

# MANAGEMENT OF DIABETIC FOOT (SECOND EDITION)

DRAFT



Ministry of Health  
Malaysia



Malaysian Endocrine &  
Metabolic Society



Malaysian  
Orthopaedic Association



Family Medicine  
Specialists  
Association of  
Malaysia



Academy of Medicine  
Malaysia

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**STATEMENT OF INTENT**

These clinical practice guidelines (CPG) are meant to be guides for clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not necessarily guarantee the best outcome in every case. Every healthcare provider is responsible for the management of his/her unique patient based on the clinical picture presented by the patient and the management options available locally.

**UPDATING THE CPG**

These guidelines were issued in 2018 and will be reviewed in a minimum period of four years (2022) or sooner if new evidence becomes available. When it is due for updating, the Chairperson of the CPG or National Advisor of the related specialty will be informed about it. A discussion will be done on the need for a revision including the scope of the revised CPG. A multidisciplinary team will be formed and the latest systematic review methodology used by MaHTAS will be employed.

Every care is taken to ensure that this publication is correct in every detail at the time of publication. However, in the event of errors or omissions, corrections will be published in the web version of this document, which is the definitive version at all times. This version can be found on the websites mentioned above.

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## LEVELS OF EVIDENCE

Level	Study design
I	Evidence from at least one properly randomised controlled trial
II -1	Evidence obtained from well-designed controlled trials without randomisation
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or group
II-3	Evidence from multiple time series with or without intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
III	Opinions of respected authorities based on clinical experience; descriptive studies and case reports; or reports of expert committees

**SOURCE: US / CANADIAN PREVENTIVE SERVICES TASK FORCE 2001**

In line with the current development in CPG methodology, the CPG Unit of MaHTAS is in the process of adapting **Grading Recommendations, Assessment, Development and Evaluation (GRADE)** in its work process. The quality of each retrieved evidence and its effect size are carefully assessed/reviewed by the CPG Development Group. In formulating the recommendations, overall balances of the following aspects are considered in determining the strength of the recommendations:

- overall quality of evidence
- balance of benefits versus harms
- values and preferences
- resource implications
- equity, feasibility and acceptability

## KEY RECOMMENDATIONS

The following recommendations are highlighted by the CPG Development Group as the key recommendations that answer the main questions addressed in the CPG and should be prioritised for implementation.

### a. Assessment

- Screening for diabetic peripheral neuropathy and peripheral arterial disease (PAD) should be performed on all diabetes mellitus patients at diagnosis and repeated at least annually.
  - Semmes-Weinstein monofilament examination should be combined with another modality in the screening of peripheral neuropathy.
  - Palpation of foot pulses should be the initial screening method for PAD.
- University of Texas Classification is the preferred classification for diabetic foot.

### b. Referral

- Active or complicated diabetic foot problems should be managed by a multidisciplinary foot care team.

### c. Prevention

- Patient education should be an integral part in the management of diabetic foot.
  - It should be given at least annually and more frequent in higher risk patients.
- Glycaemic control (with minimisation of hypoglycaemia) in the prevention of diabetic foot should be individualised.
- Patients with diabetes should be advised on appropriate footwear according to the foot risk.
- Preventive surgeries by orthopaedic surgeons trained in the procedures may be considered to prevent ulceration or re-ulceration in diabetic patients with foot deformity.

### d. Treatment

- Appropriate analgesia should be considered in painful diabetic foot.
- Antibiotics should be used as an adjunct to surgical debridement in infected diabetic foot.
- Advanced wound dressings may be offered in diabetic foot ulcer.
- Adjuvant therapy may be offered in delayed wound healing with good vascularity in diabetic foot.
- Revascularisation should be offered in diabetes patients with peripheral arterial disease.
- Surgical debridement by trained healthcare providers should be considered in diabetic foot ulcer which:
  - fails to respond to non-surgical debridement
  - is deep and infected at presentation

## **GUIDELINES DEVELOPMENT AND OBJECTIVES**

### **GUIDELINES DEVELOPMENT**

The members of the Development Group (DG) for these Clinical Practice Guidelines (CPG) were from the Ministry of Health (MoH), Ministry of Higher Education and private healthcare. There was active involvement of a multidisciplinary Review Committee (RC) during the process of the CPG development.

A systematic literature search was carried out using the following electronic databases: mainly Medline via Ovid and Cochrane Database of Systemic Reviews and others e.g. PubMed and Guidelines International Network (refer to **Appendix 1** for **Example of Search Strategy**). The search was limited to literature published on humans and in English. In addition, the reference lists of all retrieved literature and guidelines were searched to further identify relevant studies. Experts in the field were also contacted to identify further studies. All searches were conducted from **19 Mac 2017 to 18 May 2018**. Literature searches were repeated for all clinical questions at the end of the CPG development process allowing any relevant papers published before **31 July 2018** to be included. Future CPG updates will consider evidence published after this cut-off date. The details of the search strategy can be obtained upon request from the CPG Secretariat.

References were also made to other CPGs on diabetic foot such as:

- Diabetic Foot Problems: Prevention and Management (National Institute for Health and Care Excellence, 2015)
- Diabetic Foot Australia guideline on footwear for people with diabetes (Journal of Foot and Ankle Research, 2018)

The CPGs were evaluated using the Appraisal of Guidelines for Research and Evaluation (AGREE) II prior to them being used as references.

A total of eight clinical questions were developed under different sections. Members of the DG were assigned individual questions within these sections (refer to **Appendix 2** for **Clinical Questions**). The DG members met 33 times throughout the development of these guidelines. All literature retrieved were appraised by at least two DG members using Critical Appraisal Skill Programme checklist, presented in evidence tables and further discussed in each DG meetings. All statements and recommendations formulated after that were agreed upon by both the DG and RC. Where evidence was insufficient, the recommendations were made by consensus of the DG and RC. This CPG is based largely on the findings of systematic reviews, meta-analyses and clinical trials, with local practices taken into consideration.

The literature used in these guidelines were graded using the US/Canadian Preventive Services Task Force Level of Evidence (2001), while the grading of recommendation was done using the principles of GRADE (refer to the preceding page). The writing of the CPG follows strictly the requirement of AGREE II.

On completion, the draft of the CPG was reviewed by external reviewers. It was also posted on the MoH Malaysia official website for feedback from any interested parties. The draft was finally presented to the Technical Advisory Committee for CPG, and the HTA and CPG Council MoH Malaysia for review and approval. Details on the CPG development methodology by MaHTAS can be obtained from Manual on Development and Implementation of Evidence-based Clinical Practice Guidelines published in 2015 (available at [http://www.moh.gov.my/penerbitan/mymahtas/CPG\\_MANUAL\\_MAHTAS.pdf](http://www.moh.gov.my/penerbitan/mymahtas/CPG_MANUAL_MAHTAS.pdf)).

## **OBJECTIVES**

The objectives of the CPG are to provide evidence-based recommendations on the management of diabetic foot in the following aspects:

- a. assessment
- b. referral
- c. prevention
- d. treatment

## **CLINICAL QUESTIONS**

Refer to **Appendix 2**

## **TARGET POPULATION**

### **1. Inclusion Criteria**

All patients with diabetes mellitus who are at risk or have developed diabetic foot

### **2. Exclusion Criteria**

None

## **TARGET GROUP/USERS**

This document is intended to guide those involved in the management of diabetic foot at any healthcare level including:

- i. doctors
- ii. allied health professionals
- iii. trainees and medical students
- iv. patients and their advocates
- v. professional societies

## **HEALTHCARE SETTINGS**

Primary and secondary/tertiary care settings

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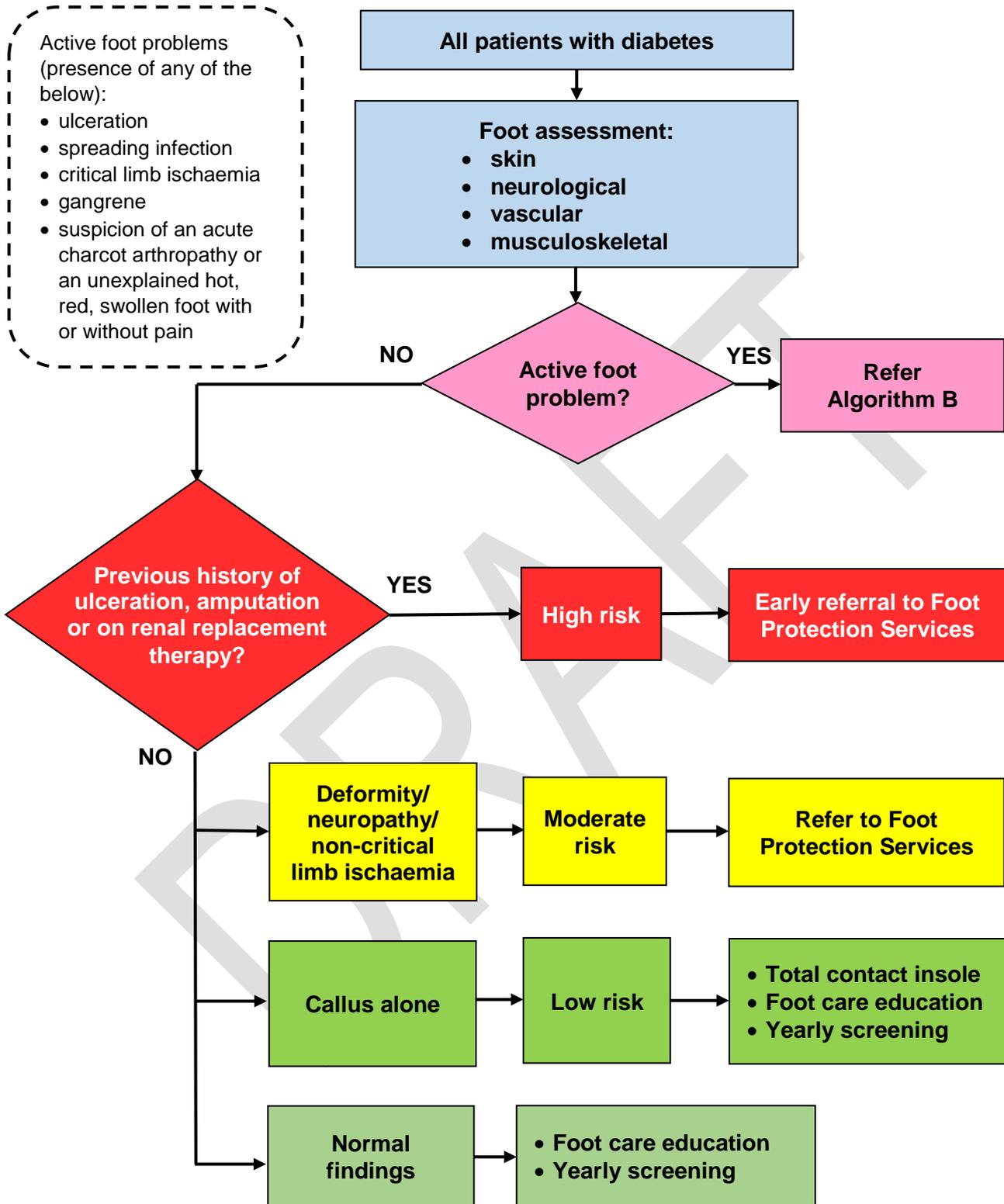
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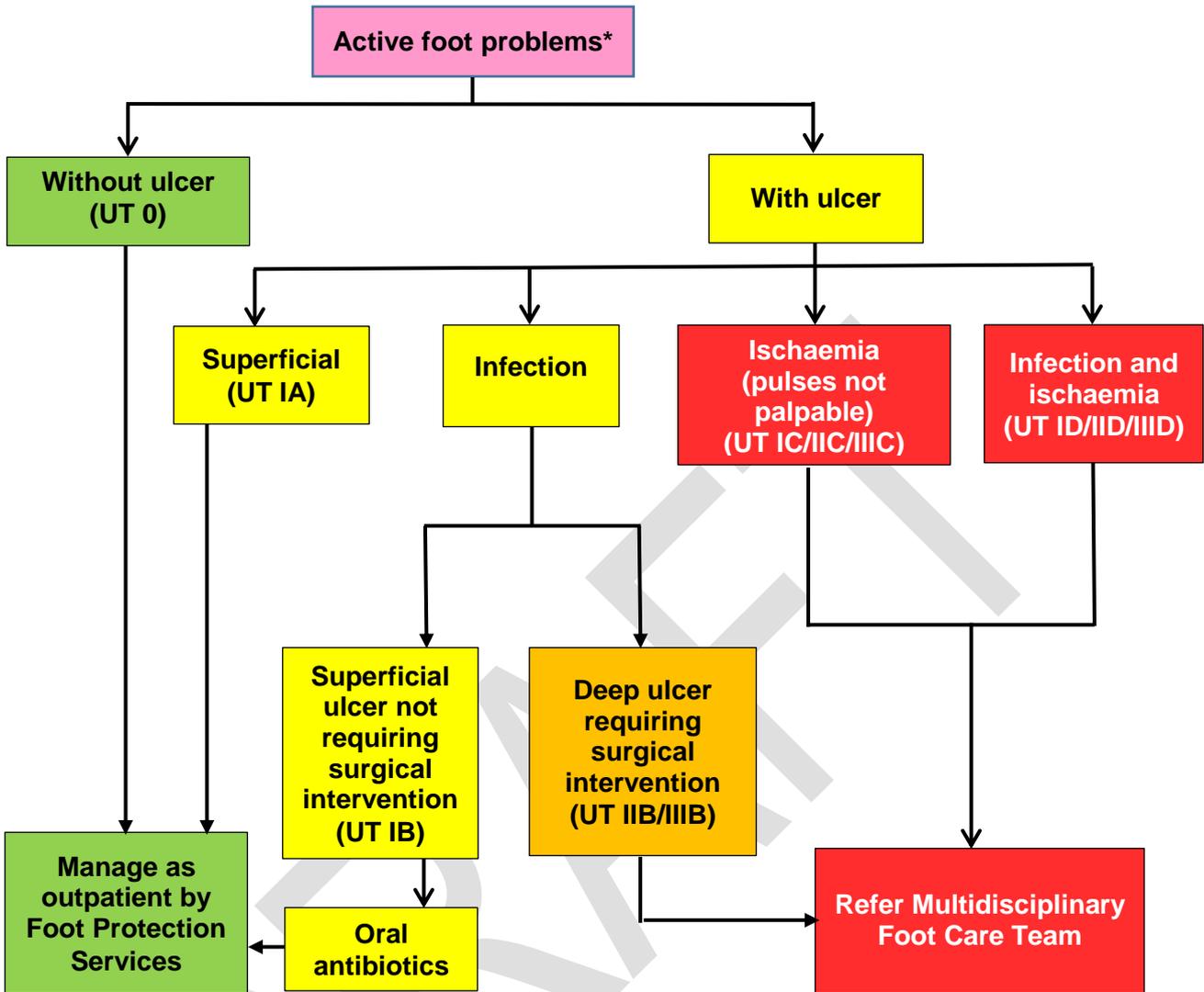
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**ALGORITHM A. SCREENING OF DIABETIC FOOT**



