

Malaysian clinical practice guidelines for management of diabetic foot: A synopsis for the primary care physician

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Abstract

Diabetic foot requires careful attention and coordinated management by a dedicated team. Screening, prevention, adequate assessment, and appropriate referral are crucial to prevent complications. Multimodal treatment and rehabilitation are recommended to ensure a better quality of life and reduction of amputation rate in people with diabetic foot.

Introduction

Diabetic foot is defined as infection, ulceration, or destruction of tissues of the foot associated with neuropathy and/or peripheral arterial disease (PAD) of people with diabetes mellitus (DM).¹

According to the Malaysian National Health and Morbidity Surveys, the prevalence of diabetes has been increasing from 11.6% in 2006 to 15.2% in 2011 and further to 17.5% in 2015. The prevalence increased across age groups from 5.5% among those 18 to 19 years of age to a peak of 39.1% among those 70 to 74 years of age.² Overall, the cost of management of type 2 DM (T2DM) in 2011 was RM1.40 billion, which corresponded to 9.21% of the entire Ministry of Health (MoH) budget.³

The high prevalence of diabetes in adults increases the risk of foot problems, mainly due to neuropathy and/or PAD.⁴ Up to 50% of people with DM are asymptomatic of diabetic peripheral neuropathy (DPN)⁵ and about one million amputations are performed on people with diabetes each year worldwide.¹ Diabetic foot requires careful attention and coordinated management, preferably by a multidisciplinary foot care team.

Methods of Clinical Practice Guidelines Development

The evidence-based Clinical Practice Guidelines (CPG) on Management of Diabetic Foot (Second Edition) were developed by a multidisciplinary Development Group from the MoH and Ministry of Education, guided by a multidisciplinary Review Committee. A systematic review method was used, starting with a protocol including objectives and clinical questions. Then a systematic literature search was carried out primarily using the Medline and Cochrane Systemic Review databases. The reference lists of all retrieved literature and guidelines were also searched to identify relevant studies. Experts in the field were also contacted for further relevant studies. References were also made to other existing CPGs on diabetic foot.

All literature retrieved were appraised using Critical Appraisal Skill Programme checklist, presented in evidence tables, and further discussed in each Development Group meeting. All statements and recommendations formulated were agreed upon by both the Development Group and Review Committee. Where evidence was insufficient, the recommendations were made using the expert opinion of the teams. The CPG was largely based on the findings of systematic reviews or meta-analyses and clinical trials, with local practices taken into consideration.

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The level of evidence was based on the US/ Canadian Preventive Services Task Force Level of Evidence, while the grading of recommendation used the principles of Grading Recommendations, Assessment, Development, and Evaluation (GRADE). The writing of the CPG followed strictly the requirement of Appraisal of Guidelines for Research and Evaluation (AGREE) II.

On completion, the draft of the CPG was reviewed by external reviewers and posted on the MoH Malaysia official website for any interested parties to give feedback. The draft was finally presented to the Technical Advisory Committee for CPG, and the Health Technology Assessment and CPG Council MoH Malaysia for final review and approval. The manuscript was then written based on the approved CPG as mentioned in Supporting Information section.

Diagnosis and Assessment

All people with diabetes should be assessed for diabetic foot at risk. They should be screened, diagnosed, investigated, classified, and stratified to ensure optimal management. Assessment of DPN should be performed at diagnosis and repeated annually.⁶ Early detection of diabetic foot at risk and appropriate interventions will minimize complications and healthcare costs.⁷

History Taking

Proper management of diabetic foot is initiated by good history taking, which includes general (risk factors for diabetic foot), medical (underlying concurrent medical condition), and individual diabetic foot history (vascular or neuropathic symptoms). Predictors for increased risk of foot ulceration in diabetes include a previous history of ulceration or lower extremity amputations and a longer duration of diabetes.⁸ Refer to the Diabetic Foot Assessment Form for full history taking on diabetic foot.

Physical Examination

Physical assessment is an important step in the screening and diagnosing of diabetic foot problems, including complications. This includes proper inspection and palpation of the foot.

• **Skin**

Skin changes due to vascular insufficiency

may be present, for example, skin atrophy, nail atrophy, diminished pedal hair, prolonged capillary refill time (>2 seconds), and reduced skin temperature.

