Evidence-Based Clinical Summary

BACKGROUND
In Australia the prevalence of type 2 diabetes has increased dramatically over the past two decades, meaning an ever-increasing population of people who are at risk of developing foot complications. It is estimated that 15% of people with diabetes will develop a foot ulcer during their lifetime. The pathophysiology of foot ulceration is complex and multifactorial. Foot ulceration is a leading cause of hospitalisation for people with diabetes. Failure of foot ulcers to heal can lead to amputation.

Of those who have an amputation, about half will experience a subsequent amputation of the other limb. Five-year survival for those who have had limb amputation is poor. Diabetes related foot complications are more prevalent in the elderly, suggesting a further increase in this condition as the population ages and diabetes prevalence increases.

Aboriginal and Torres Strait Islander people are more than three times as likely to have diabetes as non-Indigenous Australians. Aboriginal and Torres Strait Islander people living in remote areas are more likely to have diabetes than those living in non-remote areas. Aboriginal and Torres Strait Islander people also experience the greatest risk of amputation.

ASSESSMENT
Risk Factors
Preventing foot complications begins with identifying those at risk. Risk of foot ulceration and amputation is increased in patients with the following four factors:
- Previous foot ulceration or previous amputation
- Peripheral neuropathy
- 10g monofilament sensitivity
- Vibration perception (tuning fork or biothesiometer)
- Neuropathy Disability Score – ankle (Achilles) reflexes and the sensory modalities of pinprick, vibration and temperature perception
- Peripheral arterial disease – circulation
- Palpation of peripheral pulses
- Ankle-brachial pressure index (ABPI)
- Toe-brachial pressure index
- Foot deformity
- 6 point scale (1 point for each characteristic) - Score of 3 or above indicates foot deformity.
  - Small muscle wasting
  - Charcot foot deformity
  - Bony prominence
  - Prominent metatarsal heads
  - Hammer or claw toes
  - Limited joint mobility

There is evidence to suggest that the following factors increase risk of foot complications:
- Visual impairment
- Kidney disease
- Poor glycaemic control
- Ill-fitting footwear
- Socio-economic disadvantage

While peripheral neuropathy is the leading risk factor for foot ulceration, a pivotal event, such as trauma from footwear, is also needed for most ulcers to occur.

PREVENTION
A significant reduction in major and total amputation was demonstrated with the implementation of a foot protection program.

Although the research evidence is inconsistent, foot education was considered by the Expert Panel to be important for preventing foot complications. Education, services and programs for people with particular needs will need to be delivered in culturally appropriate and sensitive ways.

INFORMATION SOURCE
This summary is an extract from the National Evidence Based Guideline on Prevention, Identification and Management of Foot Complications in Diabetes (approved by the Chief Executive Officer of the National Health and Medical Research Council [NHMRC] on 6 April 2011, under Section 14A of the National Health and Medical Research Council Act 1992). These findings are based on the best available evidence following a systematic literature review of research studies and expert opinion.

The guideline was developed in consultation with a panel of experts to provide information to assist decision making. The information in this sheet is equally relevant to people with type 1 or type 2 diabetes.

The relevance and appropriateness of the information and recommendations in this document depend on individual circumstances. The primary references and further details are contained within the full guideline, technical report and systematic literature review, all available online via www.bakeridi.edu.au

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MANAGEMENT
The use of an ulcer grading system and score provides a standardised approach to the documentation of ulcer severity and assists communication between health care providers.

Debridement
The first priority of management of foot ulceration is to prepare the surface and edges of a wound to facilitate healing. If foot pulses are present, non-viable tissue should be removed from the wound bed and surrounding callus removed. If foot pulses are absent, assessment and management of the peripheral vasculature is mandatory before removal of non-viable or necrotic tissue is considered. Referral to a vascular surgeon and/or multidisciplinary team is suggested in this situation.

Removal of non-viable tissue can be quickly and effectively accomplished by local sharp debridement. Other forms of debridement include:
- Mechanical (e.g. the wet to dry method of soaking the wound with a wet gauze and then removing non-viable tissue that has dried onto it).
- Autolytic (e.g. using hydrogels that when applied to a dry wound complement the body’s natural debridement process)
- Sterile larvae (maggot) therapy.

Clinical experience suggests that local sharp debridement should be considered as the first step of management in order to avoid one or more other modalities, depending on the clinical presentation or response of a wound. Debridement should be repeated as often as required to remove all non-viable tissue.

Dressing
All foot ulcers require regular inspection, cleansing and dressing. For non-ischaemic ulcers dressings need to provide a warm and moist wound environment, absorb excess exudate and protect the wound for optimal healing.