**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.

**University of Texas Classification of Diabetic Foot**

	GRADE 0	GRADE I	GRADE II	GRADE III
STAGE A	Pre- or post-ulcerative lesion completely epithelialised	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 ischaemia	With ischaemia	With ischaemia	With ischaemia
STAGE D	With infection and ischaemia	With infection and ischaemia	With infection and ischaemia	With infection and ischaemia

UT: University of Texas

## 1. INTRODUCTION

Diabetic foot can be defined as infection, ulceration or destruction of tissues of the foot associated with neuropathy and/or peripheral arterial disease of people with diabetes mellitus (DM).<sup>IWGDF, 2016</sup> About 80% of non-traumatic lower limb amputations in diabetic patients are preceded by a foot ulcer. Around 50% of people with diabetes die within five years of developing a foot ulcer, and up to 70% die within five years after an amputation.<sup>NICE, 2015</sup> It also accounts for substantial health care resources. Thus, it is a major burden to the patient, carers and the healthcare system.

According to World Health Organization, the global prevalence of diabetes among adults of >18 years of age has risen from 4.7% (108 million) in 1980 to 8.5% (422 million) in 2014.<sup>WHO, 2017</sup> According to the National Health and Morbidity Surveys, the prevalence of diabetes has been increasing from 11.6% in 2006 to 15.2% in 2011 and further 17.5% in 2015. The prevalence continued to increase in all age groups, from 5.5% among the 18 - 19 years of age, and reaching its highest at 39.1% among the 70 - 74 years of age.<sup>NHMS, 2015, level III</sup> Overall cost for management of type 2 diabetes mellitus (T2DM) in 2011 was RM1.40 billion corresponded to 9.21% of the entire MoH budget.<sup>Feisul IM et al., 2017, level III</sup>

The high prevalence of diabetes in adults increases the risk of foot problems, mainly due to neuropathy and/or peripheral arterial disease.<sup>NICE, 2015</sup> Up to 50% of patients with diabetes are asymptomatic of diabetic peripheral neuropathy<sup>ADA, 2017</sup> and about one million amputations are performed on diabetic patients each year worldwide.<sup>IWGDF, 2016</sup> Diabetic foot requires careful attention and coordinated management, preferably by a multidisciplinary foot care team. Optimal management of diabetic foot can reduce the incidence of infection-related morbidities, the need and duration for hospitalisation, and the incidence of major limb amputation.<sup>Lipsky BA et al., 2004</sup> Intensive efforts by all healthcare providers is required and guidelines are needed to ensure standardisation in diabetic foot care.

This evidence-based CPG is an updated version replacing the first edition of 2004. It is meant to address the main issues related to the aspects of care for diabetic foot especially the variation in practices in local setting. This CPG will help to identify diabetic patients at risk of foot complications and standardise the management in an evidence-based approach.

## 2. ASSESSMENT

All patients with DM should be assessed for diabetes foot at risk. They should be screened, diagnosed, classified and stratified to ensure optimal management.

### 2.1 Screening

#### a. Peripheral Neuropathy

Peripheral neuropathy of the foot is a common complication in patients with DM. It accounts for up to 50% of patients.<sup>Tesfaye S et al., 2010, level III</sup> It may involve large fibre nerves (for touch, vibration, position perception and muscle control), small fibre nerves (for thermal perception, pain and autonomic function) or both. As half of the diabetic patients with peripheral neuropathy are asymptomatic, screening is important to identify those with diabetic foot at risk.<sup>ADA, 2017</sup>

Screening for peripheral neuropathy should be performed on all patients with DM. Early detection and interventions of diabetic foot at risk will minimise complications and healthcare cost.<sup>MoH, 2004</sup> There are various screening tools that can be used and these are discussed below.

- **Semmes-Weinstein monofilament examination**

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 the touch/pressure indicates loss of protective sensation (LOPS). Refer to **Appendix 3** on **Semmes-Weinstein Monofilament Examination**.

In patients with DM compared with nerve conduction study (NCS), SWME had the following features in detecting diabetic peripheral neuropathy.<sup>Feng Y et al., 2009, level III</sup>

- sensitivity: 57% (95% CI 44 to 68) to 93% (95% CI 77 to 99)
- specificity: 75% (95% CI 64 to 84) to 100% (95% CI 63 to 100)

In patients (aged <18 years old) with type 1 diabetes mellitus (T1DM), compared with NCS, SWME had a sensitivity and specificity of 19 - 73% and 64 - 87% respectively.<sup>Hirschfeld G et al., 2014, level III</sup>

In a meta-analysis of 19 diagnostic studies, the pooled sensitivity and specificity of SWME for detecting diabetic peripheral neuropathy in diabetes as compared with NCS were 0.53 (95% CI 0.32 to 0.74) and 0.88 (95% CI 0.78 to 0.94) respectively.<sup>Wang F et al., 2017, level III</sup>

- **Tuning fork**

Tuning fork is used to detect the loss of vibration sense. The commonly used tuning fork is 128-Hz.

In patients (aged <18 years old) with T1DM, compared with NCS, tuning fork has a sensitivity and specificity of 1 - 19% and 87 - 99% respectively.<sup>Hirschfeld G et al., 2014, level I</sup>

In patients with DM compared to vibration perception threshold (VPT), tuning fork has a sensitivity and specificity of 97% and 42% respectively.<sup>Kästenbauer T et al., 2004, level III</sup>

- **Neuropen**

Neuropen consists of a 10-g monofilament at one end of the tool to assess touch/pressure sensation and a Neurotip™ at the other end to test pain sensation.

In adult patients with DM compared with VPT, Neuropen has sensitivity and specificity of 74.0 - 81.6% and 68.0 - 83.0% respectively.<sup>Bracewell N et al., 2012, level III; Paisley AN et al., 2002, level III</sup>

In adult diabetic patients, compared with neuropathy disability score (NDS), Neuropen has a sensitivity and specificity of 81.5% and 71.0% respectively.<sup>Paisley AN et al., 2002, level III</sup>

- **Ipswich Touch Test**

Ipswich Touch Test (IpTT) is performed by touching the tip of the index finger for 1 - 2 seconds on the tips of the first, third and fifth toes of both feet. The presence of LOPS is defined as IpTT score ≤4 insensate of the six sites.

In patients with DM, IpTT with ≥2 of six insensate areas, compared with a VPT of ≥25 V which signifies at-risk feet, has a sensitivity of 76 - 85% and specificity of 90 - 92%.<sup>Madanat A et al., 2015, level III; Rayman G et al., 2011, level III</sup>

In patients with DM, IpTT accuracy is comparable with SWME. The sensitivities and specificities are:<sup>Sharma S et al., 2014, level III</sup>

- 81.2% and 96.4% respectively if performed by healthcare providers
- 78.3% and 93.9% respectively if performed by caregivers

- **VibraTip**

VibraTip provides a constant vibratory stimulus at 128-Hz for vibration sense examination. VibraTip has a sensitivity and specificity of 79.0 - 92.0% and 82.0 - 94.0% respectively compared with VPT in diabetic patients. Nizar H et al., 2014, level III; Bracewell N et al., 2012, level III

However, NICE medical technology guidance recommends that high quality diagnostic accuracy study comparing VibraTip with 10-g monofilament and calibrated tuning fork is needed to establish its effectiveness. NICE, 2014

- **Neuropad**

Neuropad is an indicator pad applied to both soles at the level of the first through second metatarsal heads for 10 minutes. In the presence of moisture from sweating, the time for colour to change from blue to uniform pink in the indicator test is recorded. A colour change of >10 minutes indicates sudomotor dysfunction.

In adult patients with T2DM, compared with NDS, Neuropad has a sensitivity and specificity of: Papanas N et al., 2011, level III

- 95% and 75% respectively, if NDS  $\geq 3$  (mild neuropathy)
- 91% and 96% respectively, if NDS  $\geq 6$  (moderate neuropathy)
- 91% and 95% respectively, if NDS  $\geq 9$  (severe neuropathy)

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%. Assessment of peripheral neuropathy should be performed at diagnosis and repeated annually. CPG T2DM, 2016

## **b. Peripheral Arterial Disease**

Screening of peripheral arterial disease (PAD) should be done annually in all patients with DM. This includes a minimum of history taking and complete physical examination especially palpating foot pulses. IWGDF, 2016

Use of bedside non-invasive tests to exclude PAD is recommended. Among the tests that can be used are ankle brachial index (ABI), toe brachial index (TBI) and continuous wave Doppler (CWD). PAD can be excluded when: IWGDF, 2016

- ankle brachial index (ABI) is 0.9 - 1.3
- toe brachial index is  $\geq 0.75$
- there is presence of triphasic pedal Doppler arterial waveforms (PDAW)

Refer to **Appendix 5 on Diabetic Foot Assessment Form.**

### **Recommendation 1**

- Screening for diabetic peripheral neuropathy and peripheral arterial disease (PAD) should be performed on all diabetes mellitus patients at diagnosis and repeated at least annually.
  - Semmes-Weinstein monofilament examination should be combined with another modality\* in the screening of peripheral neuropathy.
  - Palpation of foot pulses should be the initial screening method for PAD.