• **Neurological**

A monofilament test and vibration perception are used to assess DPN, which is a major independent risk factor for diabetic foot ulceration. It may involve large fiber nerves (for touch, vibration, position perception, and muscle control), small fiber nerves (for thermal perception, pain, and autonomic function), or both. The commonly used screening tools are:

Semmes-Weinstein Monofilament Examination

A Semmes-Weinstein monofilament examination (SWME) is easy to perform and widely available locally. The examination uses a 5.07/10-g monofilament which exerts a buckling force when it bends. Inability to sense touch or pressure (>3 out of 10 sites) indicates loss of protective sensation. SWME should be combined with another modality in the screening of peripheral neuropathy. Refer to **Figure 1**.

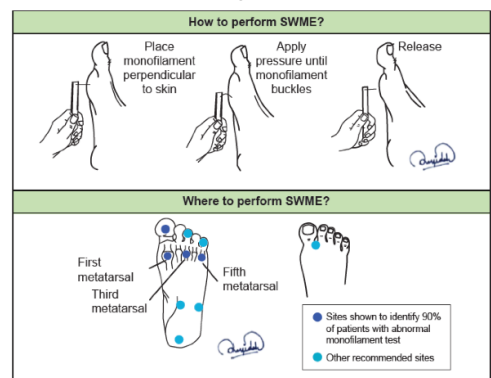


Figure 1. Semmes-Weinstein monofilament examination (SWME)

Tuning Fork Test

A tuning fork is used to detect the loss of vibration sense. The most commonly used tuning fork is 128 Hz. Refer to **Figure 2**.

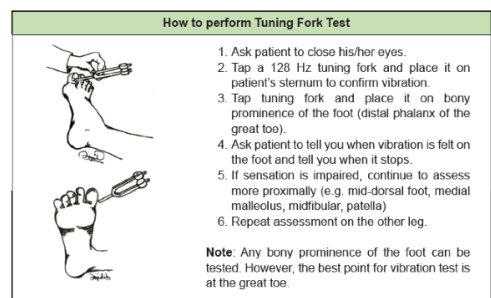


Figure 2. Tuning fork examination

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Neuropathy should be assessed with 10-g monofilament and one other modality (e.g. pin prick, vibration sense with 128 Hz tuning fork, etc.). These increase the sensitivity of detecting peripheral neuropathy by 87%.⁶

• **Vascular**

Vascular assessment includes mandatory palpation of the femoral, popliteal, posterior tibial, and dorsalis pedis artery pulses. Critical limb ischemia is defined as rest pain with ulcers or tissue loss attributed to arterial occlusive disease. It is associated with substantial loss of limb and life.⁹

Palpation of foot pulses should be the initial screening method for PAD. Among the tests that can be used to exclude PAD are¹:

- Ankle-brachial index (normal value 0.9–1.3)
- Toe-brachial index (normal value ≥0.75)
- Continuous wave Doppler (presence of triphasic waveforms)

Thus, screening for DPN and PAD should be performed on all patients with diabetes at diagnosis and repeated at least annually. Those with DPN and PAD should be referred appropriately. Refer to Algorithm A.

• **Musculoskeletal**

Musculoskeletal complications in diabetic foot include ulcers, infections, and deformities (e.g. Charcot neuroarthropathy).



Conventional radiography may be helpful in diabetic foot for initial imaging to detect osteolysis, arterial calcification, gas shadow, malalignment, and peri-articular fragmentation.

Refer to the Diabetic Foot Assessment Form for the full physical examination of diabetic foot.

