamase inhibitor (piperacillin/tazobactam)<br>▪ clindamycin (oral or parenteral) plus third-generation cephalosporin (cefotaxime, ceftriaxone or ceftazidime)<br>▪ carbapenem (imipenem/cilastatin, meropenem, or ertapenem) |

*cont'd.*

*Notes*

1. *The agents suggested in this section are for empiric therapy prior to the availability of final culture and susceptibility results. Dosages must be adjusted based upon the creatinine clearance.*
2. *Knowledge of local epidemiology must also guide therapeutic choices, as some agents (e.g., beta-lactams) are ineffective against MRSA.*
3. *Antibacterial therapy should be guided by available culture results. If culture results are unavailable to guide therapy, or there is any doubt about the most appropriate antimicrobial regimen, discussion with an infectious disease consultant may be prudent.*
4. *Duration of therapy is based on clinical response. However, typical treatment courses for skin and soft-tissue infections range from seven (mild) to 21 (severe) days, and the treatment of osteomyelitis may require four to six weeks of parenteral or several months of antimicrobial therapy. Whenever possible, it is desirable to switch to oral antimicrobial therapy to avoid complications from parenteral administration.*

*Reproduced with kind permission from the Canadian Diabetes Association.*

Additional considerations

An integrated team approach is recommended for the treatment of complicated infections.[16,65] Assessment and appropriate referral to vascular surgery should be initiated early. Similarly, orthopedic surgery, plastic surgery or podiatry (based on the centre) should be involved to manage foot deformities, resect infected bone or surgically debride tissue. It is often necessary to consult with infectious disease, endocrinology and certainly pressure-offloading experts.

### 4.2.4 Managing moisture balance

**Discussion:** Ensure optimal local wound moisture balance to promote healing by choosing an appropriate dressing for the different phases of wound healing.[11,99] Appropriate wound care and dressing selection promote healing and reduce the risk of of infection, so selecting the most appropriate dressing, at a frequency aimed at preventing periwound skin irritation while keeping the wound bed moist, is essential in managing moisture balance.[44,71]

## 4.3 Select the appropriate dressings and/or advanced therapy.

**Discussion:** The dressings selected may have a considerable effect on the outcome of diabetic foot ulcers. However, there is insufficient evidence to recommend a specific dressing type for diabetic foot ulcers.[100]

The general principles of wound management involve the provision of a moist wound environment, debridement of nonviable tissue (nonischemic wounds) and offloading of pressure areas.[16] It cannot be overstated that for uncomplicated diabetic foot ulcers, dressing choice should always be secondary to correcting high plantar pressures and preventing repetitive trauma.[101] Dressings, however, are required to adequately manage moisture, minimize the risk of infection,[102] manage shear forces[103] and help maintain optimal wound temperature.[104] Choice of dressing should be based on these factors as well as cost and patient preferences. It is important that clinicians and patients jointly select the right dressing and therapies after following the previous steps in the Wound Prevention and Management Cycle.

Specifically, one should consider that dressings with increased bulk may increase plantar pressures over the wound itself or on the contralateral plantar surface.[105,106] Although thicker dressings may initially be considered to pad the wound and protect

it from trauma, the opposite is more likely to be true, if, in fact, the thicker dressing decreases the space for the foot in the patient's shoe or offloading device. Although dressings can significantly reduce tissue shear forces, there is insufficient published data to assess one dressing's potential over another in reducing shear.[107] Instead, the clinician is left to clinically evaluate shear force reduction by looking for increased callusing of the periwound skin or by evaluating the presence of sub-keratotic hematoma or hemorrhage.[108]

Because of their plantar location, dressings generally are at high risk of saturation due to sweating or external moisture sources such as daily showering. In patients who prefer self-managed care, a simple non-adhesive dressing that can be changed daily is supported by the literature as a means of managing the moisture balance in the wound and increasing patient adherence to therapy.[109] The ongoing active treatment of diabetic foot ulcers and the presence of a dressing do not negate the need for daily foot inspection. For further information on dressings, see the Product Picker series available at www.woundscanada.ca/Product-Pickers.

**Caution:** Moist wound healing is a relative contraindication for ischemic ulcers.

Advanced therapies

According to the CDA, the evidence is lacking to support the routine use of the following advanced therapies in diabetic foot ulcers, but they may be considered in non-healing, nonischemic wounds.[16]

***Negative pressure wound therapy (NPWT)***

The only data to support the use of NPWT is as a post-surgical intervention.[110] There is insufficient evidence to support the use of NPWT for the routine management of neuropathic foot ulcers.[111]

***Hyperbaric oxygen therapy (HBOT)***

There is no clinical evidence demonstrating the benefit of using HBOT in diabetic foot ulcers related to neuropathy. There is also insufficient evidence from both systematic reviews and RCTs to determine whether HBOT is effective for the treatment of chronic DFUs.[111,112] However, in the presence of diminished arterial flow, hyperbaric oxygen therapy may be of benefit.[113] Currently there is some evidence for the effectiveness of HBOT in improving the healing of diabetic leg ulcers in patients with concomitant ischemia. Larger trials of higher quality are needed before implementation of HBOT in routine clinical practice in patients with diabetic foot ulcers can be justified.[114] Unfortunately, the technology is generally not available in all medical centres.

***Biologically active dressings***

Studies related to individuals with diabetes are of exceptionally poor quality and the results are weak, so it is difficult to make any meaningful recommendations concerning the use of biologically active dressings and artificial skin grafts.

Dressing protocol for diabetic foot ulcers[110]

Prior to dressing/therapy selection the clinician needs to consider three components of care. First, whether best practice has been implemented, including the reduction of plantar pressures, management of blood glucose, control of arterial perfusion and infection, assessment of mental health and wellness, consideration of family and social supports and availability of funding for therapy. While selecting a dressing the clinician should also consider specific needs of the wound, including necrotic tissue

and bacterial and moisture balance. Finally the goals of care, such as wound healing, wound closure, pain management, exudate management, quality-of-life improvement and/or cost-effectiveness should be considered.

