

Diabetic foot problems: prevention and management of foot problems in people with diabetes

NICE guideline

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If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

Contents

| | |
|---|----|
| Introduction | 3 |
| Patient-centred care..... | 5 |
| Strength of recommendations | 6 |
| Update information..... | 8 |
| Key priorities for implementation..... | 9 |
| 1 Recommendations | 12 |
| 1.1 Care within 24 hours of a person with diabetic foot problems being admitted to hospital, or the detection of diabetic foot problems (if the person is already in hospital)..... | 12 |
| 1.2 Care across all healthcare settings | 13 |
| 1.3 Assessing the risk of developing a diabetic foot problem..... | 14 |
| 1.4 Diabetic foot problems | 17 |
| 1.5 Diabetic foot ulcer | 19 |
| 1.6 Diabetic foot infection..... | 21 |
| 1.7 Charcot arthropathy | 22 |
| 2 Research recommendations..... | 23 |
| 3 Other information..... | 26 |
| 4 The Guideline Development Group, Internal Clinical Guidelines team and NICE project team, and declarations of interests | 28 |

Introduction

Diabetes is one of the most common chronic diseases in the UK and its prevalence is increasing. In 2013, there were almost 2.9 million people in the UK diagnosed with diabetes. By 2025, it is estimated that more than 5 million people in the UK will have diabetes. In England, the number of people diagnosed with diabetes has increased by approximately 53% between 2006 and 2013, from 1.9 million to 2.9 million. The life expectancy of people with diabetes is shortened by up to 15 years, and 75% die of macrovascular complications.

The risk of foot problems in people with diabetes is increased, largely because of either diabetic neuropathy (nerve damage or degeneration) or peripheral arterial disease (poor blood supply due to diseased large- and medium-sized blood vessels in the legs), or both.

Foot complications are common in people with diabetes. It is estimated that 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives.

Diabetes is the most common cause of non-traumatic limb amputation, with diabetic foot ulcers preceding more than 80% of amputations in people with diabetes. After a first amputation, people with diabetes are twice as likely to have a subsequent amputation as people without diabetes. Mortality rates after diabetic foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation. Although people of South Asian, African and African-Caribbean family origin are more at risk of diabetes, there is no evidence that the prevalence of diabetic foot ulceration and amputation is higher in these subgroups than in the general population of people with diabetes in the UK.

Foot problems in people with diabetes have a significant financial impact on the NHS through primary care, community care, outpatient costs, increased bed occupancy and prolonged stays in hospital. A report published in 2012 by

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NHS Diabetes estimated that around £650 million (or £1 in every £150 the NHS spends) is spent on foot ulcers or amputations each year.

Reasons for the Guideline

Despite the publication of strategies on commissioning specialist services for preventing and managing diabetic foot problems, there is variation in practice in preventing and managing diabetic foot problems across different NHS settings, and amputation rates still vary up to fourfold in the UK.

This variation in practice results from a range of factors including the different levels of organisation of care for people with diabetes and diabetic foot problems. This variability depends on geography, individual trusts, individual specialties (such as the organisation and access of the diabetic foot care services) and availability of healthcare professionals with expertise in the management of diabetic foot problems.

Furthermore, the implementation of foot care screening programmes is still varied across the UK, and there is currently a lack of guidance on foot screening strategies aimed at children and young people with diabetes. There is a need for a comprehensive guideline on foot care for people with diabetes that addresses all NHS settings.

Medicines

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Patient-centred care

This guideline offers best practice advice on the care of adults, young people and children with type 1 or type 2 diabetes with, or at risk of developing, diabetic foot problems.

Patients and healthcare professionals have rights and responsibilities as set out in the [NHS Constitution for England](#) – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the [Department of Health's advice on consent](#). If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) and the supplementary [code of practice on deprivation of liberty safeguards](#).

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in [Patient experience in adult NHS services](#).

If a young person is moving between paediatric and adult services, care should be planned and managed according to the best practice guidance described in the Department of Health's [Transition: getting it right for young people](#).

Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.

Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also ‘Patient-centred care’).