\*pin prick or 128-Hz tuning fork

## 2.2 Diagnosis

### a. History

Proper management of diabetic foot is initiated by good history taking. It includes general, medical and local diabetic foot history.

Predictors for increased risk of foot ulceration in diabetes are:<sup>Crawford F et al., 2015, level I</sup>

- previous history of ulceration or lower extremity amputations (OR=6.59, 95% CI 2.49 to 17.45)
- longer duration of diabetes (OR=1.02, 95% CI 1.01 to 1.04)
- at least one absent pedal pulse (OR=1.97, 95% CI 1.62 to 2.39)
- inability to feel a 10-g monofilament test (OR=3.184, 95% CI 2.65 to 3.82)

### b. Physical Assessment

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

#### • Skin

Skin changes due to vascular insufficiency such as skin atrophy, nail atrophy, diminished pedal hair, prolonged capillary refill time (>2 seconds) and reduced skin temperature are important to be looked for during skin assessment.<sup>CPG DF, 2004</sup>

#### • Vascular

- Vascular assessment includes mandatory palpation of the femoral, popliteal, posterior tibial and dorsalis pedis artery pulses.

Compared with colour flow duplex ultrasound (CFDU) as the reference standard, non-invasive vascular assessment using CWD, ABI and TBI for detecting peripheral arterial disease in diabetic foot show highest sensitivity and specificity in CWD (74.19% and 92.86% respectively). On the other hand, ABI has a sensitivity and specificity of 45.16% and 92.68%.<sup>Tehan PE et al., 2016, level III</sup> In local setting, ABI is widely used due to its feasibility. The results of ABI may be misleading due to calcification of the arteries which give higher pressure ratio. The normal ratio is in the range of 0.9 - 1.3.

Critical limb ischaemia is defined as rest pain with ulcers or tissue loss attributed to arterial occlusive disease. It is associated with great loss of limb and life.<sup>Slovut DP, 2008, level III</sup> Patients with this condition should be referred urgently to specialist care.

#### • Musculoskeletal

Musculoskeletal complications in diabetic foot include ulcers, infections and deformities (e.g. Charcot's Arthropathy). These complications have been given less attention compared to other complications.

Probe-to-bone test is a clinical technique used in diabetic patients with a foot infection consisting of exploring the wound for palpable bone with a sterile blunt metal probe. A positive test is defined as palpating a hard or gritty substance that is presumed to be bone or joint space. It is a useful clinical modality in the assessment of osteomyelitis in diabetic foot. It has a sensitivity and specificity of 87% and 83% respectively, when compared with magnetic resonance imaging (MRI), bone histopathology or bone culture.<sup>Lam K et al., 2016, level III</sup>

- **Neurological**

Monofilament test and vibration perception are used to assess peripheral neuropathy, which is a major independent risk factor for diabetic foot ulceration. Sensory examination with a 5.07/10-g SWME monofilament is the single most practical and widely used assessment tool.<sup>CPG DF, 2004</sup>

Refer to **Appendix 5 on Diabetic Foot Assessment Form.**

## 2.3 Investigation

### a. Laboratory

There is no evidence on laboratory investigation in supporting the diagnosis of diabetic foot except in active infection.

### b. Imaging

Imaging is part of management in diabetic foot presented with ulcers, infections and deformities. The imaging modalities used are discussed below.

- **Conventional radiography**

Conventional radiography is the initial imaging modality for diabetic foot which is inexpensive and readily available. It is able to demonstrate major structural changes and its anatomical distribution.<sup>Peterson N et al., 2017, level III</sup> Possible findings are osteolysis, arterial calcification, gas shadow, malalignment and peri-articular fragmentation.

Features of osteomyelitis may not be visualised in plain radiographs until 10 - 21 days after the initial infection.<sup>Smith BJ et al., 2017, level III</sup>

- It is important to note that osteomyelitis may be present in a person with diabetes mellitus despite normal inflammatory markers, plain radiographs or probe-to-bone testing.<sup>NICE, 2015</sup>

- **Computed tomography**

Computed tomography (CT) is useful in the assessment of chronic osteomyelitis as presence of sequestrum, cloaca and involucrum can be seen in the images. However, it does not have significant advantage over plain radiograph. It is also unable to detect bone marrow oedema at early stage of infection.<sup>Peterson N et al., 2017, level III</sup>

- **Magnetic resonance imaging**

Magnetic resonance imaging (MRI) is the primary imaging modality for investigating infection in diabetic foot. In the diagnosis of osteomyelitis, MRI can be considered when it is not detected by plain radiograph.<sup>NICE, 2015</sup> MRI has a sensitivity and specificity of 93% and 75% in detecting osteomyelitis when compared with bone histopathological or culture.<sup>Lauri C et al., 2017, level III</sup>

- **Others**

Other modalities used in detection of osteomyelitis are:<sup>Lauri C et al., 2017, level III</sup>

- fluorodeoxyglucose positron emission tomography (<sup>18</sup>F-FDG-PET)
- radiolabeled white blood cell (WBC) Scintigraphy (<sup>111</sup>In-oxine)
- radiolabeled white blood cell WBC Scintigraphy (<sup>99m</sup>Tc-HMPAO)
- positron emission tomography (PET) scan has had limited use in clinical practice due to high cost and poor availability; however, in the future it may become more cost-effective as this modality has demonstrated a high level of diagnostic value.<sup>Smith BJ et al., 2017, level III</sup>

## 2.4 Risk Stratification

Patient's current risk of developing a diabetic foot or requiring an amputation is assessed using the risk stratification as shown in **Table 1**.

**Table 1. Diabetic foot risk stratification**

Diabetic foot risk	Findings
<b>Normal</b>	No abnormalities
<b>Low Risk</b>	Callus alone
<b>Moderate Risk</b>	Any of the following: <ul style="list-style-type: none"> <li>• deformity</li> <li>• neuropathy</li> <li>• non-critical limb ischaemia</li> </ul>
<b>High Risk</b>	One of the following: <ul style="list-style-type: none"> <li>• previous ulceration</li> <li>• previous amputation</li> <li>• on Renal Replacement Therapy</li> <li>• neuropathy and non-critical limb ischaemia</li> <li>• neuropathy and callus and/or deformity</li> <li>• non-critical limb ischaemia and callus and/or deformity</li> </ul>
<b>Active Diabetic Foot Problem</b>	Any of the following: <ul style="list-style-type: none"> <li>• ulceration</li> <li>• infection</li> <li>• critical limb ischaemia</li> <li>• gangrene</li> <li>• suspicion of an acute charcot arthropathy, or an unexplained hot, red, swollen foot with or without pain</li> </ul>

Source: National Institute for Health and Care Excellence. Diabetic Foot Problems: Prevention and Management. London: NICE; 2015

- Patients with active diabetic foot problem should be referred urgently and seen within 24 hours in secondary/tertiary care.

## 2.5 Classification

Diabetic foot is classified according to nature and severity of the disease. The commonly used classifications are Meggitt–Wagner (MW) and University of Texas (UT). Others include:

- Site, ischaemia, neuropathy, bacterial infection and depth (SINBAD)
- Perfusion, Extent, Depth, Infection and Sensation (PEDIS)
- Diabetic ulcer severity score (DUSS)
- Depth of the ulcer, extent of bacterial colonisation, phase of ulcer and association aetiology (DEPA)
- Size (area, depth), sepsis, arteriopathy, denervation system [S(AD)SAD]
- Curative Health Services (CHS)

There is moderate agreement between healthcare providers in the assessment of diabetic foot ulcer (DFU) using MW ( $\kappa=0.415$ , 95% CI 0.413 to 0.418) and UT ( $\kappa=0.447$ , 95% CI 0.443 to 0.50).<sup>Santema TB et al., 2016, level III</sup>

Multiple observers of multidisciplinary healthcare professionals improve reliability of three scoring systems (SINBAD, PEDIS and UT) in assessment of DFU ( $\kappa=0.94$  for UT,  $\kappa=0.91$  for SINBAD and  $\kappa=0.80-0.90$  for PEDIS).<sup>Forsythe RO et al., 2016, level III</sup>

All available systems (DUSS, UT, MW, DEPA and SINBAD) has substantial accuracy (AUC>0.8) in prediction of amputation.<sup>Jeon BJ et al., 2017, level III</sup>

In a systematic review, the classification systems for DFU prediction on lower extremity amputation had a wide range of sensitivity and specificity:<sup>Monteiro-Soares M et al., 2014, level II-2</sup>

- 45.2 - 97.4% and 65.0 - 85.8% respectively in MW (grade  $\geq 3$ )
- 52.2% and 87.5% respectively in S(AD)SAD (score>9)
- 37.6 - 67.4% and 72.6 - 80.1% respectively in CHS wound grade scale (grade $\geq 3$ )
- 100% and 49.2% respectively in DEPA (score $\geq 7$ )

Pooled accuracy on DFU characterisation variables, ranged from 0.65 (for gangrene) to 0.74 (for infection).

Of all the classification systems mentioned above, the UT and MW systems are simple and easy to use. However inclusion of stage in UT system makes it a better predictor of outcome.<sup>Oyibo SO et al., 2001, level II-2</sup> Refer to **Appendix 6 on University of Texas Classification.**

### Recommendation 2

- University of Texas Classification is the preferred classification for diabetic foot.

## 3. REFERRAL

Patients who are at moderate or high risk of developing a diabetic foot problem are referred to the multidisciplinary professionals in the field of podiatry, diabetology, biomechanics and orthoses, and wound care.<sup>NICE, 2015</sup>

Patients 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 ischaemia [refer to **Section 2.2. (b)** on vascular assessment]
- clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration)
- gangrene (with or without ulceration)

The recommended referral schedule for the diabetic foot is shown in the following table.

**Table 2. Recommended referral schedule**

Risk	Referral
<b>Normal/Low risk</b>	No referral needed. Yearly review at primary care
<b>Moderate risk</b>	Referral within three months to foot protection services
<b>High risk</b>	Early referral within two weeks to foot protection services
<b>Active diabetic foot problem</b>	Urgent referral within 24 hours to multidisciplinary foot care team

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

### 3.1 Foot Protection Team

Foot protection service provides services in prevention of diabetic foot problems for low, moderate and high risk feet and management of simple active diabetic foot problems in the community that do not require admission.<sup>NICE, 2015</sup> Foot protection team should be led by a Family Medicine Specialist or physician with special training in diabetic foot problems and supported by diabetic team (including diabetic educators), wound care team and rehabilitation services.

### 3.2 Multidisciplinary Foot Care Team

Presence of a multidisciplinary team may improve rates of amputation, hospital admission and length of stay. It is recommended that each hospital should have a multidisciplinary foot care service consisting of specialists in diabetes management, orthopaedic surgeons, vascular surgeons, rehabilitation physicians, diabetes educators, wound care team, etc. This team manages active or complex diabetic foot problems according to available guidelines.<sup>NICE, 2015</sup>

#### Recommendation 3

- Active or complicated diabetic foot problems should be managed by a multidisciplinary foot care team.

## 4. PREVENTION

### 4.1 Patient Education

Patients with neuropathy tend to ignore signs of injury due to lack of normal pain response. This will influence patient's adherence to self-care. Thus, intense education on foot care is necessary to reduce diabetic foot complications. Education should be structured and done at regular intervals repetitively for the prevention of the foot problems.<sup>IWGDF, 2016</sup>

Patient education can be provided by a physician, podiatrist or skilled healthcare practitioner providing dedicated time to explain the basic care of the foot, callus and nail. This should be done annually.<sup>IWGDF, 2016</sup>

- Healthcare professionals providing foot-care education should receive regular and updated education in the management of patients at risk for foot ulceration.

Temperature monitoring as "self-assessment tool for high-risk diabetic foot" significantly decreases risk of developing foot ulceration compared with standard therapy and structured foot examination.<sup>vanNetten JJ et al., 2016, level I</sup> However, more evidence is required to show its effectiveness.