Once the dressing is selected, the clinician should plan the length of trial of the dressing/therapy and ensure it remains part of the assessment, treatment and evaluation processes.

### Dressing Protocol

1. Choose an appropriate dressing/therapy based on product description, evidence, availability, funding, available resources, clinician education and patient acceptance.
2. Develop a customized management protocol based on the location and availability of resources and services.
3. Communicate the plan, including the length of time of product use, regular reports, images and photos as needed.
4. Communicate to clinicians, caregivers and patients the management protocol and provide follow-up information, including written and/or verbal communication to the team.
5. Initiate the management protocol, ensuring there are built-in standardized assessment parameters to measure progress toward the identified goals of care.
6. Evaluate the impact of the management protocol to identify met and unmet goals of care.
7. Reassess the management plan at least every two to four weeks, and more often if required to avoid long-term use of dressing/therapies with no evidence of improvement.

## 4.4 Engage the team to ensure consistent implementation of the plan of care.

**Discussion:** There is a need to acknowledge the chronic nature of diabetic foot ulcers. Although individual ulcers may come and go, the relative risk for re-ulceration is high,[115] and the team must understand that diabetic foot ulcers are a part of a chronic disease process that must be managed every day in the same way that blood sugars and blood pressures are managed. The patient's psychological adjustment to a chronic disease is important to disease outcomes, and the disease itself can challenge a patient's belief that they can live well with a chronic disease.[116] For some patients, psychological therapy may be required to support the consistent implementation of the elements of the care plan.

Diabetes-specific education and additional specialized training to help integrate new knowledge and transform old practices are essential. Investments must be made to ensure that health-care professionals receive specialized training in diabetes education and other chronic conditions. In addition, patients and families need education on diabetes, foot care and local wound care.[17]

### Key Interventions

Support the patient and caregivers in learning about the chronic nature of diabetic foot ulcers, including factors such as neuropathy, pressure, poor arterial flow and the implications of infection.

Facilitate referral to psychologist or social worker/Indigenous liaison services as needed.

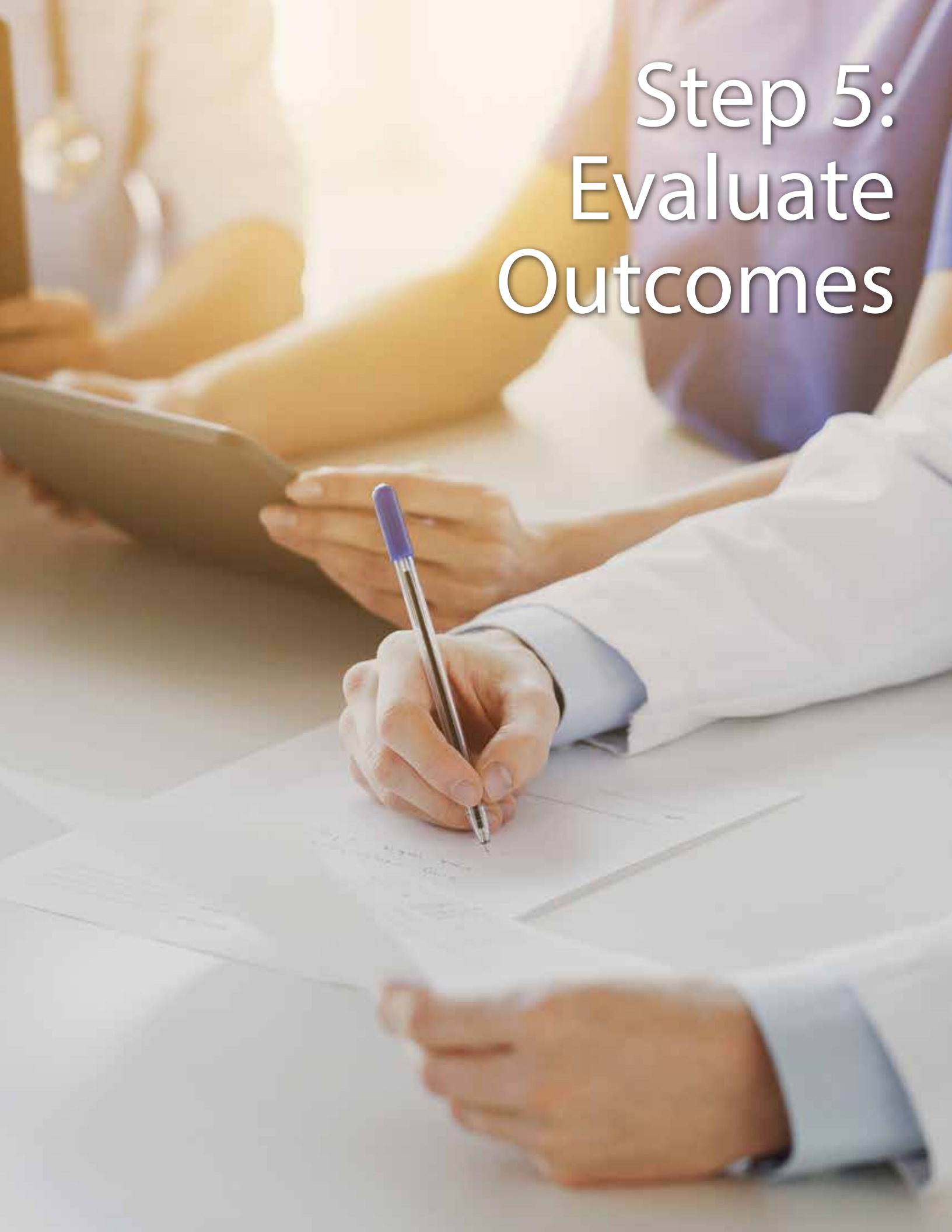
Monitor high-risk patients.