Pressure reduction
An important reason for failure of an ulcer to heal is continued trauma to the bed of the wound. This generally occurs because the foot is insensitive and the individual continues to bear weight through the wound. Evidence suggests that total contact casts increase the number of ulcers healed, reduce healing time and reduce amputation rates.

Multidisciplinary care
Best-practice management of diabetes-related foot ulceration requires coordinated and expert primary input in both the inpatient and outpatient settings. Multi-disciplinary teams consist of medical, surgical, nursing, podiatry and allied health professionals – with the appropriate skills and knowledge needed to manage this group of individuals. Some multidisciplinary teams also include an infectious disease specialist or microbiologist. The integrated approach acknowledges that no one specialist possesses all the abilities and knowledge to manage the patient.

The evidence suggests that multi-disciplinary staged care of foot ulcers was associated with substantially reduced amputation rates, foot related hospitalisation and length of hospital stay.

Antimicrobials for non-infected ulcers
Infected ulcers should be treated with antimicrobial therapy according to published antibiotic guidelines. The need for antibiotics should be determined on clinical grounds. There is no consistent evidence that the use of an antimicrobial is indicated in the management of non-infected ulceration.

Monitoring and prevention of ulcer recurrence
When monitoring the response of an ulcer to treatment, it is important to review the characteristics of the ulcer and any vascular or infective complications. Further damage can occur in people with neuropathy due to unrecognized trauma. Signs of infection, such as the presence of erythema, increasing heat, swelling, odour, or purulent discharge, should be documented and aerobic and anaerobic cultures performed.

Monitoring ulcer size with photography has significant inter-observer variation than traditional techniques (such as using a ruler) and has high patient satisfaction because it

Foot protection program
- Podiatry
- Hygiene maintenance – advice to inspect and wash feet daily
- Support hosiery
- Protective shoes (avoid constrictive footwear)
- Clinical contact initiated by client if concerned

Disclaimer: This document is a general guide to appropriate practice, to be followed subject to the clinician’s judgement and patient’s preference in each individual case.

Funding: Baker IDI Heart and Diabetes Institute, The George Institute for Global Health and Adelaide Health Technology Assessment (The University of Adelaide) acknowledge the financial assistance provided by the Australian Government Department of Health and Ageing. The development of the full recommendations has not been influenced by the views or interests of the funding body. © Commonwealth of Australia 2011

These guidelines have been endorsed by:
- Australian Diabetes Educators Association
- Australian Diabetes Society
- Australian Practice Nurses Association
- Diabetes Australia Ltd
- Pharmaceutical Society of Australia
- The Royal Australian College of General Practitioners

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The George Institute for Global Health
Baker IDI Heart & Diabetes Institute
AHTA

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Prevention, identification, and management of foot complications in diabetes

Evidence-Based Clinical Summary

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Foot Clinical Guide

Recommendations

For Assessment in Primary Care Settings

Assessing and defining risk
- Assess all people with diabetes and stratify their risk of developing foot complications. (Grade C)
- Any suitably trained healthcare professional may perform the risk assessment. (EO)
- Assess risk stratification by inquiring about previous foot ulceration and amputation, visually inspecting the feet for structural abnormalities and ulceration, assessing for neuropathy using either the Neuropathy Disability Score or a 10g monofilament and palpating foot pulses. (Grade C)
- Stratify foot risk in the following manner:
  - “low risk” - people with no risk factors and no previous history of foot ulcer/amputation
  - “intermediate risk” - people with one risk factor (neuropathy, peripheral arterial disease or foot deformity) and no previous history of foot ulcer/amputation
  - “high risk” - people with two or more risk factors (neuropathy, peripheral arterial disease or foot deformity) and/or a previous history of foot ulcer/amputation (Grade C)
- Until adequately assessed all Aboriginal and Torres Strait Islander people with diabetes are considered to be at high risk of developing foot complications and therefore will require foot checks at every clinical encounter and active follow-up. (EO)

Frequency of risk assessment
- In people stratified as having low-risk feet (where no risk factors or previous foot complications have been identified), foot examination should occur annually. (EO)
- In people stratified as having intermediate-risk or high-risk feet (without current foot ulceration), foot examination should occur at least every 3 to 6 months. (EO)

For Prevention of Foot Complications

Prevention of foot complications
- People assessed as having “intermediate risk” or “high risk” feet should be offered a foot protection program. A foot protection program includes foot care education, podiatry review and appropriate footwear. (Grade C)
- Podiatry review is an important component of a foot protection program. However, in settings where this is not possible, a suitably trained health care worker may undertake a review of the feet. (EO)
- Foot care education should be provided to all people with diabetes to assist with prevention of foot complications. (EO)