Interventions that must (or must not) be used

We usually use ‘must’ or ‘must not’ only if there is a legal duty to apply the recommendation. Occasionally we use ‘must’ (or ‘must not’) if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions that should (or should not) be used – a ‘strong’ recommendation

We use ‘offer’ (and similar words such as ‘refer’ or ‘advise’) when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, ‘Do not offer...’) when we are confident that an intervention will not be of benefit for most patients.

Interventions that could be used

We use ‘consider’ when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient’s values

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and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Update information

This guidance updates and replaces NICE guidelines CG10 (published January 2004) and CG119 (published March 2011), and will replace the recommendations on footcare in NICE guideline CG15 (published July 2004).

The original NICE guidelines and supporting documents are available here:

- [Type 2 diabetes foot problems](#) (2004) NICE guideline CG10
- [Diabetic foot problems: inpatient management](#) (2011) NICE guideline CG119
- [Type 1 diabetes](#) (2004) NICE guideline CG15

Key priorities for implementation

The GDG members chose their 10 highest ranking recommendations for implementation and a weighted average of their responses was calculated.

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in [section 1](#).

Care within 24 hours of a person with diabetic foot problems being admitted to hospital, or the detection of diabetic foot problems (if the person is already in hospital)

- Each hospital should have a care pathway for people with diabetic foot problems who need inpatient care. [\[2011\] \[1.1.1\]](#)

Care across all healthcare settings

- Commissioners and service providers should ensure that the following are in place:
 - A diabetic foot protection service (for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community).
 - A multidisciplinary foot care service (for managing diabetic foot problems in hospital and in the community that cannot be managed by the foot protection service).
 - Robust protocols and clear local pathways for the continued and integrated care of people across all healthcare settings, including emergency care and general practice. The protocols should set out the relationship between the foot protection service and the multidisciplinary foot care service.
 - Regular reviews of treatment and patient outcomes, in line with the [National Diabetes Foot Care Audit](#). [\[1.2.1\]](#)

Assessing the risk of developing a diabetic foot problem

- For adults with diabetes, assess their risk of developing a diabetic foot problem at the following times: when diabetes is diagnosed, at least annually thereafter (see recommendation 1.3.11), if problems arise, and on any admission to hospital. [\[1.3.3\]](#)

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- When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following:
 - Neuropathy (use a 10 g monofilament to test foot sensation).
 - Limb ischaemia (also see the NICE guideline on [lower limb peripheral arterial disease](#)).
 - Ulceration.
 - Callus.
 - Infection and/or inflammation.
 - Deformity.
 - Gangrene.
 - Charcot arthropathy. [1.3.4]
- Assess the person's risk of developing a diabetic foot problem using the following risk stratification:
 - Low risk: no risk factors present, for example, no signs of neuropathy, no signs of peripheral arterial disease, and no other risk factors.
 - Moderate risk: 1 risk factor present, for example, signs of neuropathy or signs of peripheral arterial disease, but without callus or deformity. Disabled adults who cannot see their feet are also at moderate risk.
 - High risk: previous ulceration or amputation, or on renal replacement therapy, or more than 1 risk factor present, for example, signs of neuropathy or signs of peripheral arterial disease, with callus or deformity.
 - Active diabetic foot problem: ulceration, spreading infection, critical ischaemia, gangrene, suspicion of an acute Charcot arthropathy, or an unexplained hot, red, swollen foot with or without pain. [1.3.6]

Assessing the risk of developing a diabetic foot problem

- Refer people with an active diabetic foot problem to the foot protection service or multidisciplinary foot care service within 24 hours for appropriate triage according to local protocols. [1.4.1]
- If any of the following active diabetic foot problems are present, refer the person to the multidisciplinary foot care service within 24 hours so they can

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be assessed and an individualised treatment plan put in place according to local protocols:

- Ulceration with fever or any signs of sepsis.
- Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration).
- Ulceration with limb ischaemia (also see the NICE guideline on [lower limb peripheral arterial disease](#)).
- Gangrene (with or without ulceration).
- Suspicion of acute Charcot arthropathy. **[1.4.2]**

Diabetic foot infection

- Offer 1 or more of the following as standard care for treating diabetic foot ulcers:
 - Off-loading.
 - Control of foot infection.
 - Control of ischaemia.
 - Wound debridement.
 - Moist wound dressings if appropriate. **[1.5.4]**
- All hospital, primary care and community settings should have antibiotic guidelines covering the care pathway for managing diabetic foot infections that take into account local patterns of resistance. **[1.6.6]**