Support patient self-management to ensure daily foot examinations, appropriate footwear selection and use, injury recognition and accessing of the appropriate facility for care.

Educational and academic institutions are encouraged to incorporate best practice guidelines into their basic nursing, medical and allied health-care professional curricula. These institutions also have an obligation to keep up to date with advances in diabetic foot wound prevention, assessment and management strategies, and to develop standardized curricula to implement and evaluate these changes in practice settings.[11]

Patient education has been touted as the key to early recognition and prevention of foot ulceration in neuropathic patients; however, this information is being challenged in the published literature. Dorresteijn et al., in a Cochrane Review on patient diabetic foot self-examination education, found that although patient education may increase foot examinations by patients in the short term, there was insufficient evidence that education alone will reduce the incidence of new ulceration in patients at risk.[117] The IWGDF found that there was low-level evidence to support patient education for daily foot exams as the sole factor in preventing re-ulceration.[92] However, there is stronger evidence that indicates a multifaceted approach can prevent recurrent ulceration in at-risk persons with diabetes.[92] This approach combines monitoring by a high-risk professional foot team in combination with proper footwear and patient education.

One of the methods shown to ensure that the patient is actively engaged in their treatment regimen is self-management.[116] The evidence base to support the use of specific self-management and footwear interventions for the prevention of recurrent plantar foot ulcers is strong.[54,55] Providing patients with tools for self-management such as skin thermometers can be an effective component of self-management because skin at risk heats up before it breaks down. Evolving use of a simple objective measurement of increased plantar pressures may aid in self-management to prevent foot ulcers.[92] The future may see pressure-sensing socks or insoles as early warning indicators of increased plantar pressures and risk of ulceration.[92]



# Step 5: Evaluate Outcomes

# Step 5: Evaluate Outcomes

## Recommendations

### 5.1 Determine if the outcomes have met the goals of care.

**Discussion:** Using validated and responsive assessment tools and patient feedback, the clinician should determine if the goals of care have been met. Goals are patient-specific, may not involve complete closure of a wound and may not be those the clinician would choose. If goals have been met, begin discharge planning by reviewing self-management strategies (see Section 5.3). If goals change, refer back to the Wound Prevention and Management Cycle to guide treatment based on new goals.

### 5.2 Reassess patient, wound, environment and system if goals are partially met or unmet.

**Discussion:** If the goals are not met or only partially met, clinicians should revaluate the patient systemically.

Sheehan et al. demonstrated that a 50% reduction in wound surface area of diabetic foot ulcers at four weeks is a good predictor of wound healing at 12 weeks.[118] If the wound is not healing, it requires a full reassessment to determine if all factors that affect healing have been managed. If healing still does not occur, a biopsy should be performed to rule out disease.

If the wound is not healing at the expected rate, the clinician should consider the possibility of missed infection, vascular compromise, malignancy, inadequate offloading, or lack of patient engagement in care. According to the RNAO guidelines, these parameters can quickly change with a high risk of infection and amputation, so frequent monitoring is required.[22]

The most common reason for delayed healing is inadequate offloading.[22] Increasing evidence suggests that the majority of patients with diabetes are non-adherent to using offloading devices or footwear on a regular basis.[119] In a study by Armstrong et al., patients with diabetic foot ulcers used the prescribed offloading device (a removable cast walker) only 30% of the time during ambulation.[93] To prevent and facilitate healing of foot ulcers, pressure redistribution must be addressed with an appropriate offloading device, and barriers to patient adherence must be explored.

### 5.3 Ensure sustainability to support prevention and reduce risk of recurrence.

**Discussion:** One important component in sustainability is active patient engagement in managing their care and making choices that will optimize their health status. Although studies specifically evaluating the outcome of educational interventions are few and provide low-level evidence,[119,120] providing education regarding healthy choices and proper foot care makes sense and is likely cost effective.[119]

Patients and their families learn through different modalities partially due to learning styles, literacy and the individual's primary language. Written material should be available in the relevant language and at a font size appropriate for the reader who may have impaired vision. A demonstration of recommended diabetic foot care techniques

can have a positive influence in retention of information and does not require the ability to read.[121,122]

Whatever the method or methods used, patients should have the opportunity to take part in evidence-informed educational activities, including self-management programs that have specific aims and learning objectives, meet the needs of the patient and promote the patient's ability to manage their own health, if appropriate.[123–128]

In addition to self-management, patients with diabetes need the continued support of their professional health-care team. An important component of this support is an annual foot inspection that includes monofilament testing (but more frequently based on the results of a validated diabetic foot risk screening tool)[22,119,129] as well as a foot inspection every time they visit their primary care provider.

## Conclusion

Diabetic foot ulcers can have devastating complications, including infection, amputation and even death, so prevention should be the most important consideration for patients and health-care professionals.

Once an ulcer develops, however, aggressive management involving a co-ordinated multidisciplinary team is required. Teams must recognize that the patient and their overall well-being are at the centre of care. They need to support knowledge dissemination to individuals with diabetes on how to care for their feet, detect problems early and seek help in a timely manner when problems arise.[105,106,119,124]

Moreover, multidisciplinary teams must recognize that their goals relate not only to management of the acute and chronic wound, but also to correction via the appropriate treatment pathway of the factors that have led or may lead to ulceration. In achieving these goals, teams may then be successful at breaking the cycle of diabetic foot ulcer development and recurrence, and preserving limbs. Teams should have the full support of health-care organizations that recognize and promote ulcer prevention. This will reduce hospital admissions, length of stay and amputations—thus reducing the burden on the health-care system and improving the health outcomes and quality of life of patients.