In prevention of ulcer recurrence, education as part of integrated foot care programme, together with life-long observation, professional foot treatment and adequate footwear, should be done one to three monthly.<sup>IWGDF, 2016</sup>

Refer to **Appendix 4 on Patient education materials.**

#### Recommendation 4

- Patient education should be an integral part in the management of diabetic foot at least annually and more frequent in higher risk patients.

#### 4.2 Metabolic Control

Hyperglycaemia causes increased risk of microvascular and macrovascular complications in diabetes. This increased risk is associated with foot ulcerations that may lead to limb amputations.

In a systematic review, intensive control [haemoglobin A1c (HbA1c) 6 - 7.5%] compared with less intensive glycaemic control showed:<sup>Hasan R et al., 2016, level I</sup>

- decrease in risk of amputation (RR=0.65, 95% CI 0.45 to 0.94)
- slower decline in sensory vibration threshold (MD= -8.27, 95% CI -9.75 to -6.79)

However, there was no effect on other neuropathic changes (RR=0.89, 95% CI 0.75 to 1.05) or ischaemic changes (RR=0.92, 95% CI 0.67 to 1.26).

In a Cochrane systematic review on the prevention of diabetic neuropathy, intensive glycaemic control (HbA1c <7.0%) compared with less intensive glycaemic control significantly reduced the risk of developing neuropathy in T1DM but not in T2DM at ≥12 months follow-up. However, this was associated with an increased risk of severe hypoglycaemia, weight gain, hospitalisations and deaths in both T1DM and T2DM.<sup>Callaghan BC et al., 2012, level I</sup>

Glycaemic control must be individualised.<sup>T2DM, 2016</sup> Targets of HbA1c individualised to patient's profile is shown in **Table 3**. Adequate glycaemic control with minimisation of hypoglycaemia is advocated to reduce the incidence of DFUs and infections, with subsequent risk of amputation.<sup>Hasan R et al., 2016, level I</sup>

**Table 3. Individualised HbA1c targets**

Individualised A1c targets and patient's profile		
Tight (6.0 - 6.5%)	6.6 - 7.0%	Less tight (7.1 - 8.0%)
<ul style="list-style-type: none"><li>• Newly diagnosed DM</li><li>• Younger age</li><li>• Healthier [long life expectancy, no cardiovascular disease (CV) complications]</li><li>• Low risk of hypoglycaemia</li></ul>	<ul style="list-style-type: none"><li>• All others</li></ul>	<ul style="list-style-type: none"><li>• Co-morbidities (coronary disease, heart failure, renal failure, liver dysfunction)</li><li>• Short life expectancy</li><li>• Prone to hypoglycaemia</li></ul>

Source: Malaysian Endocrine & Metabolic Society and Ministry of Health Malaysia. Management of Type 2 Diabetes Mellitus (5th Edition). Kuala Lumpur: MEMS & MoH; 2015

#### Recommendation 5

- Glycaemic control (with minimisation of hypoglycaemia) in the prevention of diabetic foot should be individualised.

#### 4.3 Preventive Foot Wear

Mechanical loading of the feet during activities, e.g. walking or standing, exposes pressure on the plantar surface causing compression and shear stress. The pressure and stress are

aggravated by foot deformities (e.g. hammer and claw toes) which are common in patients with diabetes.

Appropriate footwear is important for all patients with diabetes. Its importance increases with higher risk of developing DFU. Recommendations of footwear according to foot risk status are shown in **Table 4.** van Netten et al., 2018

- The following should be checked each time before and after wearing the footwear:
  - presence of foreign or penetrating objects
  - signs of abnormal pressure, trauma or ulceration of the feet
- Patients and caregivers should be educated on the appropriate footwear to prevent foot ulceration.

**Table 4. Footwear advice**

Risk status	Actions
All foot at-risk	<ul style="list-style-type: none"> <li>• Advise on using footwear that fits, protects and accommodates the shape of the feet (with socks). Refer to <b>Appendix 6 on Footwear advice.</b></li> </ul>
Moderate or high-risk	<ul style="list-style-type: none"> <li>• Prescribe footwear with:               <ul style="list-style-type: none"> <li>○ custom-made in-shoe orthoses or insoles for people with foot deformity or pre-ulcerative lesions</li> <li>○ off-loading orthoses or insoles for people with healed plantar foot ulcer</li> </ul> </li> <li>• Review prescribed footwear periodically to ensure it still fits, protects, and supports the foot</li> <li>• Advise on wearing footwear at all times, both indoors and outdoors</li> </ul>
Foot ulceration	<ul style="list-style-type: none"> <li>• Prescribe appropriate offloading devices for ulcer healing</li> </ul>

**Adapted:** van Netten JJ, Lazzarini PA, Armstrong DG, et al. Diabetic Foot Australia guideline on footwear for people with diabetes. J Foot Ankle Res. 2018;1:2

In a systematic review on footwear and off-loading interventions in diabetes patients with neuropathy: Bus SA et al., 2015, level I

- custom-made insoles showed fewer recurrent metatarsal head ulcers compared with standard insoles at 15 months (p=0.007)
- custom-made footwear with in-shoe plantar pressure reduction significantly reduced foot ulcer incidence when worn >80% daily compared with custom-made footwear without in-shoe plantar pressure reduction (25.7% vs 47.8%)

Intensive footwear therapy with prescribed footwear had significantly reduced first/recurrent ulcer compared with ready-made footwear in diabetes patients with neuropathy, deformity, previous ulceration and minor amputation.

**Recommendation 6**

- Patients with diabetes should be advised on appropriate footwear according to the foot risk.

**4.4 Preventive Surgery**

Preventive foot surgery is a procedure to prevent foot ulceration or re-ulceration in patients with diabetes. It is important to consider history of previous ulceration and/or amputation when assessing a patient for preventive surgery to set treatment strategy and determine prognosis.

### a. Gastrocnemius-soleus fascia recession

Gastrocnemius-soleus fascia recession performed on plantar ulcers under the metatarsal heads in diabetic foot patients with neuropathic ulcer (Wagner grade 2 or 3):<sup>van Bael K et al., 2016, level II-3</sup>

- Increases ankle dorsiflexion to 14.5° and mobility at two weeks post-operation
- complete ulcer healing in 71% of patients at 20 days post-operation and the remaining at 30 - 34 days post-operation
- no ulcer recurrences and remains free of new ulcers in other areas at one year

Adverse events of the procedure are:

- subcutaneous hematoma (completely resolve within three weeks)
- neuropraxia of the sural nerve (persist for several months)

### b. Achilles tendon lengthening (modified White's technique)

Achilles tendon lengthening shows:

- no recurrence of ulcer and improved foot function in 92% of diabetic foot patients with history of healed forefoot ulcers, neuropathy, dorsiflexion of  $\leq 18^\circ$  and good vascularity<sup>Batista F et al., 2011, level II-3</sup>
- significantly less recurrence of ulcers at seven months follow-up in patients with total contact cast compared with those with total contact cast alone (15% vs 59%) and persists at two years (38% vs 81%)<sup>van Netten JJ et al., 2016, level I</sup>
- no major adverse events<sup>van Netten JJ et al., 2016, level I</sup>

### c. Percutaneous Tenotomy

When percutaneous tenotomy is performed, the ulcers at the:

- tip of the toe without osteomyelitis heal within three weeks<sup>Tamir E et al., 2008, level III</sup>
- tip of the toe with osteomyelitis heal within eight weeks<sup>Tamir E et al., 2008, level III</sup>
- tip of the toe heal in 98% of ulcers<sup>Tamir E et al., 2014, level III</sup>
- dorsal aspect of the toes heal in in 92% of ulcers at four weeks<sup>Tamir E et al., 2014, level III</sup>
- plantar metatarsal head do not heal<sup>Tamir E et al., 2014, level III</sup>

There are no serious complications following the procedure.<sup>Tamir E et al., 2014, level III; Tamir E et al., 2008, level III</sup>

### d. Osteotomy

Corrective surgery performed on metatarsal head ulcers shows lower rate of recurrence and amputation compared with conservative treatment ( $p=0.0013$ ).<sup>van Netten JJ et al., 2016, level I</sup>

Preventive surgery should only be done by foot and ankle surgeons or general orthopaedic surgeon privileged for these procedures.

#### Recommendation 7

- Preventive surgeries by orthopaedic surgeons trained in the procedures may be considered to prevent ulceration or re-ulceration in diabetic patients with foot deformity\*.

\*restricted ankle dorsiflexion, equinus contracture, claw toe, hammer toe or mallet toe

## 5. TREATMENT

### 5.1 Pharmacotherapy

The main pharmacotherapies in diabetic foot are analgesics and antimicrobial agents.

### a. Analgesics

The causes of pain in diabetic foot are peripheral neuropathy, ischaemia and infection. The treatment is similar with other painful conditions.

For mild to moderate pain, the WHO analgesic ladder recommends using simple analgesics (e.g. paracetamol or non-steroidal anti-inflammatory drugs). Additional weak opioids (e.g. tramadol or dihydrocodeine) should be considered in moderate pain. Strong opioids like morphine should be offered to patients with moderate to severe pain. In neuropathic pain, adjuvants are used at all steps of the analgesic ladder.<sup>MoH, 2013(a)</sup> Examples of the adjuvants are antidepressant (e.g. amitriptyline or duloxetine) and anticonvulsant (e.g. gabapentin or pregabalin).<sup>MoH, 2013(b)</sup>

### b. Topical antimicrobial

Wound treatments aim to alleviate symptoms, promote healing and avoid adverse outcomes. Topical antimicrobial therapy has been used on DFUs, either for treatment of clinically infected wounds or for prevention of infection in uninfected wounds. There are two major groups of topical antimicrobials which are discussed below. Refer to **Appendix 8 on Types of infections in diabetic foot and suggestion of treatment.**

#### • Antiseptics

Antiseptics are a type of disinfectant that can be used on intact skin and some open wounds to kill or inhibit micro-organisms.

Iodine dressing is commonly used in infected wound in the local setting. A systematic review showed that antiseptic effect of iodine was not inferior to other antiseptic agents and did not impair wound healing.<sup>Vermeulen H et al., 2010, level I</sup>

Although there is no recent evidence on chlorhexidine, it has been widely used as wound antiseptics locally.

#### • Topical antibiotics

Most topical antibiotics used in diabetic foot have efficacy against gram-positive bacteria (e.g. bacitracin, mupirocin, retapamulin), with a smaller number demonstrating efficacy against gram-negative bacteria (e.g. neomycin, silver sulphadiazine). Some antibiotics that are used systemically (e.g. gentamicin, metronidazole, clindamycin) have also been formulated for topical use.<sup>Dumville JC et al., 2017, level I</sup>

In a Cochrane systematic review, topical antimicrobial dressing was more effective than non-antimicrobial dressing in wound healing of diabetic foot (RR=1.28, 95% CI 1.12 to 1.45). However, there were no significant difference in adverse events between topical antimicrobial agent and non-antimicrobial agent.<sup>Dumville JC et al., 2017, level I</sup>

The following topical antibiotics may be used in diabetic foot:<sup>Dumville JC et al., 2017, level I</sup>

- bacitracin C
- fusidic acid
- gentamicin
- getronidazole
- gupirocin
- neomycin
- silver sulphadiazine

### c. Systemic antibiotics

In a Cochrane systematic review, ertapenem with or without vancomycin was more effective in clinical resolution of infections than tigecycline in diabetic foot (RR=0.92, 95% CI 0.85 to 0.99). There was no significant difference in clinical resolution rates of infection in comparison of other antibiotics. There was also no significant difference in adverse events between different antibiotics.<sup>Selva Olid A et al., 2015, level I</sup>

In another Cochrane systematic review, there was no significant difference in MRSA eradication rate in non-surgical wounds (diabetic foot) in any of the following comparisons:<sup>Gurusamy KS et al., 2013, level I</sup>

- daptomycin vs vancomycin/semisynthetic penicillin (RR=1.13, 95% CI 0.56 to 2.25)
- ertapenem vs piperacillin/tazobactam (RR=0.71, 95% CI 0.06 to 9.10)
- moxifloxacin vs piperacillin/tazobactam followed by amoxicillin/clavulanate (RR=0.87, 95% CI 0.56 to 1.36)

- 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 (C&S) report.<sup>NAG, 2014</sup>
- 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, regimen with lowest cost should be selected. For moderate and severe infections, broad spectrum antibiotics are used initially until C&S results are available.<sup>NICE, 2015</sup>
- Antibiotics should not be given for:<sup>NICE, 2015</sup>
  - prevention of infections in diabetic foot
  - >14 days for the treatment of mild soft tissue infection in diabetic foot

### Recommendation 8

- Appropriate analgesia should be considered in painful diabetic foot.
- Antibiotics should be used as an adjunct to surgical debridement in infected diabetic foot.