Grades of Recommendation

A Body of evidence can be trusted to guide practice
B Body of evidence can be trusted to guide practice in most situations
C Body of evidence provides some support for recommendation(s) but care should be taken in its application
D Body of evidence is weak and recommendation must be applied with caution
EO Expert Opinion (where research evidence is not available)

For Management of Foot Complications in Primary Care Settings

Predicting outcomes from foot ulcer
- A foot ulcer is serious and needs to be managed immediately. (EO)

Tools for grading of foot ulcer severity
- Foot ulcer severity can be graded on the basis of wound depth, presence of infection (local, systemic or bone) and presence of peripheral arterial disease. Ulcer grading helps determine the degree of risk to the person and limb. The University of Texas (UT) wound classification system is the most useful tool for grading foot ulcers. (Grade C)

Interventions for ulcer management
- Wound debridement
  - Local sharp debridement of non-ischaemic wounds should be performed as it improves ulcer healing. (EO)
  - Topical hydrogel dressings may be considered for autolytic debridement to assist the management of non-ischaemic, non-healing ulcers with dry, non-viable tissue. (Grade B)
- Wound dressings and other topical treatments
  - There is insufficient evidence to demonstrate the superiority of any one wound dressing over another in management of ulcers. This means that the dressing plan will need to be tailored to the specific characteristics of the wound. In non-ischaemic ulcers, create a moist wound environment. In ischaemic ulcers create a moist wound environment using a dry, non-adherent dressing, until the wound has been reviewed by someone with experience in peripheral arterial disease. (EO)
  - Pressure reduction, redistribution of pressure or offloading of the wound
    - Pressure reduction, otherwise referred to as redistribution of pressure or offloading, is required to optimise the healing of plantar foot ulcers. (Grade B)
    - Offloading of the wound can be achieved with the use of a total contact cast or other device rendered irremovable. (Grade B)
    - Other removable offloading devices may be considered in particular settings (e.g. wounds that require more regular debridement and dressing changes) or where patient factors (e.g. significant risk of falls) do not allow the use of an irremovable device. (EO)

Types of care
- People with diabetes-related foot ulceration are best managed by a multi-disciplinary foot care team. (Grade C)
- The following factors should always precipitate referral to a multi-disciplinary foot care team:
  - deep ulcers (probe to tendon, joint or bone)
  - ulcers not reducing in size after 4 weeks despite appropriate treatment
  - the absence of foot pulses
  - ascending cellulitis and
  - suspected Charcot’s neuroarthropathy (e.g. unilateral, red, hot, swollen, possibly aching foot)

If access to a multi-disciplinary foot care team is limited, foot ulceration or foot complications other than those above should be managed by a General Practitioner together with a podiatrist and/or wound care nurse. (EO)

Remote expert consultation with digital imaging should be made available to people with diabetic foot ulceration living in remote areas who are unable to attend a multi-disciplinary foot care team/service for management. (Grade C)

For Specialist Settings

Management in specialist settings
- The following may be considered for foot ulcers in specialist centres, as part of a comprehensive wound management program:
  - Topical negative pressure therapy (Grade B)
  - Hyperbaric oxygen therapy (Grade B)
  - Larval therapy (Grade C)
  - Skin replacement therapies
    - Cultured skin equivalents (Grade B)
    - Skin grafting (Grade D)

Foot Clinical Guide

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Prevention, identification and management of foot complications in diabetes
Quick Decision Guide

**Assessment**

- **Ulcer Present**
  - **Y**
  - Previous Ulcer or Amputation
    - **N**
    - Peripheral Neuropathy
      - Use Neuropathy Disability Score or 10g monofilament
    - Peripheral Arterial Disease
      - Use foot palpation, ABI/ABI using Doppler ultrasound
    - Foot Deformity
      - Hallux deformity, hammer/claw toe, callus, flat or high arched feet, wide feet, Charcot’s neuroarthropathy
    - Does the ulcer have an adequate blood supply?
      - **N**
      - Two or more of these
        - Ischaemic
          - Adequate blood supply
            - Keep wound dry
              - Non-adherent dressing
            - Pressure reduction device
              - Need for very frequent debridement
              - Need for regular dressing changes
              - Significant risk of falls
            - Removable device
          - Non-ischaemic
            - Adequate blood supply
            - Dressing selection based on wound characteristics
              - Moist wound environment
            - Regular inspection of dressing
            - Plantar foot ulcer
              - Pressure reduction device
              - Removable device
            - Significant risk of falls
        - Intermediate Risk
          - **Y**
          - Offer foot protection program:
            - Foot care education
            - Hygiene maintenance
            - Podiatry review
            - Footwear check
            - Client initiated contact
          - foot examination every 3-6 months
        - High Risk
          - **Y**
          - Use University of Texas Wound Grading System
          - Grade Ulcer
            - Does the ulcer have an adequate blood supply?
              - **N**
              - Keep wound dry
                - Non-adherent dressing
              - Keep wound dry
                - Non-adherent dressing
            - Refer to vascular surgeon
              - Deep ulcer (probe to tendon, joint or bone)
              - Ulcer not reducing in size after 4 weeks despite treatment
              - Absence of foot pulses
              - Ascending cellulitis
              - Suspected Charcot’s neuroarthropathy
          - **Y**
          - One of these
            - Foot deformity
              - Hallux deformity, hammer/claw toe, callus, flat or high arched feet, wide feet, Charcot’s neuroarthropathy
            - Peripheral neuropathy
              - Use Neuropathy Disability Score or 10g monofilament
            - Foot deformity
              - Hallux deformity, hammer/claw toe, callus, flat or high arched feet, wide feet, Charcot’s neuroarthropathy
          - Low Risk
            - Provide foot care education
            - Annual foot examination