Diabetic Foot Assessment Form¹⁰

| | | | | | |
|---|--|--|----------------|-----------|--------------------|
| DATE: _____ | | | | | |
| PERSONAL DATA | | | | | |
| NAME: _____ | | | | | |
| IDENTIFICATION CARD NUMBER: _____ | | | | | |
| MEDICAL HISTORY | | | | | |
| <input type="checkbox"/> Newly diagnosed (on admission) <input type="checkbox"/> High blood sugar: _____ <input type="checkbox"/> Symptomatic: _____ <input type="checkbox"/> Others: _____ | Treatment: <input type="checkbox"/> Never sought medical treatment <input type="checkbox"/> Self-treated <input type="checkbox"/> Traditional/alternative treatment | Other medical condition: <input type="checkbox"/> Ischemic Heart Disease <input type="checkbox"/> Stroke <input type="checkbox"/> Hypertension <input type="checkbox"/> Hyperlipidemia <input type="checkbox"/> Others: _____ | | | |
| <input type="checkbox"/> Known case of Diabetes Mellitus (DM) Duration: _____ years Date of diagnosis: _____ Type of DM: <input type="checkbox"/> Type 1 <input type="checkbox"/> Type 2 <input type="checkbox"/> Others: _____ | Current medical treatment: <input type="checkbox"/> Nil <input type="checkbox"/> Diet alone <input type="checkbox"/> Medication: <input type="checkbox"/> Oral Anti-Diabetic Agents: _____ <input type="checkbox"/> Insulin: _____ <input type="checkbox"/> Combined: _____ | Complications: <input type="checkbox"/> Peripheral Arterial Disease <input type="checkbox"/> Neuropathy <input type="checkbox"/> Nephropathy <input type="checkbox"/> Others: _____ | | | |
| SYMPTOMS | | | | | |
| | Right | | Left | | Description |
| | Yes | No | Yes | No | |
| Paresthesia (Pins & Needles) | | | | | |
| Claudication/Rest pain | | | | | |
| Foot ulcer | | | | | |
| Amputation | | | | | |
| Orthosis/Prosthesis | | | | | |
| Footwear | Indoor | | Outdoor | | |
| | | | | | |

(Kindly ✓ the appropriate box)

| FOOT | | | | | | | |
|---|-------|----|--|------|-------------|---|-------------|
|  | | |  | | | | |
| GENERAL EXAMINATION | | | | | | | |
| | Right | | Left | | Description | | |
| | Yes | No | Yes | No | | | |
| Skin condition | | | | | | | |
| Corn/callosity | | | | | | | |
| Ulcer | | | | | | | |
| Bunions | | | | | | | |
| Lesser toe deformities | | | | | | | |
| Charcot joints | | | | | | | |
| NEUROLOGICAL EXAMINATION | | | | | | | |
| | Right | | Left | | Description | | |
| | Yes | No | Yes | No | | | |
| Muscle wasting | | | | | | | |
| Presence of proprioception | | | | | | | |
| Abnormal monofilament test (>3/10) | | | | | | | |
| Presence of vibration perception | | | | | | | |
| VASCULAR EXAMINATION | | | | | | | |
| | Right | | Left | | Description | | |
| | Yes | No | Yes | No | | | |
| Atrophic skin changes | | | | | | | |
| Dystrophic nail | | | | | | | |
| Absence of hair | | | | | | | |
| Abnormal temperature gradient | | | | | | | |
| Capillary refill >3 seconds | | | | | | | |
| PALPABLE PULSE | | | | | | | |
| | Right | | | Left | | | Description |
| | ++ | + | - | ++ | + | - | |
| ++ (Normal) + (Weak) - (Absent) | | | | | | | |
| Dorsalis pedis artery (DPA) | | | | | | | |
| Posterior tibial artery (PTA) | | | | | | | |
| Popliteal artery (PA) | | | | | | | |
| Femoral artery (FA) | | | | | | | |

(Kindly ✓ the appropriate box)

| ANKLE-BRACHIAL INDEX (ABI) ASSESSMENT | | | | | |
|--|---------------|---|------|---|--|
| | Right | | Left | | Description |
| Brachial (mmHg) | | | | | |
| Dorsalis pedis (mmHg) | | | | | |
| Posterior tibial (mmHg) | | | | | |
| ABI | | | | | Use either DPA or PTA, whichever is higher |
| RISK STRATIFICATION | | | | | |
| Low risk | Moderate risk | | | High risk | |
| | | | | | |
| MANAGEMENT PLAN | | | | | |
| Referral: <input type="checkbox"/> Orthopedic <input type="checkbox"/> Vascular <input type="checkbox"/> Endocrine <input type="checkbox"/> Primary Care <input type="checkbox"/> Others: _____ | | Follow-up: <input type="checkbox"/> 3-monthly <input type="checkbox"/> 6-monthly <input type="checkbox"/> Yearly <input type="checkbox"/> Others: _____ | | Foot care education checklist: <input type="checkbox"/> Foot hygiene <input type="checkbox"/> Nail care <input type="checkbox"/> Footwear advice <input type="checkbox"/> Routine foot check <input type="checkbox"/> Emollient use <input type="checkbox"/> Wound care <input type="checkbox"/> Recognizing active foot problems (e.g. infection/erythema/ulcer) <input type="checkbox"/> Things to avoid (e.g. massage/soak/reflexology/self-treatment) | |
| Assessed by Name: | | Signature: | | Date: | |

Risk Stratification

A patient's current risk of developing a diabetic foot or requiring amputation is assessed using a practical risk stratification, as shown in **Table 1**.