Charcot arthropathy

- Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present or pain is not reported.
[1.7.2]
- Refer the person urgently (within 24 hours) to the multidisciplinary foot care service to confirm the diagnosis, and offer non-weight-bearing treatment until definitive treatment can be started. **[1.7.3]**

1 Recommendations

The following guidance is based on the best available evidence. The [full guideline](#) [hyperlink to be added for final publication] gives details of the methods and the evidence used to develop the guidance.

Unless stated otherwise, the recommendations apply to children, young people and adults with diabetes.

1.1 Care within 24 hours of a person with diabetic foot problems being admitted to hospital, or the detection of diabetic foot problems (if the person is already in hospital)

The recommendations in this section were originally published in the NICE guideline on the inpatient management of diabetic foot problems (NICE guideline CG119), which has been replaced by this guideline.

- 1.1.1 Each hospital should have a care pathway for people with diabetic foot problems who need inpatient care. [2011]
- 1.1.2 A named consultant should be accountable for the overall care of the person, and for ensuring that healthcare professionals provide timely care. [2011]
- 1.1.3 Refer the person to the multidisciplinary foot care team within 24 hours of the initial examination of the person's feet. Transfer the responsibility of care to a consultant member of the multidisciplinary foot care team if a diabetic foot problem is the dominant clinical factor for inpatient care. [2011]
- 1.1.4 The named consultant and the healthcare professionals from the existing team should remain accountable for the care of the person unless their care is transferred to the multidisciplinary foot care team. [2011]

1.2 *Care across all healthcare settings*

- 1.2.1 Commissioners and service providers should ensure that the following are in place:
- A diabetic foot protection service (for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community).
 - A multidisciplinary foot care service (for managing diabetic foot problems in hospital and in the community that cannot be managed by the foot protection service).
 - Robust protocols and clear local pathways for the continued and integrated care of people across all healthcare settings, including emergency care and general practice. The protocols should set out the relationship between the foot protection service and the multidisciplinary foot care service.
 - Regular reviews of treatment and patient outcomes, in line with the [National Diabetes Foot Care Audit](#).
- 1.2.2 The foot protection service should be led by a podiatrist with specialist training in diabetic foot problems, and should have access to healthcare professionals with skills in the following areas:
- Diabetology.
 - Biomechanics.
 - Tissue viability.
- 1.2.3 The multidisciplinary foot care service should be led by a named healthcare professional, and consist of specialists with skills in the following areas:
- Diabetology.
 - Podiatry.
 - Diabetes specialist nursing.
 - Vascular surgery.
 - Microbiology

- Orthopaedic surgery.
 - Orthotics and/or biomechanics.
 - Interventional radiology.
 - Casting.
 - Tissue viability.
- 1.2.4 Healthcare professionals may need to discuss, agree and make special arrangements for disabled people and people who are housebound or living in care or nursing homes, to ensure equality of access to foot care assessments and treatments.
- 1.3 *Assessing the risk of developing a diabetic foot problem***
- Frequency of assessments**
- 1.3.1 For children with diabetes who are younger than 12 years, give them, and their parents or carers (as appropriate), basic foot care advice. Children younger than 12 should not need an annual assessment of their feet unless a diabetic foot problem is found or suspected.
 - 1.3.2 For young people with diabetes who are 12–17 years, the paediatric care team or the transitional care team should carry out an annual assessment of their feet and provide education about foot care. If a diabetic foot problem is found or suspected, the paediatric care team or the transitional care team should refer them to the appropriate specialist.
 - 1.3.3 For adults with diabetes, assess their risk of developing a diabetic foot problem at the following times: when diabetes is diagnosed, at least annually thereafter (see recommendation 1.3.11), if problems arise, and on any admission to hospital.