**Prevention**

- Provide foot care education
- Annual foot examination
- Foot care education
- Hygiene maintenance
- Podiatry review
- Footwear check
- Client initiated contact
- Foot protection program
  - Foot care education
  - Hygiene maintenance
  - Podiatry review
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**UNIVERSITY OF TEXAS WOUND GRADING SYSTEM**

<table>
<thead>
<tr>
<th>Grade/depth: “How deep is the wound?”</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth</td>
<td>0</td>
</tr>
<tr>
<td><strong>A</strong></td>
<td>Pre- or post-ulcerative lesion completely epithelialized</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>Pre- or post-ulcerative lesion completely epithelialized with infection</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Pre- or post-ulcerative lesion completely epithelialized with ischemia</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>Pre- or post-ulcerative lesion completely epithelialized with infection and ischemia</td>
</tr>
</tbody>
</table>

**Stage/Comorbidities:**
- Is the wound infected, ischemic, or both?

**DEFINITIONS**
- **Autolytic** - Destruction of a cell through the action of its own enzymes
- **Erythema** - Redness of the skin
- **Fibrinogen** - A protein produced by the liver that promotes blood clotting
- **Insensate** - Lacking sensation or awareness
- **Ischaemia** - Insenste, restriction in blood supply
- **Neuroischaemic foot** - Cool, insensate, pulseless foot with poor perfusion
- **Neuropathic foot** - Insensate, warm, well-perfused foot with bounding pulses
- **Nonischaemic** - Adequate arterial blood supply
- **Peripheral neuropathy** - Damage to nerves of the peripheral nervous system causing loss of feeling

**TOOLS FOR PREDICTING FOOT ULCER OUTCOMES**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcutaneous oxygen saturation (TcPO2) on dorsum of foot and toe pressure</td>
<td>TcPO2 &gt;25mmHg and toe pressure &gt;45mmHg indicates ulcers more likely to improve or heal</td>
</tr>
<tr>
<td>X-ray and bone/leukocyte nuclear scans</td>
<td>Presence of osteomyelitis indicates increased risk of amputation</td>
</tr>
<tr>
<td>Ankle peak systolic velocity measurements using Duplex ultrasound</td>
<td>Low velocities indicate increased risk of ulcer non-healing</td>
</tr>
<tr>
<td>Skin perfusion pressure using a radioisotope clearance method</td>
<td>Lower skin pressures indicates increased risk of ulcer non-healing</td>
</tr>
<tr>
<td>Capillary perfusion using macro aggregated albumin scanning</td>
<td>Poor circulation associated with ulcer non-healing, good circulation associated with ulcer healing</td>
</tr>
<tr>
<td>Hyperspectral imaging of oxyhaemoglobin and deoxyhaemoglobin</td>
<td>Positive index indicates greater healing than negative index</td>
</tr>
<tr>
<td>Plasma fibrinogen</td>
<td>Fibrinogen &gt;300 mg/dl indicates greater risk of amputation</td>
</tr>
</tbody>
</table>

**SEVEN ESSENTIAL SKILLS FOR TARGETED LIMB SALVAGE**

1. Perform haemodynamic and anatomic vascular assessment with revascularisation, as necessary
2. Perform neurological examination
3. Perform site-appropriate culture technique
4. Perform wound assessment and staging/grading of infection and ischaemia
5. Perform site-specific bedside and intraoperative incision and debridement
6. Initiate and modify culture-specific and patient-appropriate antibiotic therapy
7. Perform appropriate postoperative monitoring to reduce risk of re-ulceration and infection