## 5.2 Wound Management

Wound care is important in the management of diabetic foot. Ideally, it should alleviate symptoms, provide wound protection and facilitate healing. Selection of interventions (e.g. dressings and adjuvant therapy) will aid the healing process.

### a. Non-surgical Intervention

#### i. Dressing

Appropriate wound dressing is done to maintain adequate moisture and/or remove dead tissue. There are two types of dressing i.e. basic and advanced. Refer to **Appendix 9 on Types of wound dressings in diabetic foot.**

- **Basic wound contact dressings**

Basic wound contact dressing is the minimal dressing for diabetic ulcer in the absence of advanced wound dressings. It uses gauze with or without paraffin coating.

- **Advanced wound dressings**

Advanced wound dressings are used for dry, sloughy and/or wet wound. Two Cochrane systematic reviews of low to moderate quality clinical trials compared different dressings as follows:

- **Hydrogel dressing**

Hydrogel dressing significantly increased ulcer healing compared with basic wound contact dressings in diabetic foot.<sup>Wu L et al., 2015, level I</sup>

- **Alginate dressing**

There was no significance difference in ulcer healing between alginate and foam, silver-hydrofibre or basic wound contact dressings in diabetic foot.<sup>Wu L et al., 2015, level I</sup>

- **Hydrofibre dressing**  
There was no significance difference in ulcer healing between hydrofibre and iodine-impregnated or basic wound contact dressings in diabetic foot. <sup>Wu L et al., 2015, level I</sup>
- **Foam dressing**  
There was no significance difference in ulcer healing between between foam and alginate, matrix-hydrocolloid or basic wound contact dressings in diabetic foot. <sup>Wu L et al., 2015, level I</sup>
- **Hydrocolloid dressing**  
Fibrous-hydrocolloid dressings (with or without antimicrobial components) and hydrocolloid-matrix dressings showed no significant difference in the healing rates of DFUs compared with alternative dressings (e.g. basic wound contact dressing, alginate dressing or foam dressing). <sup>Dumville JC et al., 2013, level I</sup>
- **Other dressings**
  - Hyaluronic acid dressing significantly increased ulcer healing compared with basic wound care dressings. <sup>Wu L et al., 2015, level I</sup>
  - There was no significance difference in ulcer healing between iodine-impregnated dressing or protease-modulating matrix dressing and basic wound contact dressings. <sup>Wu L et al., 2015, level I</sup>

Meanwhile, silver-impregnated dressings should be reserved for use in wounds with or at risk of high bioburden or local infection. <sup>International Consensus, 2012, level III</sup>

There was no serious adverse event reported in one of the above reviews. It was concluded that there was no robust evidence on differences between wound dressings for any outcome in DFUs. Thus, healthcare providers may consider the cost of dressings and patient's preference when choosing the type of dressings for the patients. <sup>Wu L et al., 2015, level I</sup>

#### **Recommendation 9**

- Advanced wound dressings may be offered in diabetic foot ulcer.

#### **ii. Adjuvant therapy**

Adjuvant therapy is used to promote wound healing.

- **Negative pressure wound therapy**

Negative pressure wound therapy (NPWT) is a procedure in which a vacuum dressing is used to promote wound healing. It is used for clean exudative wounds with poor granulation.

In DFU, when compared with advanced moist wound therapy-hydrogels and alginate, NPWT shows:

- better wound healing <sup>Dumville JC et al., 2013, level I; Noble-Bell G et I., 2008, level I</sup>
- decreased foot ulcer surface areas ( $p=0.006$ ) <sup>Akbari A et al., 2007, level I</sup>
- shorter duration of therapy <sup>Dumville JC et al., 2013, level I; Noble-Bell G et I., 2008, level I</sup>
- fewer amputations ( $RR=0.35$ , 95% CI 0.17 to 0.74) <sup>Dumville JC et al., 2013, level I</sup>
- no significant difference in treatment-related complications (i.e. infection, cellulitis and osteomyelitis) <sup>Dumville JC et al., 2013, level I</sup>

- **Maggot debridement therapy**

Maggot is used for debridement of wounds with necrotic tissues.

Maggot debridement therapy (MDT) shows better wound closure (>50% of wound area) after 10 days compared with autolytic debridement with hydrogel in DFU. However, there is no significant difference in complete wound healing between both groups. <sup>Elraiyah T et al., 2016, level I</sup>

In a local technology review, MDT decreases wound size and prepares the wound for faster closure compared with conventional therapy. However, the rate of wound closure was not significantly higher than conventional therapy. More clinical research is warranted to provide further additional evidence on the effectiveness for its use in wound healing.<sup>MoH, 2008</sup>

- **Hyperbaric oxygen therapy**

Hyperbaric oxygen therapy (HBOT) is used to increase oxygenation and antimicrobial effect that can improve the healing of chronic ulcer.

Compared with hyperbaric air or standard care as adjunct treatment in DFU, HBOT shows:<sup>Elraiayah T et al., 2016, level I</sup>

- faster healing rate (OR=14.25, 95% CI 7.08 to 28.68)
- reduction in amputation rate (OR=0.30, 95% CI 0.10 to 0.89)

HBOT is more effective than control in chronic DFUs in terms of:<sup>Kranke P et al., 2015, level I</sup>

- improvement in transcutaneous oxygen tensions after treatment (RR=9.00, 95% CI 4.68 to 13.32)
- ulcers healing at six weeks (RR=4.61, 95% CI 2.3 to 9.08) and six months (RR=2.71, 95% CI 1.53 to 4.83)
- reduction of ulcers area (MD=18.10, 95% CI 1.40 to 34.79)
- reduction of major amputations (RR=0.20, 95% CI 0.10 to 0.38)

In a local study, 86.7% of patients in HBOT group achieved complete ulcer healing at six months follow-up compared with only 60% in the control group ( $p < 0.001$ ). It should be noted that HBOT is an adjunctive therapy to the standard management of chronic DFU.<sup>YazidMB et al., 2017, level II-1</sup>

### Recommendation 10

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

## b. Surgical Intervention

- **Revascularisation**

The prevalence of peripheral arterial disease (PAD) is 24% among urban high-risk Malaysian with diabetes.<sup>Amudha K et al., 2003</sup> Revascularisation improves the healing of ischaemic diabetes ulcer. Without revascularisation, patients with DFU are at higher risk of having an amputation. Revascularisation, when feasible, can be achieved either by bypass surgery or endovascular procedures.<sup>Heikkila K et al., 2018, level II-2</sup>

In a Cochrane systematic review on patients requiring revascularisation, compared with percutaneous transluminal angioplasty (PTA), bypass surgery had higher:<sup>Antoniou GA et al., 2017, level I</sup>

- technical success rates (OR=2.26, 95% CI 1.49 to 3.44)
- primary patency rate at one year (OR=1.94, 95% CI 1.20 to 3.14)

However, in the same review, bypass surgery and endovascular treatment showed no difference in clinical improvement, amputation rates, re-intervention rates or mortality within the follow-up period in patients with chronic limb ischaemia. In patients with high surgical risk, endovascular treatment may be advisable.<sup>Antoniou GA et al., 2017, level I</sup>

In another systematic review, open surgery showed higher limb salvage rates and lower minor amputation rates compared with endovascular procedure in diabetes patients with ulcerated foot. Major amputation was only 3.5% within 30 days post-revascularisation.<sup>Hinchliffe</sup>

There was also no significant difference between both intervention modalities in terms of early post-interventional non-thrombotic and peri-interventional complications.<sup>Antonίου GA et al., 2017, level I</sup> Special precautions should be considered in patients with renal impairment in procedures where intravascular contrast is used.<sup>MoH CKD, 2018</sup>

A Cochrane systematic review of moderate quality primary papers which included diabetes with PAD, antiplatelet therapy (with aspirin or aspirin plus dipyridamole) vs placebo or no treatment after peripheral arterial bypass surgery at 12 months showed better primary grafts patency (OR=0.42, 95% CI 0.22 to 0.83) especially in prosthetic grafts.<sup>Bedenis R et al., 2015, level I</sup>

### Recommendation 11

- Revascularisation should be offered in diabetes patients with peripheral arterial disease.
  - Antiplatelet therapy should be considered as part of post-revascularisation treatment.

### • Debridement

Debridement is a process of removing necrotic or foreign tissue from a wound to promote healing. There are three common types of debridement which are autolytic, mechanical and sharp (surgical).

In a systematic review, an old randomised control trial (RCT) comparing surgical debridement and conventional wound dressing in DFUs showed:<sup>Elrayah T et al., 2016, level I</sup>

- shorter healing time with surgical debridement (46.7 vs 128.9 days;  $p < 0.001$ )
- no significant difference in healing rate, infective complications and relapses of ulcerations

NICE guidelines recommend that debridement of DFU in either hospital or community should only be done by healthcare professionals with relevant training and skills.<sup>NICE, 2015</sup>

Although there is insufficient evidence, the CPG DG opines that surgical debridement is a good option as it has shown good wound closure and rapid wound healing based on clinical experience. It is done when the non-surgical debridement fails or when the wound is deep and infected.

### Recommendation 12

- Surgical debridement by trained healthcare providers should be considered in diabetic foot ulcer which:
  - fails to respond to non-surgical debridement
  - is deep and infected at presentation

### • Reconstruction

Soft-tissue reconstruction in diabetic foot is a challenge and usually delayed until the patient is optimised medically, and the infection is well-controlled. Primary closure of the wound may not be feasible and secondary healing may not be reliable if the infection is not well-controlled. Therefore, reconstruction surgery (e.g. skin grafts, flaps or tissue expansion) is vital in the management for patients with diabetic foot.

In a Cochrane systematic review, treatment of foot ulcers using skin grafts/tissue replacements showed:<sup>Santema TB et al., 2016, level I</sup>

- higher incidence of complete closure (RR=1.49, 95% CI 1.21 to 1.85)
- lower incidence of lower limb amputations (RD= -0.06, 95% CI -0.10 to -0.01)
- lower incidence of infections (RR=0.72, 95% CI 0.53 to 0.98)
- no significant difference in ulcer recurrence

Dermal or skin grafting should be considered as an adjunct to standard care when the healing of DFU has not progressed with the advice of multidisciplinary foot care service.<sup>NICE, 2015</sup>

### Recommendation 13

- Skin grafting may be considered as an adjunct to standard care in the management of diabetic foot ulcer.

## c. Rehabilitation

### ● Ulcer management

Off-loading is a key treatment strategy for the management of DFU. It can be done by using non-removable [e.g. total contact cast (TCC) and instant total contact cast] or removable (e.g. removable cast walker, therapeutic footwear and padding) devices.