Developing and sustaining successful integrated teams that have a strong impact require standardized education, motivated health-care workers, supportive organizations and strong associations that engage provincial/territorial and federal support.[22,124] The results will have not only a huge impact financially, but also socially, emotionally and psychologically for patients and their communities.

To diminish the detrimental consequences associated with diabetic foot ulcers, Canadians deserve an overall structure that is designed to meet the needs of patients requiring preventative and often chronic disease care, rather than simply responding to acute problems when they occur. Factors to consider include the following:

- well-defined treatment pathways and timely access to care in each community
- implementation of interprofessional guidelines for education, screening, risk reduction, treatment
- self-management education for patients and family members
- establishment of services to detect individuals who are at risk, through annual foot examination of all patients and regular screening with the frequency determined by risk
- universal preventative foot care services at the point of care for people living with diabetes
- public reimbursement for preventative shoes, socks and offloading devices for individuals with no private insurance coverage
- establishment of integrated teams with specialized education to deliver timely and effective treatment if foot complications arise
- auditing of all aspects of the service to ensure that local practice meets accepted national and international standards of care[7,74]

This paper will serve as a guide to providing a systematic approach for the prevention and management of diabetic foot ulcers and assisting organizations in the successful development and implementation of programs to support patients and their teams.

# References

# References


1. Canadian Diabetes Association. Diabetes Statistics in Canada. 2006. Available from: www.diabetes.ca/how-you-can-help/advocate/why-federal-leadership-is-essential/diabetes-statistics-in-canada.
2. Canadian Institute for Health Information (CIHI). Compromised Wounds: Costly and a System-wide Problem. August 2013. Available from: www.cihi.ca/en/health-system-performance/quality-of-care-and-outcomes/compromised-wounds-costly-and-a-system-wide.
3. Palumbo PJ, Melton LJ III. Peripheral vascular disease and diabetes. In: Diabetes in America: Diabetes Data. Government Printing Office, Washington. 1985. Available from: https://archive.org/stream/diabetesinameric00nati/diabetesinameric00nati_djvu.txt.
4. Armstrong DG, Holtz-Neiderer K, Wendel C, Mohler MJ, Kimbriel HR, Lavery LA. Skin temperature monitoring reduces the risk for diabetic foot ulceration in high-risk patients. Am J Med. 2007;120(12):1042–1046.
5. Narayan KMV, Zhang P, Kanaya AM, Williams DE, Engelgau MM, Imperatore G, et al. Diabetes: The pandemic and potential solutions. In: Disease Control Priorities in Developing Countries (2nd edition). New York: Oxford University Press; 2006.
6. Schoen C, Osborn R, Huynh PT, Doty M, Zapert K, Peugh J, et al. Taking the pulse of health care systems: Experiences of patients with health problems in six countries. Health Aff (Millwood). 2005;Suppl Web Exclusives:W5–509–25.
7. Cheung C, Alavi A, Botros M, Sibbald RG, Queen D. The diabetic foot: A reconceptualization. Diabetic Foot Canada. 2013;1(1):11–12. Available from: www.diabeticfootcanadajournal.ca/journal-content/view/the-diabetic-foot-a-reconceptualization.
8. Orsted HL, Keast DH, Forest-Lalande L, Kuhnke JL, O'Sullivan-Drombolis D, Jin S, et al. Skin: Physiology, anatomy and wound healing. In: Foundations of Best Practice for Skin and Wound Management. A supplement of Wound Care Canada; 2017.
9. Orsted HL, Keast DH, Forest-Lalande L, Kuhnke JL, O'Sullivan-Drombolis D, Jin S, et al. Best practice recommendations for the prevention and management of wounds. In: Foundations of Best Practice for Skin and Wound Management. A supplement of Wound Care Canada; 2017.
10. Sibbald RG, Orsted HL, Coutts PM, Keast DH. Best practice recommendations for preparing the wound bed: Update 2006. Wound Care Canada. 2006;4(1):15–29.
11. Registered Nurses' Association of Ontario (RNAO). Clinical Best Practice Guidelines: Assessment and Management of Foot Ulcers for People with Diabetes (2nd Edition). 2013. Available from: http://rnao.ca/sites/rnao-ca/files/Assessment_and_Management_of_Foot_Ulcers_for_People_with_Diabetes_Second_Edition1.pdf.
12. Kuhnke JL, Botros M, Elliot J, Rodd-Nielsen E, Orsted H, Sibbald RG. The case for diabetic foot screening. Wound Care Canada. 2013;1(2):1–7.
13. Lowe J, Sibbald G, Taha NY, Lebovic G, Rambaran M, Martin C, et al. The Guyana diabetes and foot care project: Improved diabetic foot evaluation reduces amputation rates by two-thirds in a lower middle income country. International Journal of Endocrinology. 2015(2015):920124. Available from: www.hindawi.com/journals/ije/2015/920124/.
14. Orsted HL, Botros M. Inlow's 60-Second Diabetic Foot Screen gets a new look! Wound Care Canada. 2018;16(1):26–29.

15. Woodbury MG, Sibbald RG, Ostrow B, Persaud R, Lowe JM. Tool for rapid & easy identification of high risk diabetic foot: Validation & clinical pilot of the simplified 60 second diabetic foot screening tool. PLoS One. 2015;10(6):e0125578.

16. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association Clinical Practice Guidelines. Canadian Journal of Diabetes. 2013;37(S1):S1–S212. Available from: http://guidelines.diabetes.ca/app_themes/cdacpg/resources/cpg_2013_full_en.pdf.

17. Driver V, LeBretton JM, Allen L, Park NJ. Neuropathic wounds; The diabetic wound. In: Bryant RA, Nix DP (eds.). Acute and Chronic Wounds: Current Management Concepts (5th edition). St. Louis, Missouri: Elsevier; 2016. p. 239–262.