Assessing the risk of developing a diabetic foot problem

- 1.3.4 When examining a person's feet, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following:
- Neuropathy (use a 10 g monofilament to test foot sensation).
 - Limb ischaemia (also see the NICE guideline on [lower limb peripheral arterial disease](#)).
 - Ulceration.
 - Callus.
 - Infection and/or inflammation.
 - Deformity.
 - Gangrene.
 - Charcot arthropathy.
- 1.3.5 Interpret ankle brachial pressure index results carefully because calcified arteries may falsely elevate results.
- 1.3.6 Assess the person's risk of developing a diabetic foot problem using the following risk stratification:
- Low risk: no risk factors present, for example, no signs of neuropathy, no signs of peripheral arterial disease, and no other risk factors.
 - Moderate risk: 1 risk factor present, for example, signs of neuropathy or signs of peripheral arterial disease, but without callus or deformity. Disabled adults who cannot see their feet are also at moderate risk.
 - High risk: previous ulceration or amputation, or on renal replacement therapy, or more than 1 risk factor present, for example, signs of neuropathy or signs of peripheral arterial disease, with callus or deformity.
 - Active diabetic foot problem: ulceration, spreading infection, critical ischaemia, gangrene, suspicion of an acute Charcot

arthropathy, or an unexplained hot, red, swollen foot with or without pain.

Managing the risk of developing a diabetic foot problem

- 1.3.7 For people who are at low risk of developing a diabetic foot problem, continue to carry out annual foot assessments, emphasise the importance of foot care, and advise them that they could progress to moderate or high risk (also see recommendation 1.3.11).
- 1.3.8 Refer people who are at moderate or high risk of developing a diabetic foot problem to the foot protection service (also see recommendations 1.2.2 and 1.3.11).
- 1.3.9 For people at moderate or high risk of developing a diabetic foot problem, the foot protection service should:
 - Assess the feet.
 - Give advice about and provide skin and nail care of the feet.
 - Assess the biomechanical status of the feet, including the need to provide specialist footwear and orthotics.
 - Assess the vascular status of the lower limbs.
 - Liaise with other healthcare professionals (for example, the person's GP) about the person's diabetes management and risk of cardiovascular events.
- 1.3.10 The foot protection service should assess newly referred people as follows:
 - Within 2–4 weeks for people who are at high risk of developing a diabetic foot problem.
 - Within 6–8 weeks for people who are at moderate risk of developing a diabetic foot problem.
- 1.3.11 Depending on the person's risk of developing a diabetic foot problem, carry out reassessments at the following intervals:

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- Annually for people who are at low risk.
- Frequently (for example, every 3–6 months) for people who are at moderate risk.
- More frequently (for example, every 1–2 months) for people who are at high risk, if there is no immediate concern.
- Very frequently (for example, every 1–2 weeks) for people who are at high risk, if there is immediate concern.

Consider more frequent reassessments for people who are at moderate or high risk.

Patient information and support for people at risk of developing a diabetic foot problem

1.3.12 Provide consistent, relevant information and clear explanations to people with diabetes and/or their family members or carers (as appropriate) at the following times: when diabetes is diagnosed, during assessments, and if problems arise. Information should include the following:

- Basic foot care advice and the importance of foot care.
- Foot emergencies and who to contact.
- Footwear advice.
- The person's individual risk of developing a foot problem.
- Information about diabetes and the importance of blood glucose control.

1.4 *Diabetic foot problems*

Referral for people with an active diabetic foot problem

1.4.1 Refer people with an active diabetic foot problem to the foot protection service or multidisciplinary foot care service within 24 hours for appropriate triage according to local protocols.

1.4.2 If any of the following active diabetic foot problems are present, refer the person to the multidisciplinary foot care service within

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24 hours so they can be assessed and an individualised treatment plan put in place according to local protocols:

- Ulceration with fever or any signs of sepsis.
- Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration).
- Ulceration with limb ischaemia (also see the NICE guideline on [lower limb peripheral arterial disease](#)).
- Gangrene (with or without ulceration).
- Suspicion of acute Charcot arthropathy.

Patient information and support for people with a diabetic foot problem

1.4.3 Provide consistent, relevant information and clear explanations as part of the individualised treatment plan for people with a diabetic foot problem. Information should include the following:

- A clear explanation of the person's foot problem.
- Pictures of diabetic foot problems.
- Care of the other foot and leg.
- Foot emergencies and who to contact.
- Footwear advice.
- Wound care.
- Information about diabetes and the importance of blood glucose control.

