

North West Podiatry Services
Diabetes Clinical Effectiveness Group

Guidelines for the Prevention and Management of Foot Problems for People with Diabetes

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INTRODUCTION

The Clinical Effectiveness Group (CEG) for the Prevention and Management of Foot Problems for People with Diabetes was initiated by the North West Regional Podiatry Heads of Service. It was the final CEG to look at clinical guidance and evidence based medicine in line with the Clinical Governance framework identified within the NHS plan (DOH, 2004).

The first edition of these guidelines came out in 2004 and was presented at the Society of Chiropodists and Podiatrists annual conference. It was subsequently widely used across the North West Region to benchmark NHS Podiatry services and was adopted by Podiatry services in various other regions as best practice guidelines.

It has triggered two regional audits of Podiatry provision around Diabetes, the first of which was presented at the Wounds UK annual conference in 2005 and the second was presented at the Society of Chiropodists and Podiatrists annual conference in 2007. The guidelines and first audit also won a national Wounds UK award for best management of diabetic foot ulcers in 2006.

Key national stakeholders who have recognised the guidelines include Diabetes UK, Foot in Diabetes UK, PRODIGY, the National Electronic Library for Health and the Society of Chiropodists and Podiatrists.

In 2012, the latest process of reviewing these guidelines began. This review of the guidance follows the publication of several key documents relating to the diabetic foot including: Inpatient Management of Diabetic Foot Problems (NICE, 2011), QOF Quality Standard 10 (NICE, 2011), Putting Feet First (Diabetes UK, 2012) and the updated Podiatry Competency Framework for Integrated Diabetic Footcare (TRIEPodD-UK, 2012). The main aim of this document remains the same - to provide NHS Podiatry Services with best practice clinical guidance.

We have detailed essential and desirable standards for NHS Podiatry services to benchmark themselves against in view of the disparity that exists across the region. In 2006 Dr Sue Roberts, National Clinical Director for the National Service Framework for Diabetes, highlighted a five fold difference in amputation rates within the North West. Six years on and the publication of the Diabetes Atlas (Rightcare, 2012) demonstrates that these differences still remain.

The NHS in England spends £650 million per year on foot ulcers and amputations due to poor quality care (NHS Diabetes, 2012). The goals of best clinical outcomes, reducing costs and ensuring equity of care are common to all NHS Podiatrists across the region. We hope that these guidelines continue to assist NHS Podiatrists, their managers and commissioners to review, plan and provide best foot health care for people with diabetes.

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1. Risk Identification

Evidence Statement

As part of an annual review, trained personnel should examine patient's feet to detect risk factors for ulceration (NICE, 2004 - Grade A evidence).

A holistic patient assessment should be performed. This should include a footwear assessment and a management plan agreed with the patient.

1.1 PATIENT ASSESSMENT

Essential standards

All children, young people and adults with diabetes will receive a service which encourages partnership in decision making, supports them in managing their diabetes and helps them to adopt and maintain a healthy lifestyle (DOH, 2004).

Practitioners should use a Care Planning approach to management. Care planning is defined as a process that actively involves people in deciding, agreeing and sharing responsibility for how to manage their diabetes and its' complications. It aims to help people with diabetes achieve optimal health by partnering with healthcare professionals to learn about, manage and cope with diabetes and its related conditions in their daily lives.

Care planning is underpinned by the principles of patient-centeredness and partnership. It is an ongoing process of communication, negotiation and joint decision-making in which both the person with diabetes and the healthcare professional(s) make an equal contribution to the consultation (DOH, 2004).

A baseline and subsequent assessment for complications in the feet of all patients with diabetes should be performed at the primary assessment. Both feet should always be examined and evidence that appropriate consideration has been given to the following 12 aspects of assessment before identifying a tailored management plan:

1. **Identify patient perception of problem and their related perceived needs:** Current beliefs, effect on life, barriers to acting on standard advice.
2. **Medical history:** such as Rheumatoid Arthritis, Peripheral Vascular Disease, Renal disease, familial.
3. **Surgical history:** such as vascular, orthopaedic, amputation.
4. **Medication:** complete list of medication should be obtained including over the counter, herbal and recreational.
5. **Diabetes status:** latest HbA1c, current pre-meal blood sugars.

- 6. Activity levels:** high, moderate, low.
- 7. Peripheral vascular status:** palpable foot pulses, intermittent claudication, ischaemic pain, venous disease, oedema.
- 8. Peripheral neuropathy status:** 10g monofilament or 128 MHz tuning - fork.
- 9. Foot type:** excess pronation / hyper-mobility, excess supination / rigidity, toe / foot deformity, ankle equinus.
- 10. Footwear:** plantar cushioning, toe box depth / width, flexible / rigid rocker sole.
- 11. Vision**
- 12. Social factors:** social isolation, housebound, ability to self-care, smoking, alcohol.

- Reassessment of the foot should be performed on an annual basis where no previous complications have been found (Appendix 1).
- If a patient is admitted into hospital, immediate (within 4 hours) assessment of the foot on admission by a member of the admitting medical / nursing team Including:
 - Removal of dressings in situ.
 - Assessment for clinical signs of infection.
 - Other inflammatory indications (Charcot, fracture, dislocation, critical limb ischaemia) (NICE, 2011).

Desirable Standards

- Lipid levels.
- Blood pressure.
- BMI/waist measurement.
- Patient's Renal Function.

1.2. VASCULAR ASSESSMENT

Evidence statement

Regular (at least annual) visual inspection of a patient's feet, assessment of foot sensation and palpation of foot pulses by trained personnel is important for the detection of risk factors for ulceration (NICE, 2004 - Grade A evidence).

Essential standards

- Pedal pulses (Dorsalis Pedis and Posterior Tibial) should be palpated and the results recorded.
- If both pedal pulses in one foot are not palpable, the patient should be identified as "increased risk".
- If pulses are not palpable, a Doppler assessment should be performed to determine arterial pulse presence and quality of signal, followed by Ankle Brachial Pressure Index (ABPI) test if the pulse flow is considered mono-phasic (See Advanced Vascular Assessment - Appendix 2).
- Assess for symptoms of claudication / ischemia (Edinburgh claudication questionnaire - Appendix 2).

Desirable standards

- Popliteal and Femoral pulse palpation and insonation with handheld Doppler (NICE, 2012).
- Assessment of other key cardiovascular risks - smoking, blood pressure, lipids, lack of exercise (NICE, 2012).

1.3. NEUROLOGICAL ASSESSMENT

Evidence statement

Testing of foot sensation should be carried out using a validated / calibrated 10g monofilament or by detecting vibration perception (NICE, 2004 - Grade A Evidence). Monofilaments should not be used to test more than ten patients in one session and should be left for at least 24 hours to recover between sessions (NICE, 2004 - Grade C Evidence). (Manufacturers guidance on the life span and replacement of the filament should be followed).