18. Public Health Agency of Canada. Reducing the risk of type 2 diabetes and its complications. In: Diabetes in Canada: Facts and Figures from a Public Health Perspective. In: Diabetes in Canada: Facts and Figures from a Public Health Perspective. 2011. Available from: www.phac-aspc.gc.ca/cd-mc/publications/diabetes-diabete/facts-figures-faits-chiffres-2011/chap4-eng.php.

19. Orsted HL, Searles G, Trowell H, et al. Best practice recommendations for the prevention, diagnosis and treatment of diabetic foot ulcers: Update 2006. Wound Care Canada. 2006;4(1):57–71.

20. Hinchliffe RJ, Brownrigg JRW, Apelqvist J, EBoyko EJ, Fitridge R, Mills JL, et al. IWGDF Guidance on the Diagnosis, Prognosis and Management of Peripheral Artery Disease in Patients with Foot Ulcers in Diabetes. 2015. Available from: www.iwgdf.org/files/2015/website_pad.pdf.

21. Strauss M, Barry D. Vascular assessment of the neuropathic foot. J Prosth Orthot. 2005;17(2S):35–37.

22. Registered Nurses' Association of Ontario (RNAO). Nursing Best Practice Guideline: Assessment and Management of Foot Ulcers for People with Diabetes. Toronto, ON: RNAO, 2005.

23. Canadian Association of Wound Care. Advances for the Management of Diabetic Foot Complications. Session workbook. 2016.

24. Alavi A, Sibbald RG, Nabavizadeh R, Valaei F, Coutts P, Mayer D. Audible handheld Doppler ultrasound determines reliable and inexpensive exclusion of significant peripheral arterial disease. Vascular. 2015;23(6):622–629.

25. Bus SA, van Netten JJ, Lavery LM, Monteiro-Soares M, Rasmussen A, Jubiz Y, et al. IWGDF Guidance on the Prevention of Foot Ulcers in At-Risk Patients with Diabetes. 2015. Available from: www.iwgdf.org/files/2015/website_prevention.pdf.

26. Hingorani A, LaMuraglia GM, Henke P, Meissner MH, Loretz L, Zinszer KM, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg. 2016;63(2):3S–21S.

27. Bus SA, Maas M, Cavanagh PR, Michels RP, Levi M. Plantar fat-pad displacement in neuropathic diabetic patients with toe deformity: A magnetic resonance imaging study. Diabetes Care. 2004;27(10):2376–2381.

28. Nubé VL, Molyneaux L, Yue DK. Biomechanical risk factors associated with neuropathic ulceration of the hallux in people with diabetes mellitus. J Am Podiatr Med Assoc. 2006;96(3):189–197.

29. ElMakki AM, Tamimi AO, Mahadi SI, Widatalla AH, Shawer MA. Hallux ulceration in diabetic patients. J Foot Ankle Surg. 2010;49(1):2–7.

30. Rogers LC, Frykberg RG, Amstrong DG, Boulton AJM, Edmonds M, Ha Van G, et al. The Charcot foot in diabetes. Diabetes Care. 2011;34(9):2123–2129.

31. Zimny S, Schatz H, Pfohl M. The role of limited joint mobility in diabetic patients with at-risk foot. Diabetes Care. 2004;27(4):942–946.

32. Ulbrecht JS, Wukich DK. The Charcot foot: Medical and surgical therapy. Curr Diab Rep. 2008;8(6):444–451.

33. Lavery LA, Higgins KR, Lanctot DR, Constantinides GP, Zamorano RG, Athanasiou KA, et al. Preventing diabetic foot ulcer recurrence in high-risk patients: Use of temperature monitoring as a self-assessment tool. Diabetes Care. 2007;30:14–20.

34. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, et al. for the American College of Foot and Ankle Surgeons. Diabetic foot disorders. A clinical practical guideline (2006 revision). J Foot Ankle Surg. 2006;45(5Suppl.):S1–S66.

35. Botros M, Goettl K, Parsons L, Menzildzic S, Morin C, Smith T, et al. Best practice recommendations for the prevention, diagnosis and treatment of diabetic foot ulcers. Wound Care Canada. 2010;8(4).

36. Kravitz SR, McGuire J, Shanahan S. Physical assessment of the diabetic foot. Advances in Skin and Wound Care. 2003;16(2):68–75.

37. Williams, A. Footwear assessment and management: Understanding shoe construction and materials aids in properly fitting patients. Podiatry Management. 2007. Available from: http://podiatrym.com/cme/Oct07%20CME.pdf.

38. Dros J, Wewerinke A, Bindels PJ, van Weert HC. Accuracy of monofilament testing to diagnose peripheral neuropathy: A systematic review. Ann Fam Med. 2009;7:555–558.

39. Iverson MM, Tell G2, Espehaug B, Midthjell K, Graue M, Rokne B, et al. Is depression a risk factor for diabetic foot ulcers? 11-years follow-up of the Nord-Trødelag Health Study (HUNT). Diabetes and its Complications. 2015;29(1):20–25.

40. Hill J, Nielsen M, Fox M. Understanding the social factors that contribute to diabetes: A means to informing health care and social policies for the chronically ill. Perm J. 2013;17(2):67–72.

41. Baranowski S, Ayello EA. Wound Care Essentials: Practice Principles (3rd Edition). Lippincott Williams & Wilkins: 2008.

42. Oyibo SO, Jude EB, Tarawneh I, Nguyen HC, Harkless LB, Boulton AJ. A comparison of two diabetic foot ulcer classification systems: The Wagner and the University of Texas wound classification systems. Diabetes Care. 2001;24(1):84–88.

43. Ince P, Abbas ZG, Lutale JK, et al. Use of the SINBAD classification system and score in comparing outcome of foot ulcer management on three continents. Diabetes Care. 2008;31(5): 964–967.