1.4.4 If people present with a diabetic foot problem, take into account that they may have an undiagnosed, increased risk of cardiovascular disease that may need further investigation and treatment.

1.5 *Diabetic foot ulcer*

Investigation

1.5.1 If a person has a diabetic foot ulcer, assess and document the size, depth and position of the ulcer.

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- 1.5.2 Use a standardised system to document the severity of the foot ulcer, such as the SINBAD (Site, Ischaemia, Neuropathy, Bacterial Infection and Depth) or the University of Texas classification system.
- 1.5.3 Do not use the Wagner classification system to assess the severity of a foot ulcer.

Treatment

- 1.5.4 Offer 1 or more of the following as standard care for treating diabetic foot ulcers:
 - Off-loading.
 - Control of foot infection.
 - Control of ischaemia.
 - Wound debridement.
 - Moist wound dressings if appropriate.
- 1.5.5 Offer non-removable casting to off-load plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot ulcers.
- 1.5.6 In line with the NICE guideline on [pressure ulcers](#), use a pressure-redistributing device and strategies to minimise the risk of pressure ulcers developing.
- 1.5.7 Debridement in hospital should only be done by healthcare professionals from the multidisciplinary foot care team, using the technique that best matches their specialist expertise and clinical experience, the site of the diabetic foot ulcer and the person's preference.
- 1.5.8 Debridement in the community should only be done by healthcare professionals with the relevant training and skills, continuing the care described in the person's treatment plan.
- 1.5.9 Offer negative pressure wound therapy after debridement, on the advice of the multidisciplinary foot care service.

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- 1.5.10 When deciding about wound dressings and off-loading, take into account the clinical assessment of the wound and the person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances.
- 1.5.11 Consider dermal or skin substitutes as an adjunct to standard care only when healing has not progressed and on the advice of the multidisciplinary foot care service.
- 1.5.12 Do not offer the following treatments, unless as part of a clinical trial:
 - Electrical stimulation therapy, autologous platelet-rich plasma gel, regenerative wound matrices and dalteparin.
 - Growth factors (granulocyte colony-stimulating factor [G-CSF], platelet-derived growth factor [PDGF], epidermal growth factor [EGF] and transforming growth factor beta [TGF- β]).
 - Hyperbaric oxygen therapy.
- 1.5.13 When deciding the frequency of follow-up as part of the treatment plan, take into account the overall health of the person, how healing has progressed, and any deterioration.
- 1.5.14 Ensure that the frequency of monitoring set out in the person's individualised treatment plan is maintained whether the person is being treated in hospital or in the community.

1.6 *Diabetic foot infection*

Investigation

- 1.6.1 If a diabetic foot infection is suspected and a wound is present, send a soft tissue or bone sample from the base of the debrided wound for microbiological examination. If this cannot be obtained, take a superficial swab because it may provide useful information on the choice of antibiotic therapy.

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- 1.6.2 Consider an X-ray of the person's affected foot (or feet) to determine the extent of the foot problem.
- 1.6.3 Think about osteomyelitis if the person has a local infection, a deep foot wound or a chronic foot wound.
- 1.6.4 Be aware that osteomyelitis may be present despite normal inflammatory markers, X-rays or probe-to-bone testing.
- 1.6.5 If osteomyelitis is suspected but is not confirmed by initial X-ray, consider MRI to confirm the diagnosis.

Treatment

- 1.6.6 All hospital, primary care and community settings should have antibiotic guidelines covering the care pathway for managing diabetic foot infections that take into account local patterns of resistance.
- 1.6.7 Do not offer antibiotics to prevent foot infections.
- 1.6.8 Start antibiotic treatment for suspected foot infection as soon as possible. Take cultures and samples before, or as close as possible to, the start of antibiotic therapy.
- 1.6.9 Choose the antibiotic therapy based on the severity of the foot infection, the care setting, and the person's preferences, clinical situation and medical history and, if more than one regimen is appropriate, select the one with the lowest acquisition cost.
- 1.6.10 Use the clinical response to antibiotics and the results of the microbiological examination to decide the targeted antibiotic regimen.
- 1.6.11 Do not offer tigecycline unless other antibiotics are not suitable.
- 1.6.12 For mild foot infections, offer oral antibiotics with activity against gram-positive organisms.