Essential standards

- Neuropathy should be identified using a 10g Monofilament and / or 128 MHz tuning fork
- The International Working Group on the Diabetic Foot (2011) advised monofilament testing at 3 sites. The sites suggested are under the hallux and the 1st and 5th metatarsals. The application of the monofilament should be repeated twice at the same site but alternate this with at least one 'sham' application in which no filament is applied. Protective sensation is present at each site if patient correctly answers 2 out of 3 applications. Protective sensation is absent with 2 out of 3 incorrect answers and the patient is considered to be at risk of ulceration. In the absence of strong clinical evidence this is the North West Podiatry Services Diabetes CEG recommendation.
- The International Working Group on the Diabetic Foot (2011) advised the 128 MHz tuning fork is applied on a bony part on the dorsal side of the distal phalanx of the 1st toe. This application should be repeated twice but alternate with at least one 'sham' application, in which the tuning fork is not vibrating. The test is positive if the patient correctly answers 2 out of the 3 applications and negative (at risk of ulceration) with 2 out of 3 incorrect answers.
- Assessment of painful neuropathic symptoms (LANNS Scale Assessment Tool - Appendix 3)

Desirable standards

Neurological assessment may also involve the following tests

- A neurothesiometer assessment (>25V = reduced perception threshold).
- Neuropathy disability score (Appendix 4).

1.4. FOOT DEFORMITY ASSESSMENT

Evidence Statement

Any deformity occurring in a diabetic foot with other risk factors, such as prominence of the metatarsal heads, clawing of the toes, Charcot prominences or hallux valgus, increases ulcer risk (Abbott et al, 2002).

Essential standards

Reported markers of increased risk are as follows (NICE, 2004):

- Foot Pathologies:
 - Plantar Callus.
 - Nail pathologies.
 - Skin infections.
 - Previous ulceration or amputation.
- Foot / toe structural abnormality.
- Footwear suitability.

Desirable standards

- None identified.

The assessment should enable the patient to be placed into one of the following categories which will aid identification of foot ulceration / amputation risk and guide subsequent clinical management.

Risk Category (National Minimum Skills Framework, 2011)

- **Low risk** (normal sensation, palpable pulses)
- **Increased/High risk** (neuropathy & / or absent pulses +/- intermittent Claudication +/- deformity or skin changes or previous ulcers)
- **Emergency Foot; Ulceration / Charcot** (new ulceration, cellulitis, new or sudden discolouration / pain / swelling)

2. Management of the ‘LOW RISK’ Foot

Aims:

To prevent patients from developing risk factors for ulceration / amputation.

- To improve knowledge and encourage self care (NICE, 2004) and to improve outcomes.

Essential standards

- Agree a management plan with the patient depending on the clinical need.
- Arrange patient education – either group or one to one.
- Arrange re-assessment for risk factors for foot ulceration on an annual basis.
- Consider diabetes control and modifiable cardio-vascular risk factors and refer as appropriate.
- Clarify emergency access to Foot Protection Team (FPT) (NICE, 2004; National Minimum Skills Framework, 2011).

Desirable standards

- Inform patient specifically on the key vascular risks associated with diabetes and lower limb arterial disease, namely heart attacks, strokes and amputations.
- Negotiate a clinical management plan based on their individual modifiable risks.

2.1. HEALTH EDUCATION & BEHAVIOURAL CHANGE

Evidence Statements

Diabetes NSF (DOH, 2001) and NICE guidelines [60 &10] reinforce the value of education in empowering our patients. This will lead to more informed patients allowing collaboration between the professionals and patients.

Educational interventions can improve foot care knowledge and behaviour in the short term (NICE, 2003).

It is recommended that structured education is made available to all people with diabetes (NICE, 2003).

The provision of patient education is a central pillar to diabetes care. Education has been shown to reduce foot ulceration and complications (Valk et al, 2004). Education should aim not only to improve an individual's knowledge but also to increase confidence and skills to enable the person with diabetes to take increased control over their own condition. A person with diabetes should be offered tailored information which should include:

- Details of when and where to seek advice (Including out of hours service provision).
- What service to expect regarding foot care.
- Potential consequences of neglecting their feet.
- How to manage symptoms (e.g. pain).

All details of education provided should be recorded in the patient's notes and arrangements for follow up included.

Essential standards

- All people with diabetes should have access to foot health educational materials in a variety of formats, verbal, written, images, etc.

Desirable standards

- All podiatrists should use a care planning approach to a consultation in an attempt to develop an agreed, negotiated, goal focussed approach to management (NHS Diabetes, 2006; Graffey et al, 2009).

3. Management of the Increased / High Risk Foot

Aim

To help prevent patients with identified risk factors from developing ulceration / amputation.

Evidence statement

Patients with risk factors for ulceration should be referred to a foot protection team (NICE, 2004 - Grade A evidence).

The roles of the FPT may include: Specialist surveillance of people at risk, including those who are hospital in-patients; Education of other Health Care Professionals (HCP's) in the routine examination and definition of the 'at risk' foot; Close liaison with the Multidisciplinary Team(MDT); Management of selected cases of foot disease in the community depending on the nature of the problem and the skills and experience of the FPT and their ability to manage the patient in partnership with the MDT; Sharing care with the MDT of selected cases of foot disease; Sharing long-term management with other HCP's of people with successfully treated disease (National Minimum Skills Framework, 2011).

Essential Standards

- Regular Podiatry treatment by a Podiatrist. Provision of skin and nail care with frequency according to need (NICE, 2004; NICE Quality Standards, 2011).
- Education regarding foot care and footwear (verbal and written) (Assal J-P et al, 1985; Malone et al, 1989; Boulton et al, 1995; Apelqvist et al, 1999; SIGN, 2010 - grade A, category 1b evidence)
- Emergency access to a FPT, including self -referral, within one working day (SIGN, 2010 - Grade B evidence; NICE, 2004 - Grade A evidence).
- Assessment and review of footwear. Refer for specialist footwear opinion if appropriate (NICE, 2004 - Grade D evidence; SIGN, 2010 - Grade C evidence, category IV; Apelqvist et al, 1999).
- Assessment for provision of Orthotics (Apelqvist et al, 1999; NICE, 2004 - Grade D evidence).

- Referral for assessment of control of diabetes (SIGN, 2010 - Grade A evidence, Category 1b).
- Assessment and referral regarding other lifestyle changes including smoking, alcohol intake, exercise, weight loss (Moss et al, 1992; Beach et al, 1980; SIGN, 2010 - Grade B, Category III evidence).
- Referral for assessment and appropriate treatment of neuropathic pain including optimising glycaemic control and neuropathic analgesics, in line with NICE (2010) Neuropathic pain: pharmacological management (CG96). Painful neuropathy can be assessed using the LANNS scale, (Appendix 3).