Non-removable off-loading devices are more effective in healing DFUs compared with removable devices.<sup>Bus SA et al., 2015, level I; de Oliveira AL et al., 2015, level I; Lewis J et al., 2013, level I</sup>

TCC or walkers rendered irremovable are more effective in healing neuropathic plantar forefoot ulcers than walkers/footwear.<sup>Bus SA et al., 2015, level I</sup> TCC has shorter healing time by 12 days than removable cast walker in the management of DFU.<sup>Elrayah T et al., 2016, level I</sup>

No adverse events has been reported in the use of non-removable or removable off-loading devices.<sup>Bus SA et al., 2015, level I; de Oliveira AL et al., 2015, level I</sup>

Other available off-loading options include use of assistive devices e.g. crutches, wheelchair, walking frames and canes.<sup>CPG DF, 2004</sup>

Surgical treatment is indicated for chronic DFU or deformed diabetic foot with high plantar pressure which is not amenable to therapeutic footwear or off-loading techniques.<sup>CPG DF, 2004</sup>

### ● Post-amputation rehabilitation

Amputation is done to remove non-viable tissues due to infection and gangrene. It is performed to allow optimum function of the affected limb.<sup>CPG DF, 2004</sup> Rehabilitation of amputees encompasses pre-amputation, post-operative, pre-prosthetic and prosthetic stage, within which an amputee is provided with prosthesis. It also includes subsequent long-term monitoring and follow-up. Multidisciplinary approach is required to achieve successful re-integration of an amputee into the community.

The goals of rehabilitation for patients with amputations are as follows:<sup>SA Guidelines, level III</sup>

- musculoskeletal re-conditioning and cardiopulmonary training
- contralateral limb preservation
- emotional care related to concepts of loss, mourning and the need for peer support and education
- minimisation of systemic complications
- social re-integration
- setting realistic patient expectations and functional outcome goals

Outcomes of patients with amputations as the following.<sup>VA/DoD Guidelines, 2017, level III</sup>

- Patients with more distal amputation have better long-term functional outcomes e.g. patients with transmetatarsal amputation or toe amputation have increased ability to complete activity of daily livings compared with patients with more proximal amputation levels e.g. transtibial or transfemoral amputation.
- Patients with transtibial amputation have better mobility and decreased wheelchair used compared with patients with transfemoral amputation, hence demonstrating better quality of life. These observations were also noted in patients with knee disarticulation compared with patients with transfemoral amputation.
- Longer residual limb length helps to optimise a patient's ability in ambulation. Preserving maximum residual limb length will likely lead to improved rehabilitation outcomes for most patients. Prosthesis will be prescribed for patients with good cognitive function, vision, CV reserve and healed residual stump.

#### Recommendation 14

- Off-loading should be offered to patients with plantar diabetic foot ulcer.
- All patients with diabetic foot who has amputation should be referred for rehabilitation.

## 6. MONITORING AND FOLLOW-UP

Frequency of monitoring of patients with diabetic foot depends on risk stratification as shown below:

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

Consider:

- training caregivers in foot assessment for patients who are unable to check their own feet
- the overall health of the patients and the progression/deterioration of wound healing in deciding the frequency of follow-up as part of the treatment plan

Ensure that the frequency of monitoring in the patients individualised treatment plan is maintained whether the diabetic patients are being treated in hospital or health clinic.

## 7. CHARCOT NEUROARTHROPATHY

Charcot neuroarthropathy (CN) is common in patient with diabetes. Foot ulceration develops in 34% of patients with CN, and is 12 times more likely to undergo amputation when ulceration has developed.<sup>Sohn MW et al., 2010</sup> CN can be mistaken for cellulitis at early stage. It should be suspected in diabetes patients with inflamed foot, profound neuropathy and foot structural abnormalities in the absence of fever and elevated erythrocyte sedimentation rate.<sup>Frykberg et al., 2006</sup>

- CN is difficult to differentiate from osteomyelitis.
- Appropriate use of imaging studies, including conventional radiographs, MRI, and nuclear medicine studies can aid greatly in diagnosis and treatment guidance of CN.
- Early detection and treatment of CN can lead to better outcome, patient satisfaction

and, avoid deformity and subsequent amputation.

Imaging modalities are mainly used to differentiate between CN and osteomyelitis. The findings are as following:

- Conventional radiographs common findings include focal demineralisation, periosteal reaction and cortical destruction involving multiple joints. <sup>Womack J, 2017, level III</sup>
- CT has no additional value to conventional radiography in the diagnosis of CN. <sup>Peterson N et al., 2017, level III</sup>
- MRI is useful tools to differentiate CN from osteomyelitis and should be done early in suspected patient. <sup>Womack J, 2017, level III</sup>
- Nuclear studies (PET scan) is valuable in differentiating CN with infection, however it is difficult to access, technically demanding and expensive to perform. <sup>Peterson N et al., 2017, level III</sup>

In the presence of an ulcer and unclear of the diagnosis, a biopsy is indicated. Pathognomonic features of CN are multiple particles of bone and soft tissue embedded in the deep layers of synovium. <sup>CPG DF, 2004</sup>

The aim of managing a CN of foot and ankle is to prevent structural deformities and complications that ensues e.g. ulceration, osteomyelitis and threatened limb.

In acute phase of CN, immobilise the foot using off-loading modalities e.g. crutches, wheelchair and walking frame to reduce oedema and skin temperature. Once it is resolved, patients are allowed to use protected weight bearing (e.g. removable walker and TCC) as it helps to distribute foot pressure. Patients may be allowed to ambulate while bony consolidation occurs. <sup>CPG DF, 2004</sup>

The aim of surgery is to create a stable, painless and plantigrade foot. Surgical treatment is indicated for a severe unbraceable deformity, deformity with recurrent ulceration, joint instability, exostosis and malalignment associated with pain or potential to get skin ulceration. <sup>Idusuyi OB. 2015, level III.</sup> Common surgical procedures for CN of the foot consist of: <sup>Lowery NJ et al., 2012, level III</sup>

- exostectomy - relieves bony pressure that cannot be accommodated with orthotics means
- arthrodesis of ankle, tibiotalar and midfoot- useful for patients with instability, pain or recurrent ulceration that fail conservative treatment
- lengthening of the Achilles tendon or gastrocnemius muscle - reduces forefoot pressure and improves the alignment of the ankle and parts of the foot

Early surgical reconstruction in high risk patients can provide timely restoration of a plantigrade and stable foot and improve quality of life of the patient. <sup>Mittlmeier T et al., 2010, level III</sup>

#### **Recommendation 15**

- Charcot neuroarthropathy should be referred to the orthopaedic surgeons for immediate treatment.

## **8. IMPLEMENTING THE GUIDELINES**

The management of diabetic foot should be guided by evidence-based approach in order to provide quality care to the patients. Several factors may affect the implementation of recommendations in the CPG.

## 8.1 Facilitating and Limiting Factors

Existing facilitators for application of the recommendations in the CPG include:

- wide dissemination of the CPG (soft- and hardcopies) to healthcare providers
- regular training and updates on diabetic foot management by relevant stakeholders
- public awareness campaigns on diabetic foot during World Diabetes Day, etc.

Existing barriers for application of the recommendations of the CPG are:

- limited exposure among healthcare providers (e.g. house officers, nurses, etc.) involved in the management of diabetic foot
- different levels of care and wide variation in practice due to expertise, facilities and financial constraints
- lack of awareness among patients with diabetes on the risk of developing diabetic foot problems

## 8.2 Potential Resource Implications

To implement the CPG, there must be strong commitment to:

- ensure widespread distribution of the CPG to healthcare providers via printed and electronic copies
- reinforce regular trainings with adequate funding for healthcare providers
- involve multidisciplinary team at all levels of health care
- strengthen and maintain the National Diabetic Foot Registry
- include diabetic foot problem as national health indicator

The following is proposed as clinical audit indicator for quality management of diabetic foot:

### a. Screening for diabetic foot problems

$$\text{Percentage of annual diabetic foot screening in patients with diabetes (target > 90\%)} = \frac{\text{Number of annual diabetic foot screening in patients with diabetes}}{\text{Total number of patients with diabetes annually}} \times 100\%$$

### b. Amputation rates

$$\text{Percentage of diabetic-related major lower limb amputation} = \frac{\text{Number of diabetic-related major amputation in a period}}{\text{Total number of patients with diabetic foot problems in the same period}} \times 100\%$$

Implementation strategies will be developed following the approval of the CPG by MoH which include launching of the CPG, Quick Reference and Training Module.

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DRAFT

## EXAMPLE OF SEARCH STRATEGY

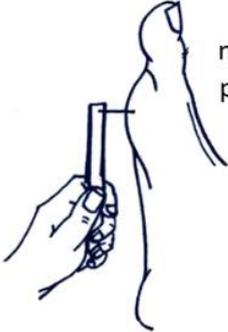
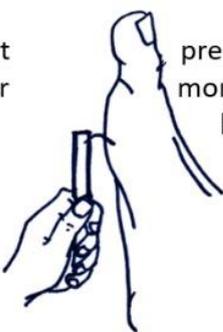
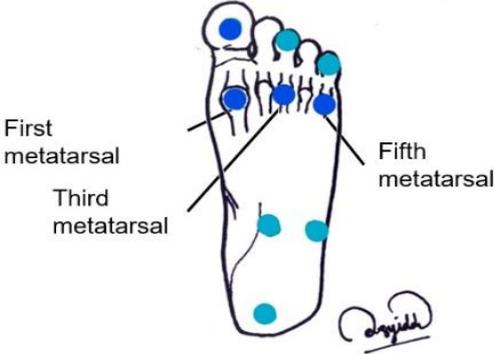
**Clinical Question:** Are the following preventive strategies safe and effective for diabetic foot at risk? - Surgery

1. DIABETIC FOOT/ (7869)
2. (diabetic adj1 (foot or feet)).tw. (6918)
3. foot ulcer, diabetic.tw. (8)
4. diabetic foot ulcer.tw. (957)
5. DIABETIC NEUROPATHIES/ (14576)
6. diabetic autonomic neuropath\*.tw. (752)
7. (diabetic adj1 (neuralgia\* or neuropath\* or polyneuropath\*)).tw. (8053)
8. painful diabetic neuropath\*.tw. (710)
9. DIABETIC ANGIOPATHIES/ (18723)
10. (diabetic adj1 (angiopath\* or microangiopath\* or vascular complication\* or vascular disease\*)).tw. (3229)
11. Diabetic ulcer.tw. (178)
12. FOOT ULCER/ (1793)
13. ((foot or plantar) adj1 ulcer\*).tw. (5346)
14. foot at risk.tw. (41)
15. feet at risk.tw. (14)
16. FOOT DEFORMITIES/ (1824)
17. ((foot or metatarsal) adj1 deformit\*).tw. (1846)
18. ARTHROPATHY, NEUROGENIC/ (1733)
19. charcot\* joint.tw. (200)
20. (neurogenic adj1 arthropath\*).tw. (54)
21. (Ischemic adj1 (foot or feet)).tw. (131)
22. (Ischaemic adj1 (foot or feet)).tw. (63)
23. Neuroischaemic.tw. (33)
24. Neuroischemic.tw. (93)
25. (Diabetic adj1 (foot infect\* or feet infect\*)).tw. (742)
26. ((foot or feet) adj1 infect\*).tw. (1321)
27. GANGRENE/ (8388)
28. gangrene\*.tw. (10435)
29. OSTEOMYELITIS/ (20349)
30. osteomyelitis\*.tw. (21182)
31. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 (90421)
32. Prevent\* surger\*.tw. (369)
33. 31 and 32 (4)

## CLINICAL QUESTIONS

1. What are the accurate screening tests for diabetic foot at risk?
2. Are the following preventive strategies safe and effective for diabetic foot at risk?
  - Metabolic control
  - Foot care
  - Foot wear
  - Surgeries
3. What are the clinical utilities and accuracy of the following tools for diagnosing foot at risk?
  - History taking
  - Physical examination
    - Musculoskeletal status
    - Vascular assessment status
    - Neurological status
  - Investigations
    - Biochemical investigation
    - Imaging
    - Vascular assessment
    - Neurological assessment
    - Assessment of plantar foot pressures
4. What are the practical clinical methods of stratification systems for classifying the diabetic foot problems?
  - International Working Group on the Diabetic Foot (IWGDF)
  - University of Texas
5. Are the following classifications accurate for diabetic foot ulcers?
  - Wagner
  - University of Texas
  - Infectious Diseases Society of America (IDSA) / IWGDF
  - PEDIS
  - SINBAD
6. Are the following treatment strategies safe and effective for neuropathic, ischaemic foot, neuroischaemic, diabetic foot ulcers, diabetic foot infections and deformity (including Charcot's Arthropathy)?
  - Non-surgical
    - Pharmacological (antibiotic regimens and antimicrobial therapies)
    - Wound management
    - Rehabilitation (off-loading techniques, etc.)
    - Adjuvant/alternatives treatment
  - Surgical
    - Debridement
    - Reconstruction
    - Revascularisation
  - Amputation (and management of amputees)
7. What are the referral criteria for diabetic foot at risk?
8. What are the effective follow-up/monitoring of diabetic foot problem?