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- 1.6.13 Do not use prolonged antibiotic therapy for mild soft tissue infections.
- 1.6.14 For moderate and severe foot infections, offer antibiotics with activity against gram-positive and gram-negative organisms, including anaerobic bacteria, as follows:
 - Moderate infections: base the route of administration on the clinical situation and the choice of antibiotic.
 - Severe infections: start with intravenous antibiotics and then reassess, based on the clinical situation¹.
- 1.6.15 Offer prolonged antibiotic treatment (usually 6 weeks) to all people with diabetes and osteomyelitis, according to local protocols.

1.7 *Charcot arthropathy*

Investigation

- 1.7.1 Be aware that if a person with diabetes fractures their foot or ankle, it may progress to Charcot arthropathy.
- 1.7.2 Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present or pain is not reported.
- 1.7.3 Refer the person urgently (within 24 hours) to the multidisciplinary foot care service to confirm the diagnosis, and offer non-weight-bearing treatment until definitive treatment can be started.
- 1.7.4 If acute Charcot arthropathy is suspected, X-ray the affected foot. Consider an MRI if the X-ray is normal but clinical suspicion still remains.

¹ See table 2 in the [Infectious Diseases Society of America \(IDSA\) guidelines](#), which shows the PEDIS grades and ISDA infection severity classifications for diabetic foot infections.

Treatment

- 1.7.5 If the multidisciplinary foot care service suspects acute Charcot arthropathy, offer treatment with a non-removable off-loading device. Only consider treatment with a removable off-loading device if a non-removable device is not advisable because of the clinical or the person's circumstances.
- 1.7.6 Do not offer bisphosphonates to treat acute Charcot arthropathy, unless as part of a clinical trial.
- 1.7.7 Monitor the treatment of acute Charcot arthropathy using clinical assessment. This should include measuring foot–skin temperature difference and taking serial X-rays until the acute Charcot arthropathy resolves. Acute Charcot arthropathy is likely to resolve when there is a sustained temperature difference of less than 2 degrees between both feet and when X-ray changes show no further progression.
- 1.7.8 People who have a foot deformity that may be the result of a previous Charcot arthropathy are at high risk of ulceration and should be cared for by the foot protection service.

2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline.

2.1 ***Negative pressure wound therapy for diabetic foot ulcers***

What is the clinical effectiveness of negative pressure wound therapy in the treatment of diabetic foot ulcers?

Why this is important

The evidence reviewed for negative pressure wound therapy was limited and of low quality. It would be useful to have more evidence for this commonly used treatment. It is proposed that a randomised controlled trial is undertaken to explore this question. The proposed study would monitor and evaluate the cure rates of foot ulcer resulting from diabetes, rates and extent of amputation (major or minor), health-related quality of life, adverse events and hospital admission rates and length of stay.

2.2 *Maggot debridement therapy*

What is the clinical effectiveness of maggot debridement therapy in the debridement of diabetic foot ulcers?

Why this is important

The evidence surrounding maggot debridement therapy was limited. It would be useful to have more evidence for this commonly used treatment. It is proposed that a randomised controlled trial is undertaken to explore this question. The proposed study would monitor and evaluate the cure rates of foot ulcer resulting from diabetes, rates and extent of amputation (major or minor), health-related quality of life, adverse events and hospital admission rates and length of stay.

2.3 *Diabetic ulcer dressings*

What is the clinical effectiveness of different dressing types (for example honey-based dressings) in treating diabetic foot problems?

Why this is important

The evidence surrounding different dressing types for diabetic foot ulcer was often limited or inconclusive. It is proposed that more randomised controlled trials are undertaken to explore this question, but alternative methodologies may also be considered in the case of treating a complex wound. The proposed study would monitor and evaluate the cure rates of foot ulcer resulting from diabetes, rates and extent of amputation (major or minor),

health-related quality of life, adverse events and hospital admission rates and length of stay.

2.4 *Monitoring frequency for people at risk of diabetic foot problems*

How often should people with diabetes who are at risk of developing foot problems be reviewed?