Desirable Standards

- All podiatrists should use a care planning approach to a consultation in an attempt to develop an agreed, negotiated, goal focussed approach to management (NHS Diabetes, 2006; Graffey et al, 2009).
- Ensure patient has had a diabetes annual review.
- Inform patient specifically on the key vascular risks associated with diabetes and lower limb arterial disease, namely heart attacks, strokes and amputation.
- Negotiate a clinical management plan based on their individual modifiable risks.

3.1. ADDITIONAL STANDARDS FOR PATIENTS IDENTIFIED WITH SUSPECTED PERIPHERAL ARTERIAL DISEASE / ISCHAEMIA

Essential standards

- Refer for full, non invasive vascular assessment of the lower limb for all people with suspected peripheral arterial disease (PAD), whether asymptomatic, or with symptoms suggestive of intermittent claudication or ischaemic rest pain (NICE, 2012. Appendix 2)
- On diagnosis of PAD, consider the need to refer for optimal medical management of cardio vascular risk factors i.e. hypertension, anti-platelet therapy and lipid lowering drugs (NICE, 2012).
- Make all people with PAD aware of smoking cessation strategies (Moss et al, 1992; SIGN, 2010 - Grade B, level III evidence). Nicotine replacement therapy has been beneficial and has been proven to positively influence patients motivated to stop smoking. Smoking is known to contribute to peripheral vascular disease (SIGN, 2006).
- Provide education regarding lifestyle changes including walking exercise, and alcohol intake or weight loss where appropriate (NICE, 2012).

Desirable Standards

- Provide full non invasive vascular assessment of the lower limb (NICE, 2012), where podiatrists with such skills are available (Appendix 2).
- Ensure rapid access to vascular specialist team is available, especially for people with suspected critical limb ischaemia (NICE, 2012).
- For people with intermittent claudication, educate about, promote and refer to supervised exercise programmes where available. Promote walking and cardiovascular exercise generally. Exercise regimes are beneficial for patients with intermittent claudication and walking distances can be improved (NICE, 2012; SIGN, 2006).

4. Management of the ‘ULCERATED’ Foot

Aim

To promote wound healing and to prevent patients with ulceration undergoing amputation.

Evidence Statements

A new foot emergency including ulceration should be referred and treated by the multidisciplinary foot care team within 24 hours (NICE, 2011). A new foot emergency has been described as:

New ulceration (wound).

New swelling.

New discolouration (redder, bluer, paler, blacker, over all or part of the foot) (NICE, 2004 - Grade D evidence).

The multidisciplinary foot care team should comprise of highly trained specialist podiatrists, orthotists, nurses with training of diabetic foot wounds and diabetologists with expertise in lower limb complications. They should have unhindered access to suites for managing major wounds, urgent inpatient facilities, antibiotics administration, community nursing, microbiology diagnostic and advisory services, orthopaedic / podiatric surgery, vascular surgery, investigational radiology and orthotics (NICE, 2004 - Grade D evidence).

4.1. MANAGEMENT OF THE ULCERATED FOOT

This section relates mainly to referrals, liaison and multidisciplinary activity that podiatrists working with diabetes related foot ulcerations need to consider.

Essential Standards

- All new foot emergencies should be referred to a MDT within one working day. All services should be working toward having access for referral and treatment by the MDT within 24 hours.
- The podiatrist should identify whether the level of skill required to manage the wound is within their competence and / or whether they have access to the necessary support e.g. diagnostics (TRIEPodD-UK, 2012). If not, there should be a pathway in place for referral to an appropriate practitioner e.g. specialist podiatrist.

- All people with diabetes related foot ulcer should be referred to a member of the multidisciplinary diabetes foot care team within twenty four hours (National Minimum Skills Framework, 2011; NICE, 2011) (Example of a MDT referral - Appendix 5).
- Pathways for re-referral back to the MDT for deteriorating or static diabetes related foot ulceration need to be established in NHS Trusts.
- Ensure that all people with critical limb ischaemia are assessed by a vascular multidisciplinary team before treatment decisions are made (NICE, 2012).
- Do not offer major amputation to people with critical limb ischaemia unless all options for revascularisation have been considered by a vascular multidisciplinary team (NICE, 2012).

Desirable Standards

- Podiatrists should have access to an opinion from Microbiology in the case of diabetes related foot infection.

4.2. ASSESSMENT OF THE ULCERATED FOOT

Essential Standards

- In addition to the previous assessment components in the risk factor identification chapter, appropriate consideration should also be given to the following:
 - **Ulcer type:** ischaemic, neuroischaemic
 - **Ulcer cause:** trauma, footwear, excess activity
 - **Ulcer status:** depth, area, slough, necrosis, callus, colonisation/infection, pain.
 - **Ulcer classification:** All Trusts should use a standard wound classification system. The CEG recommend the use of SINBAD (Ince et al, 2008) (Appendix 6).

Desirable Standards

- **Peripheral Arterial Disease (PAD)** - Full lower limb vascular assessment with appropriate use of Doppler analysis, ABPI's and access to a Vascular Team for further investigation (NICE, 2012) (Appendix 7).
- **Neuropathy** - Vibration perception threshold.
- **Foot type** - Gait analysis, foot pressure measurement, footwear.
- **Ulcer status** - x-ray, MRI scan, swab and culture, bone biopsy (NICE, 2011).

4.3. TREATMENT OF THE ULCERATED FOOT

Evidence statements

In the absence of strong clinical or cost effective evidence, health care professionals should use wound dressings that best match clinical experience, patient preference, and the site of the wound and the cost of the dressings (NICE, 2004 - Grade D evidence). When choosing wound dressings, the HCP in the MDT should take into account the wound, patient preference and the clinical circumstances and use wound dressings with the lowest acquisition cost (NICE, 2011).

Wounds should be closely monitored and dressings changed regularly (NICE, 2004 - Grade D evidence).

Dead tissue should be carefully removed from foot ulcers to facilitate healing, unless revascularisation is required (NICE, 2004 - Grade B evidence; Wounds UK, 2011). Debridement should only be done by professionals from the MDT using the technique which best matches their expertise, clinical experience, patient preference and site of the ulcer (NICE, 2011; TRIEPodD-UK, 2012).

Patients who may benefit from re-vascularisation should be referred promptly (NICE, 2004 - Grade D evidence).

The following elements need to be considered:

- a. Debridement / wound bed preparation.
- b. Wound symptom management (e.g.: infection / exudate).
- c. Offloading the ulcer area.
- d. Structured patient centred education.

A. DEBRIDEMENT / WOUND BED PREPARATION

The following statements are based mainly on consensus opinion of clinicians as published definitive evidence is still scarce (Wounds UK, 2011; EWMA, 2011).