44. International Best Practice Guidelines (IBPG): Wound Management in Diabetic Foot Ulcers. Wounds International. 2013. Available from: www.woundsinternational.com/media/best-practices/_/673/files/dfubestpracticeforweb.pdf.

45. Armstrong DG, Cohen K, Courric S, Bharara M, Marston W. Diabetic foot ulcers and vascular insufficiency: Our population has changed, but our methods have not. J Diabetes Sci Technol. 2011;5(6):1591–1595.

46. Peters EJ, Lavery LA on behalf of the International Working Group on the Diabetic Foot. Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. Diabetes Care. 2001;24(8):1442–1447.

47. Lavery L, Peters EJ, Armstrong DG. What are the most effective interventions in preventing diabetic foot ulcers? Int Wound J. 2008;5:425–433.

48. Boyko EJ, Ahroni JH, Cohen V, Nelson KM, Heagerty PJ. Prediction of diabetic foot ulcer occurrence using commonly available clinical information: The Seattle Diabetic Foot Study. Diabetes Care. 2006;29(6): 1202–1207.

49. Boulton A. The diabetic foot: Epidemiology, risk factors and the status of care. Diabetes Voice. 2005;50(special issue):5–7.

50. Lipsky BA, Berendt AR, Cornia PB, Pile JC, Peters EJG, Armstrong DG, et al. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. Clinical Infectious Diseases. 2012;54(12):e132–173.

51. Lipsky BA, Aragón-Sánchez J, Diggle M, Embil J, Kono S, Lavery L, et al. IWGDF guidance on the diagnosis and management of foot infections in persons with diabetes. Diabetes/Metabolism Research and Reviews. 2016;32:45–74.

52. Lavery LA, Armstrong DG, Murdoch DP, Peters EJ, Lipsky BA. Validation of the Infectious Diseases Society of America's diabetic foot infection classification system. Clin Infect Dis. 2007;44(4):562–565.

53. Lavery LA, Higgins KR, Lanctot DR, Constantinides GP, Zamorano RG, Armstrong DG, et al. Home monitoring of foot skin temperatures to prevent ulceration. Diabetes Care. 2004;27(11):2642–2647.

54. Sibbald RG, Mufti A, Armstrong DG. Infrared skin thermometry: An underutilized cost-effective tool for routine wound care practice and patient high-risk diabetic foot self-monitoring. Adv Skin Wound Care. 2015;28(1):37–44.

55. Mufti A, Coutts P, Sibbald RG. Validation of commercially available infrared thermometers for measuring skin surface temperature associated with deep and surrounding wound infection. Adv Skin Wound Care. 2015;28(1):11–16.

56. Lipsky BA. Bone of contention: Diagnosing diabetic foot osteomyelitis. Clin Infect Dis. 2008;47:528–530.

57. Butalia S, Palda VA, Sargeant RJ, Detsky AS, Mourad O. Does this patient with diabetes have osteomyelitis of the lower extremity? JAMA. 2008;299(7):806–813.

58. Dinh MT, Abad CL, Safdar N. Diagnostic accuracy of the physical examination and imaging tests for osteomyelitis underlying diabetic foot ulcers: Meta-analysis. Clinical Infectious Diseases. 2008;47(4):519–527.

59. Berendt AR, Peters EJ, Bakker K, Embil JM, Eneroth M, Hinchliffe RJ, et al. Diabetic foot osteomyelitis: A progress report on diagnosis and a systematic review of treatment. Diabetes Metab Res Rev. 2008;24(Suppl 1):S145–S161.

60. Grayson ML, Gibbons GW, Balogh K, Levin E, Karchmer AW. Probing to bone in infected pedal ulcers. A clinical sign of underlying osteomyelitis in diabetic patients. JAMA. 1995;273(9):721–723.

61. Aragón-Sánchez J, Lipsky BA, Lázaro-Martínez JL. Diagnosing diabetic foot osteomyelitis: Is the combination of probe-to-bone test and plain radiography sufficient for high-risk inpatients? Diabetic Medicine. 2011;28(2):191–194.

62. Morales Lozano R, González Fernández ML, Martinez Hernández D, Beneit Montesinos JV, Guisado Jiménez S, Gonzalez Jurado MA. Validating the probe-to-bone test and other tests for diagnosing chronic osteomyelitis in the diabetic foot. Diabetes Care. 2010;33:2140–2145.

63. Shone A, Burnside J, Chipchase S, Game F, Jeffcoate W. Probing the validity of the probe-to-bone test in the diagnosis of osteomyelitis of the foot in diabetes. Diabetes Care. 2006;29:945.

64. Lavery LA, Armstrong DG, Peters EJ, Lipsky BA. Probe-to-bone test for diagnosing diabetic foot osteomyelitis: Reliable or relic? Diabetes Care. 2007;30(2):270–274.

65. Registered Nurses' Association of Ontario (RNAO). Nursing Best Practice Guideline: Reducing Foot Complications for People with Diabetes. Toronto, ON: RNAO, 2004.

66. Rabjohn L, Roberts K, Troiano M, Schoenhaus H. Diagnostic and prognostic value of erythrocyte sedimentation rate in contiguous osteomyelitis of the foot and ankle. J Foot Ankle Surg. 2007;46:230–237.

67. Michail M, Jude E, Liaskos C, Karamagiolis S, Makrilakis K, Dimitroulis D, et al. The performance of serum inflammatory markers for the diagnosis and follow-up of patients with osteomyelitis. Int J Low Extrem Wounds. 2013;12:94–99.

68. Fleischer AE, Wrobel JS, Leonards A, Berg S, Evans DP, Baron RL, et al. Post-treatment leukocytosis predicts an unfavorable clinical response in patients with moderate to severe diabetic foot infections. J Foot Ankle Surg. 2011;50:541–546.