Why this is important

The evidence surrounding different monitoring frequencies for those at risk of diabetic foot problems was limited. It is proposed that a randomised controlled trial is undertaken to explore this question. The proposed study would monitor and evaluate the rates of foot ulcer or infection resulting from diabetes, rates and extent of amputation (major or minor), health-related quality of life, adverse events and hospital admission rates and length of stay as a result of different monitoring frequencies.

2.5 *Monitoring frequency for people with diabetic foot problems*

How often should people with diabetic foot problems (foot ulcers, soft tissue infections, osteomyelitis or gangrene) be reviewed?

Why this is important

The evidence surrounding different monitoring frequencies for those who have developed diabetic foot problems was limited. It is proposed that a randomised controlled trial is undertaken to explore this question. The proposed study would monitor and evaluate the cure rates of foot ulcer or infection resulting from diabetes, rates of re-ulceration, time to further ulceration, rates and extent of amputation (major or minor), and hospital and emergency admission rates and mortality as a result of different monitoring frequencies.

3 Other information

3.1 ***Scope and how this guideline was developed***

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

How this guideline was developed

NICE commissioned the Internal Clinical Guidelines team to develop this guideline. The team established a Guideline Development Group (see section 4), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

3.2 ***Related NICE guidance***

Details are correct at the time of consultation on the guideline (January 2015). Further information is available on the [NICE website](#).

Published

General

- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Medicines adherence](#) (2009) NICE guideline CG76

Condition-specific

- [Obesity](#) (2014) NICE guideline CG189
- [Exercise referral schemes to promote physical activity](#) (2014) NICE guideline PH54
- [Lipid modification](#) (2014) NICE guideline CG181
- [Pressure ulcers](#) (2014) NICE guideline CG179
- [Neuropathic pain – pharmacological management](#) (2013) NICE guideline CG173

DRAFT FOR CONSULTATION

- [Tobacco: harm reduction approaches to smoking](#) (2013) NICE guideline PH45
- [Physical activity: brief advice for adults in primary care](#) (2013) NICE guideline PH44
- [Lower limb peripheral arterial disease](#) (2012) NICE guideline CG147
- [Walking and cycling](#) (2012) NICE guideline PH41
- [Preventing type 2 diabetes: risk identification and interventions for individuals at high risk](#) (2012) NICE guideline PH38
- [Preventing type 2 diabetes: population and community-level interventions](#) (2011) NICE guideline PH35
- [Hypertension](#) (2011) NICE guideline CG127
- [Venous thromboembolism: reducing the risk](#) (2010) NICE guideline CG92
- [Depression in adults with a chronic physical health problem](#) (2009) NICE guideline CG91
- [Depression in adults](#) (2009) NICE guideline CG90
- [Brief interventions and referral for smoking cessation](#) (2006) NICE guideline PH1
- [Guidance on the use of patient-education models for diabetes](#) (2003) NICE technology appraisal guidance 60

Under development

NICE is developing the following guidance:

- [Diabetes in pregnancy](#). NICE guideline (publication expected February 2015)
- [Type 1 diabetes](#). NICE guideline (publication expected August 2015)
- [Type 2 diabetes](#). NICE guideline (publication expected August 2015)
- [Diabetes in children and young people](#). NICE guideline (publication expected August 2015)

4 The Guideline Development Group, Internal Clinical Guidelines team and NICE project team, and declarations of interests

4.1 *Guideline Development Group*

The Guideline Development Group members listed are those for the 2015 update. For the composition of the previous Guideline Development Groups, see the [full guideline](#).

Damien Longson (Chair)

Consultant Liaison Psychiatrist, Manchester Mental Health and Social Care Trust

Susan Benbow

Diabetologist, Consultant Physician in Diabetes and Endocrinology, Aintree University Hospital NHS Foundation Trust

Rachel Berrington

Diabetes Nurse Specialist, Senior Diabetes Specialist Nurse – foot lead
University hospitals of Leicester

Issak Bhojani

GP, Blackburn with Darwen

Sue Brown

Patient and carer member

Sheila Burston

Patient and carer member

Trevor Cleveland (co-opted expert member) (from October 2013)