Essential Standards

- All diabetes related foot ulcers with an undetermined depth should be probed with a blunt sterile probe to establish the full extent.
- In the absence of significant arterial disease the ulcer should be sharp debrided of all callus / necrotic / sloughy tissue (Steed, 1996).
- Management of the wound bed with appropriate debridement & dressing choice. If available refer to local Trust guidelines / formulary for appropriate wound care products.
- Where extensive tissue death of digits has occurred (local gangrene), dressings must be used which dry the necrosis out to encourage auto-amputation and discourage spread of infection via moist necrosis.
- Wounds requiring extensive debridement (bones, tendons, necrotic tissue) should be undertaken with support and consultation with the multi-disciplinary team (NICE, 2011; TRIEPoD-UK, 2012).
- Imaging:
The following patients should be referred initially for x-ray:
 - Where there is a positive probe to bone test (Grayson, 1995).
 - Suspected osteomyelitis.
 - Suspected Charcot Neuroarthropathy.
 - Patients with non healing ulcers (a minimum of 6 weeks).
 - Sausage shaped toes.
 - Where exudate is suspected to be synovial in origin.

Initially x-ray but remember osteomyelitis cannot be excluded on a plain film. If OM still suspected arrange for MR Scan or white blood cell scanning if MR scan is contraindicated.

B. INFECTION MANAGEMENT

Introduction

The presence of infection, which should be diagnosed based on clinical findings of inflammation, markedly increases the risk of foot amputation and must be addressed promptly. Although clinically uninfected wounds do not require antibiotic therapy, infected wounds do. Infections should be defined and classified according to the Infectious Diseases Society of America (IDSA) guidelines (2012) as absent, mild, moderate or severe (these are analogous to the International Working Group on the Diabetic Foot guidelines, which range from 1-4)

Evidence statement

If a Diabetic patient develops a foot infection, they should be referred to the multidisciplinary foot care team (NICE, 2004, NICE 2011). After obtaining appropriate cultures and initiating empiric antibiotic therapy, refer the patient to the multi-disciplinary team for further advice and management of the infection (2004).

Culturing

Culturing of ulcers should follow local Trust guidelines, but we recommend (in order of the reliability of results) obtaining the following specimens, after wound cleansing and debridement:

- tissue, by curettage or biopsy
- deep wound swab from soft tissue
- bone (by percutaneous biopsy or at surgery) for cases of suspected osteomyelitis.,

Superficial wound swabs are less sensitive and specific than tissue and should only be sent if it is not possible to obtain tissue. Blood cultures are rarely positive, but should be considered in patients with a severe infection.

Management

The choice of an empiric antibiotic regimen should be principally based on: 1) infection severity; 2) most likely infecting pathogen(s); and, 3) known local antibiotic resistance patterns. In general, select the narrowest spectrum regimen and the agent with the lowest overall cost appropriate for the clinical situation (Lipsky, 2012; NICE, 2011). Definitive antibiotic therapy should be based on the clinical response to empiric treatment and the results of culture and sensitivity testing. No one antibiotic regimen has been shown to be most effective so the choice depends on various clinical, microbiological and administrative factors (Lipsky, 2012; Nelson et al, 2006).

For mild to moderate infections

- In patients who have not recently received antibiotic therapy, targeting just aerobic gram-positive cocci (staphylococci and streptococci) is usually sufficient.
- For patients who have a recent history of antibiotic use or have chronic, long duration wounds, consider adding coverage against common gram-negative organisms (Enterobacteriaceae and, in selected cases, *Pseudomonas aeruginosa*).
- If the wound is complicated by ischaemia or extensive gangrene consider adding agents that cover obligate anaerobic organisms.

For severe infections

- We recommend starting broad-spectrum empiric antibiotic therapy (including against methicillin-resistant *Staphylococcus aureus* where this is prevalent, and against *Pseudomonas aeruginosa* in patients at risk for this pathogen), pending results of culture and antibiotic susceptibility tests.
- Also consider patient specific factors (e.g. allergies, renal or hepatic dysfunction) and local antibiotic guidelines.
- In patients with both soft tissue and bone infection, do not delay starting antibiotic therapy pending MRI results (NICE, 2011). For clinically stable patients with no soft tissue infection but suspected osteomyelitis, antibiotic therapy can often be held while arranging a bone biopsy,

Essential Standards

Where clinical infection is suspected, appropriate antibiotics should be commenced as soon as possible. This may be done by a variety of methods, e.g.:

- Medical Prescriber,
- Patient Group Directive,
- Non-Medical Prescriber.

Antibiotic prescription and duration of antibiotics should follow local antibiotic protocols. These should also reflect authoritative international guidance (NICE, 2011; SIGN, 2011; IDSA, 2012; IWGDF, 2012).

Desirable Standards

Patients with infections caused by antibiotic-resistant bacteria (e.g., MRSA) usually need to be decolonised; follow local Trust protocols

C. OFFLOADING THE AREA

Evidence statement

Total contact casting may be considered for people with foot ulcers unless there is severe ischaemia (NICE, 2004 - Grade B evidence). Pressure relieving support surfaces and strategies in line with “pressure ulcers” (NICE CG29).

Offer off loading. The HCP in the MDT should take into account the wound, patient preference and the clinical circumstances and use the technique with the lowest acquisition cost (NICE, 2011).

- The current evidence around offloading pressure / friction from ulcer sites is mainly based on plantar neuropathic ulceration and total contact casting continues to be the gold standard (Mueller et al, 1989; NICE, 2004). The Scotchcast boot is the main referenced option to date that has been cited for use in both neuropathic and neuro-ischaemic ulceration (Jones, 1991). Recently the use of synthetic semi rigid casting techniques has been trialled as an alternative with both neuropathic and neuroischaemic foot ulcers, involving the use of slipper casts and below knee casts (Stuart, 2006). Adhesive felt aperture padding is not currently recommended for use in the management of foot ulceration due to infection control issues.

The off loading device options are listed in descending order of current evidence strength:

- 1. Total contact cast**
(Mueller et al, 1989; Laing et al, 1991; Armstrong et al, 2001).
- 2. Removable cast walker**
(Lavery et al, 1996; Armstrong & Stacpoole-Shea, 1999).
- 3. Scotchcast boot**
(Burdon et al, 1983; Jones, 1991; McGill et al, 1996; Murdock, 1997; Knowles et al, 2002).
- 4. Slipper casts**
(Stuart, 2006)
- 5. Total contact insole**
(Janisse, 1993; Albert & Rinoie, 1994; Lobmann et al, 2001).
- 6. Poron / Cleron insoles**
(McPoil & Cornwall, 1992; Pawelka et al, 1997)

Rockers bars / soles are incorporated into total contact casts, removable cast walker and Scotch-cast boots, may be a vital element in offloading plantar (forefoot) ulceration. Current emerging studies have demonstrated their positive effect (Frykberg et al, 2002).