69. National Institute for Health and Care Excellence (NICE). Diabetic Foot Problems: Prevention and Management. 2015. Available from: www.nice.org.uk/guidance/ng19.

70. Enoch S, Price P. Should alternative endpoints be considered to evaluate outcomes in chronic recalcitrant wounds? World Wide Wounds. 2004.

71. Canadian Psychological Association (CPA). Psychology Works Fact Sheet: Diabetes. 2015. Available from: www.cpa.ca/docs/File/Publications/FactSheets/PsychologyWorksFactSheet_Diabetes.pdf.

72. National Institute for Health Care Excellence (NICE). Diabetic Foot Problems: Prevention and Management. 2015. Available from: www.nice.org.uk/Guidance/NG19.

73. Bryant RA, Nix DP. Acute and Chronic Wounds: Current Management Concepts (5th edition). St. Louis, Missouri: Elsevier; 2006.

74. 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):225–231. Available from: http://iwgdf.org/files/pg1.pdf.

75. Woodbury MG, Botros M, Kunkhe JL, Greene J. Evaluation of a peer-led self-management education programme PEP Talk: Diabetes, Healthy Feet and You. IWJ. 2013. Available from: www.cafcn.ca/PDFs/Woodbury_2013_PEP_IWJ.pdf.

76. Waters N, Holloway S. Personal perceptions of the impact of diabetic foot disease on employment. The Diabetic Foot Journal. 2009;12:119–130.

77. Public Health Agency of Canada. What Determines Health? Key Determinants. 2011. Available from: www.phac-aspc.gc.ca/ph-sp/determinants/index-eng.php#key_determinants.

78. Christman AL, Selvin E, Margolis DJ, Lazarus GS, Luis GA. Hemoglobin A1c predicts healing rate in diabetic wounds. Journal of Investigative Dermatology. 2011;131(10):2121–2127.

79. Marston WA for the Dermagraft Diabetic Foot Ulcer Study Group. Risk factors associated with healing chronic diabetic foot ulcers: The importance of hyperglycemia. Ostomy/Wound Management. 2006;52(3):26–28.

80. Markuson M, Hanson D, Anderson J, Rustvang D. The relationship between hemoglobin HbA(1c) values and healing time for lower extremity ulcers in individuals with diabetes. Adv Skin Wound Care. 2009;22(8):365–372.

81. Goldenberg R, Clement M, Hanna A, Harper W, Main A, Retnakaran R, et al. Pharmacologic Management of Type 2 Diabetes: 2016 Interim Update. Available from: http://guidelines.diabetes.ca/browse/chapter13_2016.

82. Doughty DB, Sparks B. Wound-healing physiology and factors that affect the repair process. In: Bryant RA, Nix DP (eds.). Acute and Chronic Wounds: Current Management Concepts. St Louis, Missouri: Elsevier; 2016. p. 63–81.

83. Smith RG. The effects of medications in wound healing. Podiatry Management. August 2008;27(6):195–206. Available from: www.podiatrym.com/cme/cmeaug08.pdf.

84. Preston JD, O'Neal JH, Talaga MC. Handbook of Clinical Psychopharmacology for Therapists (7th edition). Oakland, CA: New Harbinger Pub. Inc.; 2013.

85. Canadian Diabetes Association. Diet and Nutrition. 2016. Available from: www.diabetes.ca/diabetes-and-you/healthy-living-resources/diet-nutrition.

86. Canadian Diabetes Association. Physical Activity & Exercise. 2016. Available from: www.diabetes.ca/clinical-practice-education/professional-resources/physical-activity-exercise#sthash.a1hfowtW.dpuf.

87. Sanders L, Frykberg R. The Charcot foot. In: Bowker JH, Pfeifer MA (eds.). Levin and O'Neal's The Diabetic Foot (7th edition). New York, NY: Mosby Elsevier, 2008. p. 257–280.

88. Slatterfield K. How to determine the appropriate level of amputation. Podiatry Today. 2005;18(1). Available from: www.podiatrytoday.com/article/3469.

89. Rossbach P, Sheehan TP. Tips for taking care of your limb. inMotion. 2008:18(4):38–39. Available from: www.amputee-coalition.org/wp-content/uploads/2015/03/taking_care_your_limb.x26830.pdf.

90. Schaffalitzky E, Gallagher P, Maclachlan M, Ryall N. Understanding the benefits of prosthetic prescription: Exploring the experiences of practitioners and lower limb prosthetic users. Disabil Rehabil. 2011;33:1314–1323.

91. Goettl K. Foot-care practices of persons living with diabetes prior to amputation. Wound Care Canada. 2008;6(1).

92. Bus SA, Armstrong DG, van Deursen RW, Lewis J, Caravaggi CF, Cavanagh PR on behalf of the International Working Group on the Diabetic Foot (IWGDF). IWGDF Guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes. Diabetes Metab Res Rev. 2016;32(S1):25–36.

93. Armstrong DG, Lavery LA, Kimbriel HR, Nixon BP, Boulton AJ. Activity patterns of patients with diabetic foot ulceration: Patients with active ulceration may not adhere to a standard pressure off-loading regimen. Diabetes Care. 2003;26(9):2595–2597.

94. Van Duersen R. Mechanical loading and off-loading of the plantar surface of the diabetic foot. Clin Infect Dis. 2004;39(S2):S87–S91.

95. Fernandez R, Griffiths R. Water for wound cleansing. Cochrane Database Syst Rev. 2012;(2):CD003861.

96. Armstrong DG, Lavery LA, Harkless LB. Validation of a diabetic wound classification system. The contribution of depth, infection and ischemia to risk of amputation. Diabetes Care. 1998;21:84–88.

97. Embil JM, Rose G, Trepman E, Math MC, Duerksen F, Simonsen JN, Nicolle LE. Oral antimicrobial therapy for diabetic foot osteomyelitis. Foot Ankle In. 2006;27:771–779.