Table 1. Diabetic foot risk stratification⁴

| Diabetic foot risk | Findings |
|-------------------------------------|---|
| Normal | No abnormalities |
| Low Risk | Callus alone |
| Moderate Risk | Any of the following: <ul style="list-style-type: none"> • deformity • neuropathy • non-critical limb ischemia |
| High Risk | One of the following: <ul style="list-style-type: none"> • previous ulceration • previous amputation • on renal replacement therapy • neuropathy and non-critical limb ischemia • neuropathy with callus and/or deformity • non-critical limb ischemia with callus and/or deformity |
| Active Diabetic Foot Problem | Any of the following: <ul style="list-style-type: none"> • ulceration • infection • critical limb ischemia • gangrene • suspicion of an acute Charcot neuroarthropathy, or an unexplained hot, red, swollen foot with or without pain |

Classification

The University of Texas Classification¹¹ is the preferred classification for diabetic foot and is useful to decide on the further management of the diabetic foot (refer **Table 2**). Refer to Algorithm B.

Table 2. University of Texas classification of diabetic foot ulcers

| STAGE | GRADE 0 | GRADE I | GRADE II | GRADE III |
|----------------|--|---|--|------------------------------------|
| STAGE 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 |
| STAGE B | With infection | With infection | With infection | With infection |
| STAGE C | With ischemia | With ischemia | With ischemia | With ischemia |
| STAGE D | With infection and ischemia | With infection and ischemia | With infection and ischemia | With infection and ischemia |

Prevention

Patient education should be an integral part of the management of diabetic foot. It should be given at least annually and more frequently in higher-risk patients. Glycemic control (with minimization of hypoglycemia) should be individualized.

Patients should be advised on appropriate footwear according to the foot risk. Its importance increases with a higher risk of developing diabetic foot ulcer. Recommendations of footwear according to foot risk status are shown in **Table 3**.¹²

Table 3. Footwear advice¹²

| Risk status | Actions |
|------------------------------|---|
| All foot at risk | <ul style="list-style-type: none"> Advise the use of footwear that fits, protects, and accommodates the shape of the feet (with socks). |
| Moderate or high risk | <ul style="list-style-type: none"> Prescribe footwear with: <ul style="list-style-type: none"> custom-made in-shoe orthoses or insoles for people with a foot deformity or pre-ulcerative lesions off-loading orthoses or insoles for people with healed plantar foot ulcer Review prescribed footwear periodically to ensure it still fits, protects, and supports the foot Advise the wearing of footwear at all times, both indoors and outdoors |
| Foot ulceration | <ul style="list-style-type: none"> Prescribe appropriate off-loading devices for ulcer healing |

Patients with diabetic foot should be referred early for preventive surgery if all other modalities have failed. It should be performed by orthopedic surgeons trained in the procedures to prevent ulceration or re-ulceration in diabetic patients with foot deformity e.g. restricted ankle dorsiflexion, equinus contracture, claw toe, hammer toe, or mallet toe.

Treatment

• Pharmacotherapy

Appropriate analgesia should be considered in painful diabetic foot. In neuropathic pain, adjuvants are used at all steps of the analgesic ladder.¹³ Examples of adjuvants are antidepressants (e.g. amitriptyline or duloxetine) and anticonvulsants (e.g. gabapentin or pregabalin).¹⁴

Antibiotics should not be used unless there are local or systemic symptoms of infection. Local treatment including surgical debridement is important to be considered as part of the management. Antibiotic used for treatment should be based on the most recent culture and sensitivity report.¹⁵

In diabetic foot, antibiotics should be given according to the disease severity, care setting, patient's preference, clinical situation and medical history. If more than one regimen is appropriate, the regimen with lowest cost should be selected. For moderate and severe infections, broad spectrum antibiotics are used initially until culture and sensitivity results are available. Antibiotics should not be given for⁴:

- prevention of infections in diabetic foot
- >14 days for the treatment of mild soft tissue infection in diabetic foot

• Wound Management

Wound Dressings

Advanced wound dressings may be offered in diabetic foot ulcer; refer to **Table 4**.