Ottoform (Silicones)

There is no evidence for or against the use of silicone devices within the management of diabetic foot ulcerations. The group recommends that silicones should only be used with caution. They should only be used on the diabetic foot by practitioners competent in their prescription and manufacture (TRIEPodD-UK, 2012). Their effect should be monitored at each subsequent ulcer review.

Essential Standards

- Initial minimum recommended option for offloading a plantar ulcer is a 7 – 10mm poron full length insole in a Darco / Derby post operative sandal.

Desirable Standards

- Podiatrists working with diabetic foot ulcers should be able to make / provide or have access to total contact casts / removable cast walkers / other off-loading devices.

D. BEHAVIOUR CHANGE / STRUCTURED PATIENT CENTRED EDUCATION

Offer patients consistent, relevant information and clear explanations that support informed decision making and provide opportunities for them to discuss issues and ask questions. Patients should have a named contact to provide information and liaise between secondary and primary and / or community care (NICE, 2011). There is a current scarcity of published evidence linked to education / behaviour change interventions in relation to people with foot ulceration. Therefore the following recommendations are based on CEG consensus opinion.

Essential Standards

- At the point of presentation all patients with foot ulcerations should be provided with written contact details for accessing the clinic.
- All patients with a foot ulcer should receive education which encourages partnership in decision making and supports them in achieving the best clinical outcome for their presenting foot problem.
- All patient advice should be documented in the patient's notes and followed up at subsequent appointments.
- An agreed plan of management between the patient and the podiatrist should be negotiated to achieve adequate levels of care. It should be mutually acceptable to both patient and clinician.

Desirable Standards

- Where possible, patient education should adopt behaviour change strategies which encourage patient interaction both during consultations and when away from the clinic. Podiatrists working with diabetes should acquire the related skills.

4.4. WOUND DOCUMENTATION

Essential Standards

- All assessment / treatment advice and action details should be recorded in line with local Trust Documentation Policy / Information governance policy
- Informed consent using NHS consent form 3 should be considered for radical wound debridement or other interventions e.g. larval therapy. This could be supported by health education literature (appendix 10) (Haycocks and Chadwick, 2008).

Desirable Standards

- None identified

5. Management of CHARCOT NEUROARTHROPATHY

Patient Assessment

Charcot Foot is a neuroarthropathic process with osteoporosis, fracture, acute inflammation and disorganisation of foot architecture (SIGN, 2010). Referral for suspected Charcot Foot should be immediate to a multidisciplinary foot care team for immobilisation of the affected joint(s) and for long term management to prevent ulceration.

- Diagnosis should be made by clinical examination and patient history including onset supported by the use of thermography (Frykberg et al, 2000; Jeffcoate et al, 2000).

5.1. Algorithm Guidelines for Charcot Neuroarthropathy

Clinical features

- Diabetes patient presents with red, oedematous, warm and possibly painful foot.
- Evidence of sensory loss.

Differential diagnosis between Charcot Neuroarthropathy and Infection

Diagnosis / Investigations

- Good blood supply to lower limb with evidence of neuropathy.
- Assess foot for obvious signs of tissue trauma, cellulitis or systemic toxicity to rule out infection.
- History of trauma to limb may be present.
- Heat differentiation between limbs – affected limb often 2-8 degrees higher than contralateral foot when tested with thermography.
- Biochemical profile as indicated e.g. HbA1c, ESR and C-reactive protein.
- X-Ray for baseline and to exclude diabetic neuropathic fracture.

Management

1. Immobilisation urgently required until heat differentiation disappears and bone activity reduces (SIGN, 2010).
2. Patients require education on the causes and management of Charcot foot and advice on prevention of complications.
3. There is insufficient evidence to support the routine use of bisphosphonates in the acute Charcot foot (SIGN, 2010). However, there are a number of studies which indicate that Bisphosphonates may be useful in halting the acute phase of Charcot neuroarthropathy in some patients. (Anderson et al, 2004; Jude et al, 1992). All suspected Charcot foot cases to be reviewed by Consultant Physician to consider options.
4. Consider referral to an Orthopaedic surgeon for assessment and discussion of appropriate surgical procedures.

Long Term Management

1. Long term pressure relief with footwear and orthotic therapy as appropriate. Refer to Orthotist or specialist podiatrist.
2. Classify patient as high current risk and review regularly for signs of long term complications (NICE, 2004).

Appendix 1: DIABETES FOOT SCREENING SERVICE FORM

Copies: White – GP Yellow – Podiatrist Blue – Patient (please use ballpoint)

| | | | | | |
|--|--|---|--|---|--|
| Patient Details Name Address Postcode DOB Date of Exam. | | GP Details Name Address Postcode | | Podiatrist Name Treatment Centre Contact No. | |
| | | | | Smoker : Yes <input type="checkbox"/> No <input type="checkbox"/> Advised <input type="checkbox"/> | |
| Previous amputation <input type="checkbox"/> <input checked="" type="checkbox"/> Y N Details R <input type="checkbox"/> site L <input type="checkbox"/> site | | Previous ulcerations <input type="checkbox"/> <input checked="" type="checkbox"/> Y N Details R <input type="checkbox"/> site L <input type="checkbox"/> site | | 10g monofilament sensation <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Vibration Perception <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Pinprick Sensation <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Claudication <input type="checkbox"/> <input checked="" type="checkbox"/> Y N Details R <input type="checkbox"/> site L <input type="checkbox"/> site | |
| | | | | Dorsalis Pedis Pulse <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Posterior Tibial Pulse <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Callus <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Foot/Nail Deformity <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Symptoms of painful Neuropathy <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | |
| Examination Summary Current Low Risk <input type="checkbox"/> <input checked="" type="checkbox"/> Y N | | Description Normal sensation, palpable pulses | | Podiatry Action Foot Care Education <input type="checkbox"/> Screen Annually Treatment as required | |
| At Increased Risk <input type="checkbox"/> <input checked="" type="checkbox"/> Y N | | Neuropathy or absent pulses or other risk factor (see guidelines for details) | | Routine treatment 3-6 Months/Screen Annually/ Foot Care Education <input type="checkbox"/> | |
| At High Risk <input type="checkbox"/> <input checked="" type="checkbox"/> Y N | | Neuropathy or absent pulses plus deformity or skin changes or previous ulceration or amputation. | | Routine Treatment 1-3 Months/Screen Annually <input type="checkbox"/> | |
| Foot Ulcer <input type="checkbox"/> <input checked="" type="checkbox"/> Y N | | Ulceration – Chronic / stable | | Manage in Primary Care / <input type="checkbox"/> Refer to MDT Foot Clinic (& per guidelines) <input type="checkbox"/> | |
| Foot Care Emergency <input type="checkbox"/> <input checked="" type="checkbox"/> Y N | | Ulceration – Acute / Emergency (Spreading, cellulitis, critical ischaemia , systemically unwell) | | Refer Urgently to GP / A&E <input type="checkbox"/> | |
| Charcot <input type="checkbox"/> <input checked="" type="checkbox"/> Y N | | Acute Charcot Foot | | Refer urgently to GP / A&E / Diabetes MDT Foot Clinic for investigations / immobilisation <input type="checkbox"/> | |

Appendix 2: ADVANCED VASCULAR ASSESSMENT

Lower Limb pulse assessment

Assess people with suspected peripheral arterial disease by examining the femoral, popliteal and foot pulses (NICE, 2012).