**SEMMES-WEINSTEIN MONOFILAMENT EXAMINATION**

How to perform SWME?		
	<p>Place monofilament perpendicular to skin</p>	
	<p>Apply pressure until monofilament buckles</p>	
		<p>Release</p>
Where to perform SWME?		
	<p>First metatarsal</p> <p>Third metatarsal</p> <p>Fifth metatarsal</p>	
		<ul style="list-style-type: none"> <li><span style="color: blue;">●</span> Sites shown to identify 90% of patients with abnormal monofilament test</li> <li><span style="color: cyan;">●</span> Other recommended sites</li> </ul>

## PATIENT EDUCATION MATERIALS

Personal footcare should be emphasised which includes:

- checking that feet are in good order
- keeping feet clean
- providing skin care
- keeping toenails at a good length
- choosing and wearing good fitting footwear
- getting help if a problem is noticed

### Patient Education for Foot Care

Take proper care of diabetes by taking medications, following diet plan, exercising regularly, monitoring blood sugar regularly and attending appointments with the doctors. Ensure HbA1c, blood pressure, cholesterol and weight are under control.

Do not smoke as it restricts blood flow in the feet. Get help in smoking cessation if necessary.

Check feet every day in a brightly lit space looking at the top and bottom of the feet, heels, and between each toe. Check for cuts, blisters, redness, swelling or nail problems. Use a magnifying hand mirror to look at the bottom of feet or ask someone else to check it.

Keep feet clean by washing them daily with a mild soap. Use only lukewarm (below 37°C) and not hot water. Do not soak feet as this can cause dry skin. Dry by blotting or patting and carefully dry between the toes.

Keep skin soft and smooth by moisturising feet but not between the toes. Use a moisturiser daily to keep dry skin from itching or cracking over the dry areas – usually the top, the heel area and the soles. Massage the cream using small circular movements. But don't moisturise between the toes which could risk an infection to occur.

Cut toenails carefully after washing and drying feet. Cut them straight across and file the sharp edges. Don't cut nails too short, as this could lead to ingrown toenails.



Never self-treat corns or calluses. No “bathroom surgery” or medicated pads. Visit your clinic for appropriate treatment.

Wear clean, dry socks that are not too tight and are light coloured. Change socks daily. Make sure there are no holes. Consider socks made specifically for patients with diabetes with extra cushioning, no elastic tops, higher than the ankle and are made from fibers that wick moisture away from the skin. Avoid socks that have seams as they can cause rubbing or irritation leading to a blister or callus.

Keep feet warm and dry and, protect feet from hot and cold temperatures. Wear shoes at the beach or on hot pavements to protect feet from getting burnt. Don't put feet into hot water. Never use hot water bottles, heating pads or electric blankets as these can cause burns.

Never walk barefoot indoors or outdoors. Always wear appropriate shoes or slippers to avoid cuts or scratches over feet. Avoid shoes with narrow box, high heels, stilettos or footwear that have straps with no back support. Shake out shoes and feel the inside before wearing.

Put feet up when sitting. Keep the blood flowing to feet by wiggling toes and moving ankles for five minutes, 2 - 3 times a day. Don't cross legs for long periods of time.

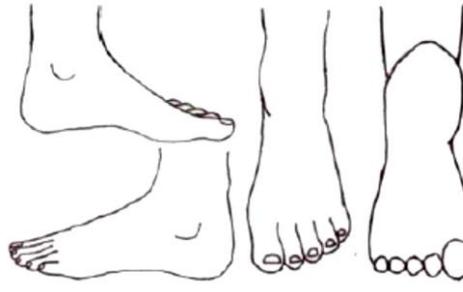
Exercise regularly to improve circulation and balance and, reduce the risk of falling. Wear athletic shoes that give support and are made for specific activities.

Periodic foot examinations are necessary when visiting diabetes clinics. Get sense of feeling and pulses checked at least once a year.

Seek treatment if there is presence of calluses or ingrown toenails. Urgent care is needed when there is presence of pain, noticeably red or discoloured areas, unusually hot areas, discharges, bad smell, an ulcer or blister or if feeling generally unwell with difficulty controlling sugar levels.

Modified: Jabatan Kesihatan WP Kuala Lumpur & Putrajaya. Panduan Penjagaan Kaki Bagi Pesakit Diabetes. JKWPKL&P, 2012 (unpublished document)

## DIABETIC FOOT ASSESSMENT FORM

DATE: _____					
<b>PERSONAL DATA</b>					
NAME: _____					
IDENTIFICATION CARD NUMBER: _____					
<b>MEDICAL HISTORY</b>					
<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 seek medical treatment <input type="checkbox"/> Self-treated <input type="checkbox"/> Traditional/alternative treatment		Other medical condition: <input type="checkbox"/> Ischaemic Heart Disease <input type="checkbox"/> Stroke <input type="checkbox"/> Hypertension <input type="checkbox"/> Hyperlipidaemia <input type="checkbox"/> Others: _____	
<input type="checkbox"/> Known case of Diabetes Mellitus (DM) Duration: _____ years Date of diagnosis: _____		Current medical treatment: <input type="checkbox"/> Nil <input type="checkbox"/> Diet alone <input type="checkbox"/> Medication: <input type="checkbox"/> Oral Anti-Diabetic Agents: _____		Complications: <input type="checkbox"/> Peripheral Arterial Disease <input type="checkbox"/> Neuropathy <input type="checkbox"/> Nephropathy <input type="checkbox"/> Others: _____	
Type of DM: <input type="checkbox"/> Type 1 <input type="checkbox"/> Type 2 <input type="checkbox"/> Others: _____		<input type="checkbox"/> Insulin: _____ <input type="checkbox"/> Combined: _____			
<b>SYMPTOMS</b>					
	Right		Left		Description
	Yes	No	Yes	No	
Paraesthesia (Pin & Needles)					
Claudication/Rest pain					
Foot ulcer					
Amputation					
Orthosis/Prosthesis					
Footwear	Indoor		Outdoor		
<b>FOOT</b>					
RIGHT			LEFT		
					
<b>GENERAL EXAMINATION</b>					
	Right		Left		Description
	Yes	No	Yes	No	
Skin condition					
Corn/callosity					
Ulcer					
Bunions					
Lesser toe deformities					
Charcot Joints					

(Kindly ✓ the appropriate box)

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)							
DorsalisPedis Artery (DPA)							
Posterior Tibial Artery (PTA)							
Popliteal Artery (PA)							
Femoral Artery (FA)							
ARTERIAL PULSE							
	Right		Left		Description		
	Yes	No	Yes	No			
Brachial (mmHg)							
Anterior Tibial (mmHg)							
Posterior Tibial (mmHg)							
Ankle-Brachial Index (ABI)							
RISK STRATIFICATION							
Low risk		Moderate risk			High risk		
MANAGEMENT PLAN							
<b>Referral:</b> <input type="checkbox"/> Orthopaedic <input type="checkbox"/> Vascular <input type="checkbox"/> Endocrine <input type="checkbox"/> Primary Care <input type="checkbox"/> Others: _____		<b>Follow-up:</b> <input type="checkbox"/> 3 monthly <input type="checkbox"/> 6 monthly <input type="checkbox"/> Yearly <input type="checkbox"/> Others: _____			<b>Foot care education checklist:</b> <input type="checkbox"/> Foot hygiene <input type="checkbox"/> Nail care <input type="checkbox"/> Foot wear advice <input type="checkbox"/> Routine foot check <input type="checkbox"/> Emollient use <input type="checkbox"/> Wound care <input type="checkbox"/> Recognising active foot problems (e.g. infection/erythema/ulcer) <input type="checkbox"/> Things to avoid (e.g. massage/soak/reflexology/self-treatment)		
<b>Assessed by Name:</b>		<b>Signature:</b>			<b>Date:</b>		

(Kindly ✓ the appropriate box)

**Source:** A Che-Ahmad, NF Mustafa, N Alias, et al. Evaluation of foot at risk among diabetic patients using diabetic foot assessment protocol in Malaysia. IIUM & MOH, 2012. (unpublished document)

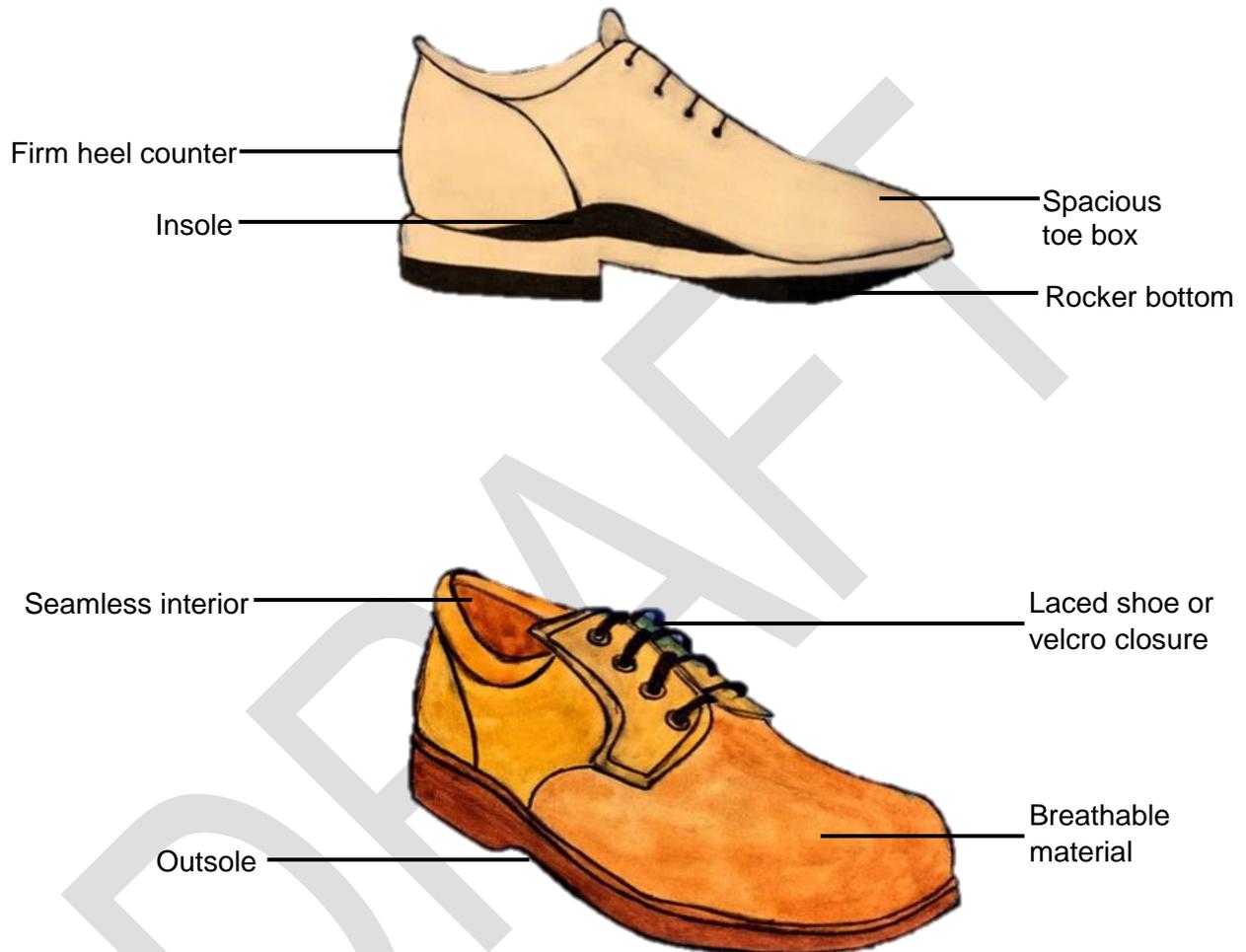
## UNIVERSITY OF TEXAS CLASSIFICATION OF DIABETIC FOOT

	GRADE 0	GRADE I	GRADE II	GRADE III
STAGE A	Pre- or post-ulcerative lesion completely epithelialised	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 ischaemia	With ischaemia	With ischaemia	With ischaemia
STAGE D	With infection and ischaemia	With infection and ischaemia	With infection and ischaemia	With infection and ischaemia

**Source:** Lavery LA, Armstrong DG, Harkless LB. Classification of diabetic foot wounds. J Foot Ankle Surg. 1996;35(6):528-531

**FOOTWEAR ADVICE**

Features of an ideal footwear for diabetic foot at risk:



**Image by:** Dr. Roslan Johari, Director, Director of Cheras Rehabilitation Hospital, Kuala Lumpur

### TYPES OF INFECTIONS IN DIABETIC FOOT AND SUGGESTION OF TREATMENT

#### 1. Diabetic Foot Infection

Antibiotics should not be used unless there are local or systemic features of infection. Local treatment including surgical debridement is important. Antibiotic selection should be based on the most recent culture and sensitivity report.