Table 4. Types of wound dressing in diabetic foot¹⁶

| No. | Types of dressing | Advantages | Disadvantages | Indications | Contraindications | Review intervals |
|--------------------------------------|---|---|--|--|--|------------------|
| Basic wound contact dressings | | | | | | |
| 1. | Gauze/basic absorbent with paraffin or similar (antiseptics or antibiotics) | <ul style="list-style-type: none"> Reduces adherence of dressing to the wound Widely available | <ul style="list-style-type: none"> Minimal exudate absorption Requires secondary dressing | All wounds | Allergy | Daily |
| Advanced wound dressings | | | | | | |
| 1. | Hydrogel | <ul style="list-style-type: none"> Provides moist environment Acts as enzymatic debridement Promotes granulation | <ul style="list-style-type: none"> Requires secondary dressing | <ul style="list-style-type: none"> Sloughy wound Dry wounds | <ul style="list-style-type: none"> Highly exudative wounds Allergy | 1–2 days |
| 2. | Alginate | <ul style="list-style-type: none"> Forms gel on wound and maintain moisture Acts as cavity filler Absorbent in exudative wounds Promotes hemostasis Low allergenic | <ul style="list-style-type: none"> Requires secondary dressing Gel can be confused with slough or pus in wound | <ul style="list-style-type: none"> Moderately or highly exudative wounds Need for hemostasis | <ul style="list-style-type: none"> Dry wounds Allergy | 2–3 days |
| 3. | Hydrofibre | <ul style="list-style-type: none"> Maintains moisture Longer wear time Non-traumatic upon removal Reduces risk of maceration Can be used on infected wounds | <ul style="list-style-type: none"> Not helpful for dry wounds Requires secondary dressings | Moderately or highly exudative wounds | Allergy | 2–5 days |
| 4. | Foam | <ul style="list-style-type: none"> Maintains moisture Highly absorbent Cushioning property | Limited size | Moderately or highly exudative wounds | <ul style="list-style-type: none"> Dry wounds Wounds that need frequent review | 2–3 days |
| 5. | Hydrocolloid | <ul style="list-style-type: none"> Maintains moisture Cleans and debrides by autolysis Easy to use Waterproof | Induces peri-wound maceration | Mildly to moderately exudative wounds | <ul style="list-style-type: none"> Dry wounds Infection Highly exudative wounds | 2–3 days |
| 6. | Silver | <ul style="list-style-type: none"> No known resistance Bactericidal | Some silver dressings discolor the wound | Infective wounds | Allergy | 3–5 days |
| 7. | Others | Not widely used - some may be used in specialized centers e.g. collagen, matrix, and regenerative dressings (cultured epidermis, growth factors, stem cells, etc.) | | | | |

Adjuvant Therapy

Adjuvant therapy may be offered in delayed wound healing in diabetic foot with good vascularity.

- Negative pressure wound therapy is a procedure in which a vacuum dressing is used to promote wound healing. It is used

for clean exudative wounds with poor granulation.¹⁷

- Maggot debridement therapy is used for the debridement of wounds with necrotic tissue. It shows better wound closure (>50% of wound area) after 10 days compared with autolytic debridement with hydrogel in diabetic foot ulcer.¹⁸

- Hyperbaric oxygen therapy is used to increase oxygenation and antimicrobial effect that can improve the healing of chronic ulcers.¹⁹⁻²¹

Revascularization

Revascularization should be offered in diabetic patients with PAD. Surgical debridement by trained healthcare providers should be considered in diabetic foot ulcer that fails to respond to non-surgical