Doppler Assessment

Using an 8MHz Doppler probe the signal from a normal healthy artery has three phases and is therefore described as triphasic.

- A triphasic sound indicates that the vessels are healthy.
- A biphasic sound is considered a normal part of the ageing process as vessels lose their elasticity.
- A monophasic sound indicates either:
 - 1) Stenosis – sound being subtly low pitched and almost continuous.
 - 2) Calcification – likened to that of a soldier marching (Baker, 1999).

Ankle Brachial Index

The ratio of the systolic pressure at the Posterior Tibial or Dorsalis Pedis artery divided by the pressure at the brachial artery is known as the ankle / brachial index. This score can give an indication of the severity of any peripheral arterial disease.

Within diabetes and in particular in patients with concomitant renal disease, vascular calcification can be evident. Therefore caution should be used when interpreting ABPI's as the reading may be falsely elevated. Despite this, ABPI is still a useful part of lower limb vascular assessment and has been shown to be a reliable indicator of cardiovascular risk in people with diabetes. It has also been recommended by NICE as part of peripheral arterial assessment (NICE, 2012).

Toe Pressures – Toe Pressures Index

Toe pressures are carried out using a special cuff, usually 25mm wide, which is placed around the digit and the pulse is measured with a Doppler ultrasound device. Normal toe pressure is approximately 10-15mmHg below the arm pressure. A pressure difference of >20mmHg between the lower limb and the toe indicates pathological changes in the blood vessels. Toe pressures of <30mmHg indicate severe ischaemia of the foot or lower leg. This technique can be useful in diabetic patients with calcification of the larger peripheral arteries. It is important to have a light touch with the Doppler probe as the small vessels in the toe may be occluded by pressure. If the great toe is missing other digits can be used but it is important that an appropriate sized cuff is used (Blackburn and Kennedy, 1999).

Pole Test

The pole test can be useful as part of a clinical vascular assessment where vascular calcification is suspected. People with diabetes are susceptible to calcification of peripheral arteries (Goss et al, 1991). This can result in misleading high blood pressure readings. The pole test is used to estimate the true blood pressure in the lower limb by elevating the leg while monitoring the pedal pulse with the Doppler probe. The height, at which the pulse disappears, is measured by a pole marked in increments of 1cm. The height in cm is multiplied by 0.735 which gives the pressure in mmHg (Sumner, 1998).

Other Assessments

This final section includes other investigations which may be used to add to the overall clinical picture of the assessment, but have a limited weak evidence base:

- Bounding pulses
- Temperatures
- Colour

Edinburgh Intermittent Claudication Questionnaire

This validated questionnaire can be used as part of symptom history taking to establish if leg symptoms are likely to be intermittent claudication. The results need to be used in conjunction with pulse examination and ABPI to aid clinical diagnosis or exclusion of PAD.

Edinburgh Intermittent Claudication Questionnaire (Leng & Fowkes, 1992)

- | | | |
|--|------------|-----------|
| 1. Do you get pain or discomfort in your legs when you walk? (If 'no' you do not need to continue with questions 2 - 5) | <u>Yes</u> | No |
| 2. Does the pain ever begin when you are standing still or sitting? | Yes | <u>No</u> |
| 3. Do you get this pain if you walk uphill or when you hurry? | <u>Yes</u> | No |
| 4. Do you get this pain when you walk at an ordinary pace on the level? | <u>Yes</u> | No |
| 5. Does this pain disappear when you rest for less than 10 minutes? | <u>Yes</u> | No |

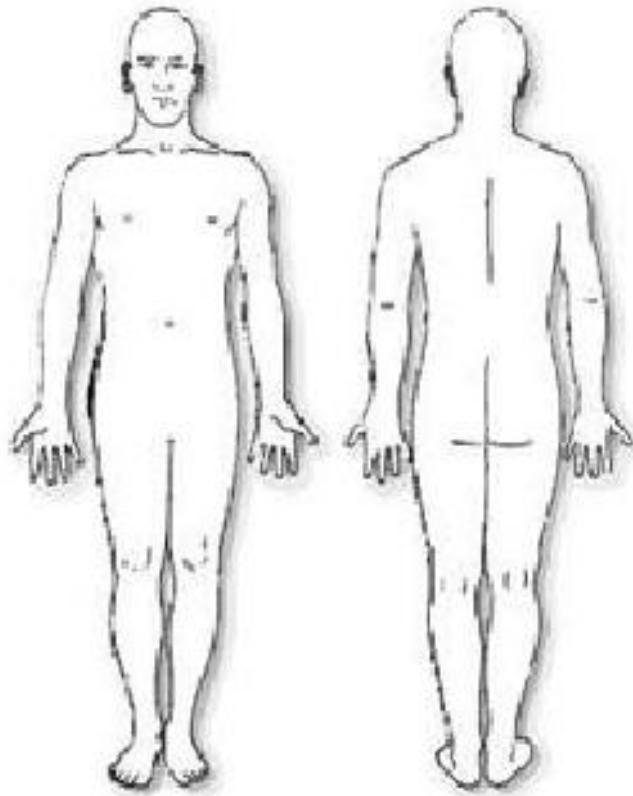
The responses 'Yes, No, Yes, Yes, Yes' indicate likely intermittent claudication.

Where full clinical vascular assessment gives non conclusive results and PAD is still suspected or thought to be severe / critical, it is essential that these patients are referred on for further vascular investigations and opinion from the Vascular Team.

APPENDIX 3- LANNS SCALE

NAME: _____ DATE: _____

This questionnaire can tell us about the type of pain that you may be experiencing. This can help in deciding how best to treat it. Please draw on the diagram below where you feel your pain. If you have pain in more than one area, **only shade in the one main area where your worst pain is.**



On the scale below, please indicate how bad your pain (that you have shown on the above diagram) has been in the last week where: '0' means no pain and '10' means pain as severe as it could be.



For scoring use only.