98. Lipsky BA, Berendt AR, Deery HG, Embil JM, Joseph WS, Karchmer AW, et al. Diagnosis and treatment of diabetic foot infections. Clin Infect Dis. 2004;39:885–910. Available from: www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient_Care/PDF_Library/Diabetic%20Foot%20Infection.pdf.

99. National Institute for Health Care Excellence (NICE). Type 2 Diabetes. 2008. Available from: www.nice.org.uk/guidance/CG66.

100. Wu L, Norman G, Dumville JC, O'Meara S, Bell-Syer SEM. Dressings for treating foot ulcers in people with diabetes: An overview of systematic reviews. The Cochrane Library. 2015. Available from: www.cochrane.org/CD010471/WOUNDS_dressings-treat-foot-ulcers-people-diabetes.

101. Lavery LA, Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJ. Diabetic foot syndrome: Evaluating the prevalence and incidence of foot pathology in Mexican Americans and non-Hispanic whites from a diabetes disease management cohort. Diabetes Care. 2003;26(5):1435–1438.

102. Dumville JC, Deshpande S, O'Meara S, Speak K. Foam dressing for healing diabetic foot ulcers. The Cochrane Library. 2013. Available from: www.cochrane.org/CD009111/WOUNDS_foam-dressings-for-healing-foot-ulcers-in-people-with-diabetes.

103. Ohura T, Takahashi M, Ohura N Jr. Influence of external forces (pressure and shear force) on superficial layer and subcutis of porcine skin and effects of dressing materials: Are dressing materials beneficial for reducing pressure and shear force in tissues? Wound Repair and Regeneration. 2008;16(1):102–107.

104. McGuiness W, Vella E, Harrison D. Influence of dressing changes on wound temperature. Journal of Wound Care. 2004;13(9):383–385.

105. Bus SA, Valk GD, van Deursen RW, Armstrong DG, Caravaggi C, Hlavácek P, et al. Specific guidelines on footwear and offloading. Diabetes Metab Res Rev. 2008;24 (Suppl.1):S192–S193.

106. Bus SA, Valk GD, van Deursen RW, Armstrong DG, Caravaggi C, Hlavácek P, et al. The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: A systematic review. Diabetes Metab Res Rev. 2008;24(Suppl. 1):S162–S180.

107. de Wert L, Schoonhoven L, Stegen JH, Piatkowski AA, Hulst RR, Poeze M, et al. Improving the effect of shear on skin viability with wound dressings. Journal of the Mechanical Behaviour of Biomedical Materials. 2016;(60):505–514.

108. Das, AK. Diabetic neuropathic foot. International Journal of Diabetes in Developing Countries. 1994;(14):85–90.

109. Hilton JR, Williams DT, Beuker B, Miller DR, Harding KG. Wound dressings in diabetic foot disease. Clinical Infectious Diseases. 2004;39(S2):S100–S103.

110. Armstrong DG, Lavery LA. Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: A multicentre, randomised controlled trial. Lancet. 2005;366:1704–1710.

111. Alavi A, Archibald G, Botros M, Brassard A, Coutts PM, Cross K, et al. An overview of advanced therapies in the management of diabetic neuropathic foot ulcers. Wound Care Canada. 2015;320E. Supplement. Available from: https://woundscanada.ca/docman/public/69-bpr-dfu-advanced-healing-supplement-final-320e/file.

112. Broussard CL. Hyperbaric oxygenation. In: Bryant RA, Nix DP (eds.). Acute & Chronic Wounds: Current Management Concepts (5th edition). St. Louis, Missouri: Elsevier; 2016. p. 361–368.

113. Lipsky BA, Berendt AR. Hyperbaric oxygen therapy for diabetic foot wounds. Diabetes Care. 2010;33(5):1143–1145. Available from: http://care.diabetesjournals.org/content/33/5/1143.

114. Stoekenbroek RM, Santema TB, Legemate DA, Ubbink DT, van den Brink A, Koelemay MJ. Hyperbaric oxygen for the treatment of diabetic foot ulcers: A systematic review. Eur J Vasc Endovasc Surg. 2014;47(6):647–655.

115. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA. 2005;293(2):217–228.

116. van de Ridder JM, Stokking KM, McGaghie WC, Ten Cate OT. What is feedback in clinical education? Med Educ. 2008;42(2):189–197.

117. Dorresteijn JA, Kriegsman DM, Assendelft WJ, Valk GD. Patient education for preventing diabetic foot ulceration. Cochrane Database Syst Rev. 2010;5:CD001488.

118. Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. Diabetes Care. 2003;26(6):1879–1882.

119. National Institute for Health and Care Excellence (NICE). Type 2 Diabetes Foot Problems: Prevention and Management of Foot Problems. Clinical Guideline. 2004.

120. Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation: Basis for prevention. Diabetes Care. 1990;13(5):513–521.

121. St. Joseph's Health Care London. Amputee Rehabilitation Program: Educational Videos. Available from: www.sjhc.london.on.ca/amputee-rehabilitation-program/educational-videos.

122. Goettl K, Keast D. Foot care for persons with type 2 diabetes: Can a teaching video improve compliance? Wound Care Canada. 2005;3(2).

123. American Diabetes Association. Standards of medical care in diabetes—2007. Diabetes Care. 2007;30(S1):S4–S41.

124. Registered Nurses' Association of Ontario (RNAO). Nursing Best Practice Guideline: Reducing Foot Complications for People with Diabetes—Revised 2007. Toronto, ON: RNAO, 2007.

125. Anti-Infective Review Panel. Anti-Infective Guidelines for Community-acquired Infections—2010. Toronto, ON: MUMS Guideline Clearing House; 2010.

126. Spencer S. Pressure relieving interventions for preventing and treating diabetic foot ulcers. Cochrane Database Syst Rev. 2000; (3):CD002302.