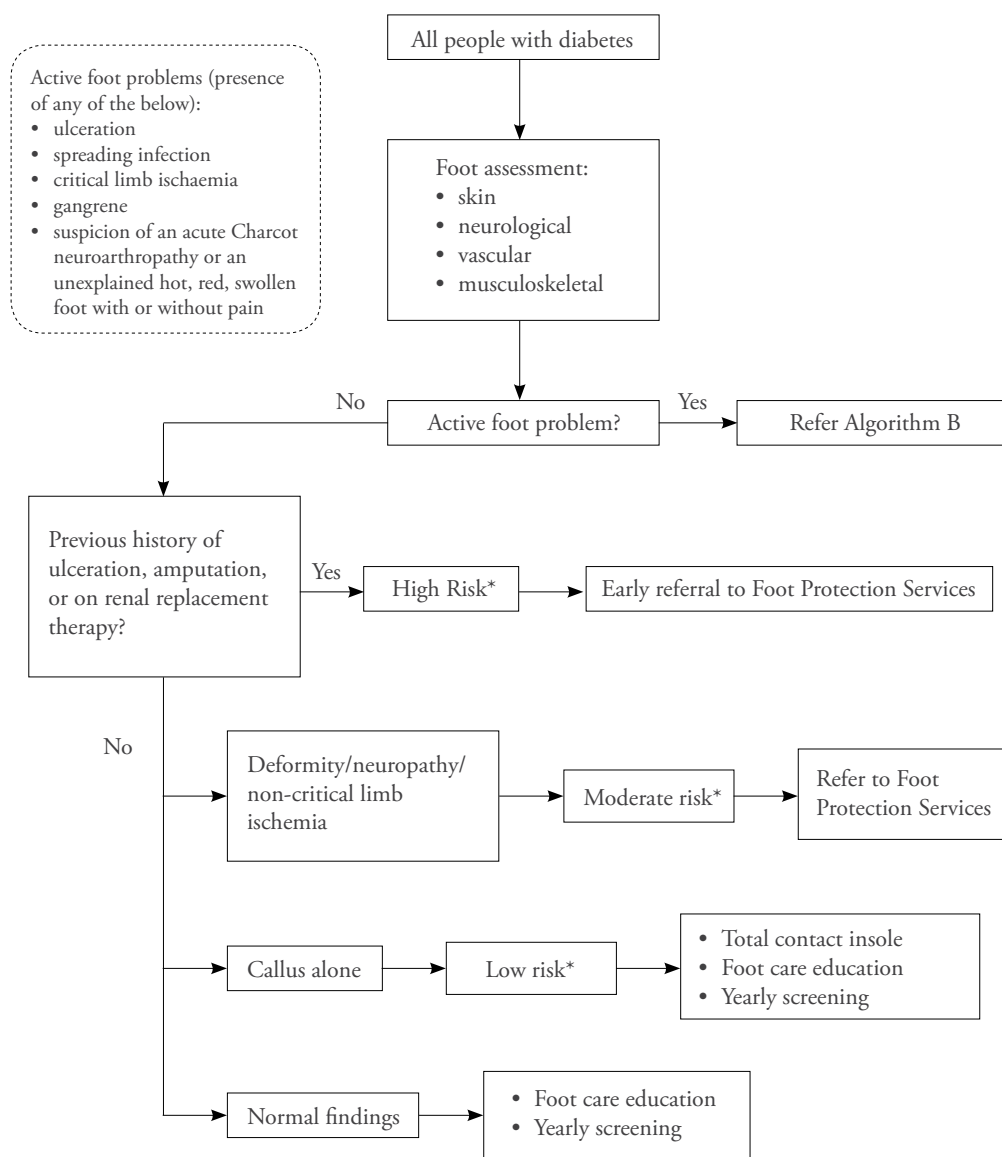
debridement, or is deep and infected at presentation.

Rehabilitation

Off-loading should be offered to people with plantar diabetic foot ulcer. Those with diabetic foot who have had amputation should be referred for rehabilitation.