Answer (a) scores 0 and answer (b) for question carries following scores.
(Q1-5, Q2-5, Q3-3, Q4-3, Q5-1, Q6-5, Q7-3) A score of 12 or more suggests pain of a predominantly neuropathic origin. Lower score does not rule out neuropathic pain

SCORE

Source: Bennett, M et al The Journal of Pain, Vol 6, No 3 March , 2005 pp 149-158 The S-LANNS Score for Identifying Pain of Predominantly Neuropathic Origin: Validation for Use in Clinical and Postal Research The Journal

Appendix 4: NEUROPATHY DISABILITY SCORE

| NDS | | | |
|------------------|-------|------|---|
| | Right | Left | |
| Tuning fork | | | Present = 0 Absent = 1 |
| Neuro tip | | | Present = 0 Absent = 1 |
| Hot/cold | | | Present = 0 Absent = 1 |
| Ankle reflex | | | Present = 0 reduced = 1 Absent = 2 |
| Total | | | Maximum score = 10 |
| NDS score | | | Mild 3-4 Moderate 5-6 Severe 7-9 |

Appendix 5: Community MDT Referral form

Rapid Access to Community Multidisciplinary Foot Team (North Manchester)

Please complete the following Proforma. Incomplete or unsigned forms will not be accepted and will be returned. Please note that the foot protection team can be contacted Monday to Friday 9.00 - 4.00.

EXCLUSION CRITERIA

- Patients not registered with a North Manchester GP.(Refer to their appropriate Trust protocol)
- Patients identified as low or increased risk of Foot ulceration.(As defined in referral protocol)

INCLUSION CRITERIA

- Any patient with diabetes presenting with new or existing foot ulceration.
- Any patient identified as high risk of foot ulceration in need of specialist assessment or referral. (As defined by integrated Diabetic Foot care pathway).
- Any patients with a high risk foot with ulceration.

GP.....
Practice.....
Tel No.....

Date.....
.....
Fax No.....

Patient Name.....
Address.....
Postcode.....

Tel no (to arrange appointment).....
Date of Birth.....
Male / Female
NHS No.....

Details of foot assessment

Ulcer Yes / No
Infection Yes / No Neuropathy Yes / No
Foot pulses present and palpable Yes / No
Comments.....
.....

Diabetes Yes / No

Medication:-

Clinical History / Reason for Referral

Can patient attend Clinic? Y/N
Does the patient need an interpreter? Y/N

Language spoken.....

Signed Print Name.....

Date..... Designation / Base.....

Tel No..... Fax all referrals to Harpurhey Health Centre on 0161 205 0516 marked for the Attention of the Community Multidisciplinary Foot Team. The Team may be contacted directly on 0161 861 2400

Appendix 6: SINBAD wound classification

The SINBAD system for classifying and scoring foot ulcers

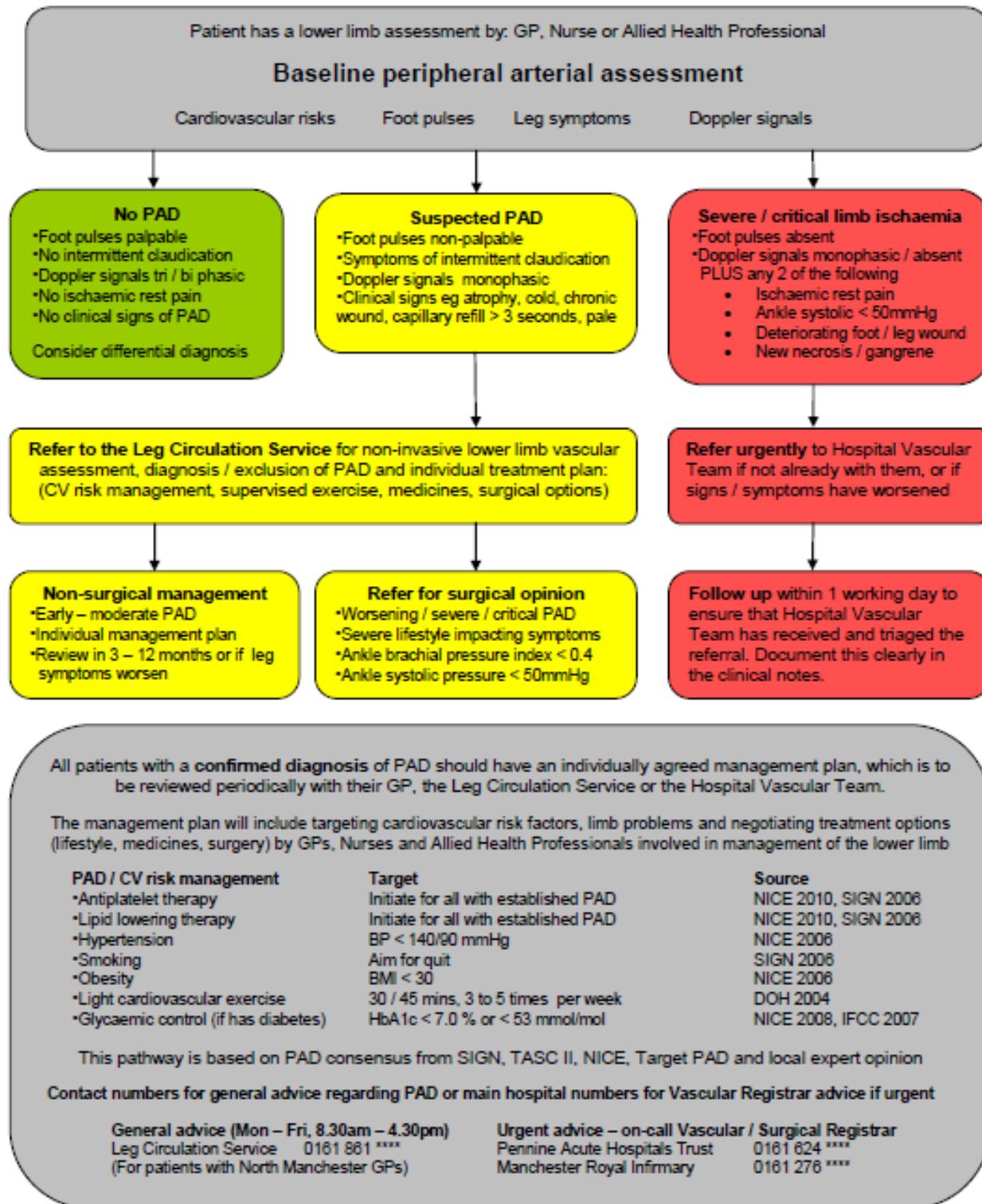
| Category | Definition | SINBAD score | Equivalent S(AD)SAD categories |
|----------------------|--|--------------|--------------------------------|
| Site | Forefoot | 0 | — |
| | Midfoot and hindfoot | 1 | — |
| Ischemia | Pedal blood flow intact: at least one pulse palpable | 0 | 0–1 |
| | Clinical evidence of reduced pedal blood flow | 1 | 2–3 |
| Neuropathy | Protective sensation intact | 0 | 0–1 |
| | Protective sensation lost | 1 | 2–3 |
| Bacterial infection | None | 0 | 0–1 |
| | Present | 1 | 2–3 |
| Area | Ulcer <1cm ² | 0 | 0–1 |
| | Ulcer ≥1cm ² | 1 | 2–3 |
| Depth | Ulcer confined to skin and subcutaneous tissue | 0 | 0–1 |
| | Ulcer reaching muscle, tendon or deeper | 1 | 2–3 |
| Total possible score | | 6 | — |