Infection/condition and likely organism involved	Suggested treatment		Comments
	Preferred	Alternative	
<b>Mild infections</b>			
a. Local infection involving skin and subcutaneous tissues	Cephalexin 500 mg PO q6h	Clindamycin 300 - 450 mg PO q8h	Duration: 1 - 2 weeks
b. Erythema <2 cm around the ulcer	<b>OR</b>	<b>OR</b>	
c. No systemic signs	Amoxicillin/Clavulanate 625 mg PO q8h	Trimethoprim/Sulphamethoxazole 5 - 10 mg/kg PO q12h	
<b>Moderate infections</b>			
a. Deep tissue infection	Ampicillin/Sulbactam 1.5 - 3 g IV q6 - 8h	Ciprofloxacin 400 mg IV q8-12h	Duration: usually 2-4 weeks; modify according to clinical response <ul style="list-style-type: none"> <li>If proven osteomyelitis: at least 4-6 weeks. Shorter duration if the entire infected bone are removed (3 to 5 days may be sufficient).</li> </ul> If antibiotic-resistant organisms are likely, treat as severe infection
b. Erythema >2 cm around ulcer	<b>OR</b>	<b>PLUS</b> Clindamycin 600mg IV q8h	
c. No Systemic Inflammatory Response Syndrome (SIRS)	Ceftriaxone 1 – 2 g q24h ±Metronidazole 500mg IV q8h		
If pseudomonas is suspected	Piperacillin/Tazobactam 4.5 mg IV q6-8h		
<b>Severe infections</b>			
All of the above and presence of SIRS	Piperacillin/Tazobactam 4.5 g IV q6-8h	Cefepime 1-2g IV q8h	Add Vancomycin 1 g IV q12h if high risk for MRSA Duration of treatment: 4-6 weeks
MRSA	Vancomycin 15-20 mg/kg IV q8-12h	Linezolid 600mg IV/PO q12h	

## TYPES OF INFECTIONS IN DIABETES FOOT AND SUGGESTION OF TREATMENT (CONT.)

### 2. Necrotising Fasciitis

Infection/condition and likely organism involved	Suggested Treatment		Comments
	Preferred	Alternative	
<b>Polymicrobial infection</b>			
Primarily occurs in patients who are immunocompromised or have certain chronic diseases e.g. diabetes mellitus  Group A <i>streptococcus</i>	Piperacillin/Tazobactam 4.5 g IV q8h  Benzylpenicillin 2 – 4 MU IV q4h <b>PLUS</b> Clindamycin 600 - 900 mg IV q8h	Cefotaxime 2 g IV q6h <b>PLUS</b> Metronidazole 500 mg IV q8h  Ampicillin/Sulbactam 1.5 g IV q8h <b>PLUS</b> Clindamycin 600 - 900 mg IV q8h	Add Vancomycin 1 g IV q12h if high risk for MRSA  Early aggressive surgical debridement essential  With septicaemia/severely refer to ICU guidelines

### 3. Osteomyelitis

Infection/condition & likely organism involved	Suggested Treatment		Comments
	Preferred	Alternative	
<b>Acute Osteomyelitis</b>			
<i>Staphylococcus aureus</i> (80%), Group A <i>Streptococcus pyogenes</i> , Rarely gram negative bacilli	<b>No open wound:</b> Cloxacillin 2 g IV q6h  <b>If gram negative bacilli by on gram stain:</b> Ciprofloxacin 400mg IV q24h <b>OR</b> Ceftriaxone 2g IV q24h	<b>Penicillin Allergy:</b> Clindamycin 300-600 mg IV q8h followed by oral therapy (same dose)	Duration: initial IV therapy for 2-4 weeks, followed by oral therapy, to complete minimum six weeks  Modify according to clinical response

Chronic Osteomyelitis			
(After three months of appropriate antibiotic therapy or presence of dead bone on X-ray)	Empirical treatment is not indicated		Minimum length six weeks but usually >3 months
Commonest organism: <i>Staphylococcus aureus</i>	Thorough surgical debridement required (removal of dead bone/ orthopaedic hardware)		Treat until inflammatory parameters are normal
	Choice of antibiotic depends on C&S result from tissue/bone		

#### 4. Suppurative Wound Infections

Infection/condition & likely organism involved	Suggested treatment		Comments
	Preferred	Alternative	
Suppurative Wound Infections			
Suppurative wound infections	<p><b>If there is surrounding cellulitis and/or presence of systemic symptoms:</b> Cloxacillin 500 mg PO/IV q6h</p> <p><b>If gram negative organisms suspected or known to be involved:</b> Gentamicin 5 mg/kg IV q24h <b>OR</b> As a monotherapy: Cefuroxime 1.5 g IV q8h</p>		<p>Change antibiotics accordingly after C&amp;S result are available</p> <p>Topical antibiotics are not recommended for treatment of wound infections as it may result in the emergence of resistant organisms</p> <p>Patient tetanus immunisation status should be assessed in all cases</p>

g: gram; mg: milligramme; PO: oral administration; q6h: every 6 hours; q8h: every 8 hours; q12h: every 12 hours; q24h: every 24 hours; SIRS: Systemic Inflammatory Response Syndrome; MRSA: *methicillin resistant Staphylococcus aureus*; IV: intravenous; MU: mega unit; ICU: Intensive Care Unit

**Adapted:** Pharmaceutical Services Division, Ministry of Health Malaysia. National Antibiotic Guideline (Second Edition). Petaling Jaya: MoH; 2014

## TYPES OF WOUND DRESSING IN DIABETIC FOOT

No.	Types of dressing	Advantages	Disadvantages	Indications	Contraindications	Review intervals
<b>Basic wound contact dressings</b>						
1.	Gauze/basic absorbent with paraffin or similar (antiseptics or antibiotics)	<ul style="list-style-type: none"> <li>• Reduces adherence of dressing to the wound</li> <li>• Widely available</li> </ul>	<ul style="list-style-type: none"> <li>• Minimal exudate absorption</li> <li>• Requires secondary dressing</li> </ul>	All wounds	Allergy	Daily
<b>Advanced wound dressings</b>						
1.	Hydrogel	<ul style="list-style-type: none"> <li>• Provides moist environment</li> <li>• Acts as enzymatic debridement</li> <li>• Promotes granulation</li> </ul>	<ul style="list-style-type: none"> <li>• Requires secondary dressing</li> </ul>	<ul style="list-style-type: none"> <li>• Sloughy wound</li> <li>• Dry wounds</li> </ul>	<ul style="list-style-type: none"> <li>• Highly exudative wounds</li> <li>• Allergy</li> </ul>	1 - 2 days
2.	Alginate	<ul style="list-style-type: none"> <li>• Forms gel on wound and maintain moisture</li> <li>• Acts as cavity filler</li> <li>• Absorbent in exudative wounds</li> <li>• Promotes haemostasis</li> <li>• Low allergenic</li> </ul>	<ul style="list-style-type: none"> <li>• Requires secondary dressing</li> <li>• Gel can be confused with slough or pus in wound</li> </ul>	<ul style="list-style-type: none"> <li>• Moderately or highly exudative wounds</li> <li>• Need for haemostasis</li> </ul>	<ul style="list-style-type: none"> <li>• Dry wounds</li> <li>• Allergy</li> </ul>	2 - 3 days
3.	Hydrofibre	<ul style="list-style-type: none"> <li>• Maintains moisture</li> <li>• Longer wear time</li> <li>• Non-traumatic upon removal</li> <li>• Reduces risk of maceration</li> <li>• Can be used on infected wounds</li> </ul>	<ul style="list-style-type: none"> <li>• Not helpful for dry wounds</li> <li>• Requires secondary dressings</li> </ul>	Moderately or highly exudative wounds	Allergy	2 - 5 days

No.	Types of dressing	Advantages	Disadvantages	Indications	Contraindications	Review intervals
4.	Foam	<ul style="list-style-type: none"> <li>• Maintains moisture</li> <li>• Highly absorbent</li> <li>• Cushioning property</li> </ul>	Limited size	Moderately or highly exudative wounds	<ul style="list-style-type: none"> <li>• Dry wounds</li> <li>• Wounds that need frequent review</li> </ul>	2 - 3 days
5.	Hydrocolloid	<ul style="list-style-type: none"> <li>• Maintains moisture</li> <li>• Cleans and debrides by autolysis</li> <li>• Easy to use</li> <li>• Waterproof</li> </ul>	Induces peri-wound maceration	Mildly to moderately exudative wounds	<ul style="list-style-type: none"> <li>• Dry wounds</li> <li>• Infection</li> <li>• Highly exudative wounds</li> </ul>	2 - 3 days
6.	Silver	<ul style="list-style-type: none"> <li>• No known resistance</li> <li>• Bactericidal</li> </ul>	Some silver dressings discolour the wound	Infective wounds	Allergy	3 - 5 days
7.	Others	Not widely used - some may be used in specialised centres e.g. collagen, matrix and regenerative dressings (cultured epidermis, growth factors, stem cells, etc.)				

**Adapted:** Ministry of Health. Wound Care Manual. Kuala Lumpur: MoH; 2014

## LIST OF ABBREVIATIONS

ABI	ankle brachial index
C&S	culture and sensitivity
CFDU	colour flow duplex ultrasound
CHS	Curative Health Services
CI	confidence interval
CPG	Clinical Practice Guidelines
CT	computed tomography
CV	cardiovascular
CWD	continuous wave doppler
DEPA	Depth of the ulcer, extent of bacterial colonisation, phase of ulcer and association aetiology
DFU	diabetic foot ulcer
DG	development group
DM	diabetes mellitus
DUSS	Diabetic ulcer severity score
GFR	Gastrocnemius-soleus fascia recession
HbA1c	haemoglobin A1c
HBOT	hyperbaric oxygen therapy
IpTT	Ipswich Touch Test
LOPS	loss of protective sensation
MaHTAS	Malaysian Health Technology Assessment Section
MD	mean difference
MDT	maggot debridement therapy
MoH	Ministry of Health
MRI	magnetic resonance imaging
MW	Meggitt–Wagner
NCS	nerve conduction study
NDS	neuropathy disability score
OR	odds ratio
PAD	peripheral arterial disease
PEDIS	Perfusion, Extent, Depth, Infection and Sensation
PET	positron emission tomography
PTA	percutaneous transluminal angioplasty
RCT	randomised control trial
RD	risk difference
RR	relative risk
S(AD)SAD	Size (area, depth), sepsis, arteriopathy, denervation system
SINBAD	Site, ischaemia, neuropathy, bacterial infection and depth
SWME	Semmes-Weinstein monofilament examination
TBI	toe brachial index
T1DM	type 1 Diabetes Mellitus
T2DM	type 2 Diabetes Mellitus
TCC	total contact cast
VPT	vibration perception threshold
UT	University of Texas
vs	versus

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