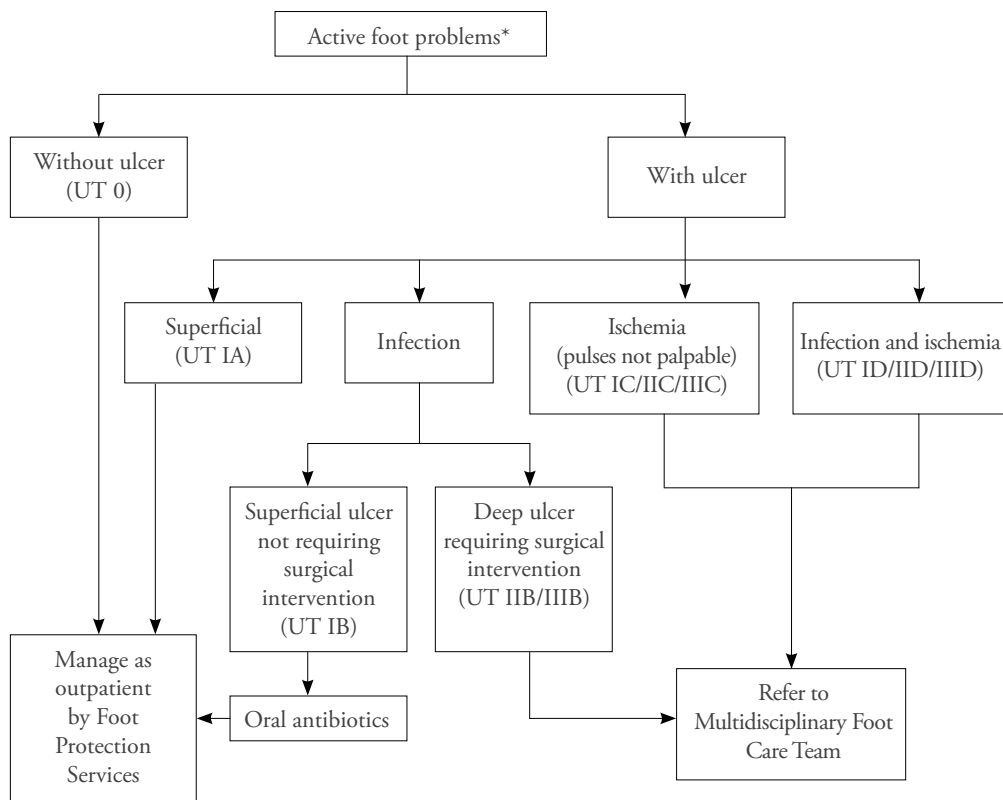
Algorithms A and B summarize the management of diabetic foot.

Algorithm A. Screening of diabetic foot



* Refer to **Table 1** on diabetic foot risk stratification.

Algorithm B. Active foot problems (with risk stratification)



* Refer urgently for admission if patients present with general illness (e.g. sepsis or diabetic emergencies) irrespective of foot problems.

* UT = University of Texas

Referral

People who are at moderate or high risk of developing a diabetic foot problem are referred to multidisciplinary professionals in the field of podiatry, diabetology, biomechanics and orthoses, and wound care.⁴ People with a limb-threatening or life-threatening diabetic foot problem should be referred urgently and managed under specialist care. Examples of such conditions include ulceration with fever or any signs of sepsis, critical limb ischemia, deep-seated soft tissue or bone infection, and gangrene.

The recommended referral schedule for diabetic foot is shown in **Table 5**.

Table 5. Recommended referral schedule

| Diabetic foot risk | Findings |
|------------------------------|---|
| Normal/Low risk | No referral needed-yearly review at primary care |
| Moderate risk | Referral within 3 months to foot protection services |
| High risk | Early referral within 2 weeks to foot protection services |
| Active diabetic foot problem | Urgent referral within 24 hours to multidisciplinary foot care team |

The referral should be addressed to:

1. The Foot Protection Service, which provides prevention and treatment of simple active diabetic foot problems in the community that do not require admission. The team should be led by a Family Medicine Specialist or physician with special training in diabetic foot problems and supported by podiatrist, diabetic team (including diabetic educator), wound care team, and rehabilitation services.

2. The multidisciplinary foot care service, which manages active or complicated diabetic foot problems in the hospital. The team is led by an orthopedic surgeon and/or physician. Subsequent referral to other specialties is made according to the main problem presented by the patient.

Monitoring and Follow-up

Frequency of monitoring of patients with diabetic foot depends on risk stratification as shown in **Table 6** below:

Table 6. Frequency of Monitoring for Diabetic Foot

| Risk | Low risk | Moderate risk | High risk | |
|-----------|----------|---------------|----------------------|-------------------|
| | | | No immediate concern | Immediate concern |
| Frequency | Annually | 3–6 months | 1–2 months | 1–2 weeks |

Supporting Information

Details of the evidence supporting the above statements can be found in Clinical Practice Guidelines on the Management of Diabetic Foot (Second Edition) 2018, available on the following websites: <http://www.moh.gov.my>

my (Ministry of Health Malaysia) and <http://www.acadmed.org.my> (Academy of Medicine). Corresponding organization: CPG Secretariat, Health Technology Assessment Section, Medical Development Division, Ministry of Health Malaysia; contactable at htamalaysia@moh.gov.my.

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