Appendix 7: PERIPHERAL ARTERIAL DISEASE CARE PATHWAY

NHS
Manchester

The Pennine Acute Hospitals NHS
NHS TRUST

Peripheral Arterial Disease (PAD) Integrated Care Pathway (for patients with North Manchester GPs)



Initiated 2011
Review 2013

Diabetic Foot Infections Antibiotic Protocol

| Infection severity | Recommended Treatment | Alternative | Treatment duration |
|--|--|---|--|
| Mild Infection | | | |
| <ul style="list-style-type: none"> ▪ Pus or inflamed wound present ▪ Limited to skin / soft tissues ▪ Inflammation extends less than 2 cm from wound ▪ Systemically well | <u>Antibiotic naïve</u> Flucloxacillin 1g QDS <u>Non antibiotic naïve</u> Doxycycline 100mg BD Or Clindamycin 300 mg QDS | <u>Antibiotic naïve</u> Doxycycline 100mg BD Or Clindamycin 300 mg QDS <u>Non antibiotic naïve</u> Discuss with Microbiology / ID | For 5 - 7 days after which treatment should be reviewed and continued or discontinued when clinically appropriate |
| Moderate Infection Pus or inflamed wound in a patient who is systemically well and/or one of the following: | <u>Antibiotic naïve</u> Flucloxacillin PO / IV 1-2g QDS +/- Metranidazole 400 mg TDS +/- Admit for Gentamycin IV <u>Non antibiotic naïve</u> Admit for IV | <u>Antibiotic naïve</u> Co-amoxiclav 625 mg TDS Or Clindamycin 450mg QDS +/- Metranidazole 400mg TDS if anaerobes suspected <u>Non antibiotic naïve</u> Admit for IV | For 5 - 7 days after which treatment should be reviewed and continued or discontinued when clinically appropriate If osteomyelitis present treat for at least 6 weeks |
| If MRSA suspected | Discuss with Microbiology / ID for oral options and treatment optimisation | Discuss with Microbiology / ID for oral options and treatment optimisation | |
| Severe Infection | Admit for IV | Admit for IV | |

Appendix 9:

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

Table 2.

Infectious Diseases Society of America and International Working Group on the Diabetic Foot Classifications of Diabetic Foot Infection

| Clinical Manifestation of Infection | PEDIS Grade | IDSA Infection Severity |
|--|-------------|-------------------------|
| No symptoms or signs of infection | 1 | Uninfected |
| Infection present, as defined by the presence of at least 2 of the following items: Local swelling or induration Erythema Local tenderness or pain Local warmth Purulent discharge (thick, opaque to white or sanguineous secretion) | 2 | Mild |
| Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). If erythema, must be >0.5 cm to ≤2 cm around the ulcer. Exclude other causes of an inflammatory response of the skin (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis). | 3 | Moderate |
| Local infection (as described above) with erythema > 2 cm, or involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis), and No systemic inflammatory response signs (as described below) Temperature >38°C or <36°C Heart rate >90 beats/min Respiratory rate >20 breaths/min or PaCO ₂ <32 mm Hg White blood cell count >12 000 or <4000 cells/µL or ≥10% immature (band) forms | 4 | Severe ^a |

Appendix 10: FOOT HEALTH EDUCATION LITERATURE

DO'S AND DON'TS

Do rest your foot as much as possible.

Do if you are diabetic keep your blood glucose levels well controlled. This is very important to help healing take place

Do give up smoking – ask your doctor, nurse or podiatrist for advice

Do keep your dressing in place and keep it dry. If you have problems with your dressing, contact your podiatrist or nurse

Do use any special footwear / insoles you have been provided with

Don't sit or stand in one position for a long time

Don't sit too close to the fire or heater

Don't stop taking antibiotics in the middle of a course as it encourages the growth of super bugs. Always consult your doctor first.

Remember ...

If you notice any change to your foot such as:

- Swelling
- Redness
- Increase in pain
- Increase in the amount of fluid coming from the ulcer
- If you develop hot or cold sweats or flu-like symptoms

Contact your podiatrist; nurse or GP immediately as these symptoms may suggest infection is present. Please refer to the contact telephone numbers on the front of this leaflet.

This leaflet was produced by the North West Clinical Effectiveness Group 2007.

FOOT ULCERS

A GUIDE FOR PATIENTS AND THEIR CARERS

CONTACT TELEPHONE NUMBERS:

.....
.....
.....
.....
.....

THIS LEAFLET HAS BEEN DESIGNED TO GIVE YOU MORE INFORMATION ABOUT YOUR FOOT ULCER

What is a Foot Ulcer?

An ulcer is a medical term for an open sore. Foot ulcers can take weeks or months to heal. Occasionally they can deteriorate and lead to severe infection, gangrene or amputation.

What causes Foot Ulcers?

- Ill fitting footwear
- Injury
- Walking Barefoot
- Poor foot hygiene
- Dry skin

Foot deformity, reduced blood supply or nerve supply to the feet can increase the risk of foot ulcers.

How are Foot ulcers treated?

Following an assessment, a plan of treatment will be agreed between yourself and your podiatrist / nurse. This will include:

1. Regular dressing of your ulcer – there are many different kinds of ulcer dressings, your podiatrist / nurse will suggest the best one for you.
2. Debridement when appropriate. Debridement is a term used to describe the removal of hard skin, or dead or infected tissue, debridement is not normally painful.

Studies have shown that appropriate debridement of foot ulcers helps them to heal faster.

Benefits of debridement:

- It reveals the full size of the ulcer.
- Reduces pressure on the edge of the ulcer.
- Reduces the risk of trapped infection.

Following debridement the ulcer may appear bigger or may bleed but it will be a cleaner ulcer.

The quickest way to debride ulcers is with a scalpel blade. If this is not appropriate a suitable dressing may be applied to encourage the ulcer to debride itself.

3. Pressure relief is an important part of your treatment plan. Any pressure exerted on your ulcer either from footwear or walking will slow down the healing process.

There are many different ways of taking pressure off your ulcer. You and your podiatrist can decide together which would be best for you.

Will I need special tests?

Sometimes tests may be necessary, these may include:

A swab from the ulcer to help identify bacteria which may be causing infection.

Circulation tests on your legs and feet.

Blood tests.

X ray or scan to help determine if infection is in the bone.

Do I need to take antibiotics?

Only if your ulcer is infected. You will receive individual advice if you develop infection.

How long do I need to take antibiotics for?

7 days to several months depending on how deep the infection is. You need to take your antibiotics regularly and complete the course.

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