Interventional and Consultant Vascular Radiologist, Sheffield Teaching Hospitals

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Nicholas Foster

Consultant Medical Microbiologist, Leeds Teaching Hospitals NHS Trust

Catherine Gooday

Principal Podiatrist, Norfolk and Norwich University Hospitals NHS Foundation Trust

Stephen Hutchins (co-opted expert member) (from November 2013)

Orthotist, Senior Clinical Lecturer in Orthotics, Directorate, Prosthetics and Orthotics, University of Salford, UK

Rachael Hutchinson

Orthopaedic Surgeon, Orthopaedic Consultant (Foot and ankle paediatrics), Norfolk and Norwich University Hospitals NHS Foundation Trust

Laurie King

Clinical Lead Podiatrist, Diabetic Foot Oxfordshire, Oxford Health NHS Foundation Trust and Seconded to Oxford University Hospitals NHS Trust

Fania Pagnamenta (co-opted expert member)

Nurse Consultant (Tissue Viability), Newcastle-upon-Tyne Hospitals NHS Foundation Trust

Gerry Rayman

Diabetologist, Consultant Physician and Head of Service, The Diabetes and Endocrine Centre and Diabetes Foot Clinic and Research Unit, Ipswich Hospital NHS Trust

Stella Vig

Vascular Surgeon, Vascular and General Surgical Consultant, Croydon University Hospital

4.2 Internal Clinical Guidelines team

Stephen Duffield (from April 2014)

Technical Analyst

DRAFT FOR CONSULTATION

Nicole Elliott (until June 2014)

Associate Director

Michael Heath (until October 2014)

Programme Manager

Vicky Gillis (from November 2013 to June 2014)

Technical Analyst

Craig Grime (from March 2013 to November 2013)

Technical Analyst

Chris Gibbons

Health Economist

Hugh McGuire (from April 2014)

Technical Adviser (from April 2014)

Stephanie Mills

Project Manager

Gabriel Rogers

Technical Adviser

Susan Spiers (from June 2014)

Associate Director

Toni Tan (until April 2014)

Technical Adviser

Susan Ellerby

Clinical Adviser

4.3 NICE project team

Christine Carson

Guideline Lead

Phil Alderson

Clinical Adviser

Claire Ruiz (until August 2013)

Guideline Commissioning Manager

Clifford Middleton (from August 2013)

Guideline Commissioning Manager

Laura Donegani (until March 2013)

Guideline Coordinator

Anthony Gildea (March 2013 to November 2014)

Guideline Coordinator

Besma Nash (from November 2013)

Guideline Coordinator

Nichole Taske

Technical Lead

Bhash Naidoo

Technical Adviser, Health Economics

Jasdeep Hayre (until June 2014)

Technical Analyst, Health Economics

Sarah Palombella

Senior Medical Editor

Asma Khalik

Medical Editor

4.4 *Declarations of interests*

The following members of the Guideline Development Group made declarations of interests. All other members of the Group stated that they had no interests to declare.

| Member | Interest declared | Type of interest | Decision taken |
|-------------------|--|---|--|
| Chizo Agwu | Chair of the Association of Children's Diabetes Clinicians | Specific, non-personal pecuniary interest | Declare and participate |
| Chizo Agwu | Received an educational grant from Ferring Pharmaceuticals to cover travel and accommodation to attend the European Society of Paediatric Endocrinology conference | Non-specific personal pecuniary | Declare and participate |
| Chizo Agwu | On the committee organising the annual Association of Children's Diabetes Clinicians conference in February 2015 | Specific non-personal pecuniary | Declare and participate |
| Susan Benbow | Partner is employed by WL Gore, which manufactures a variety of health-related products including stents in the US and also produces GORE-tex footwear | Non-specific personal family interest | Declare and participate |
| Susan Benbow | Chaired a conference for the Royal College Physicians in November 2014 on 'Diabetes in the elderly' | Personal non-pecuniary interest | Declare and participate |
| Rachel Berrington | Paid by Lilly to give quarterly talks on diabetic peripheral neuropathy | Specific personal pecuniary interest | Declare and withdraw from discussions that may relate to the topic |
| Rachel Berrington | Involved in research for the University of Nottingham on 'Evaluation of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes' | Personal non-pecuniary interest | Declare and participate |

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|-------------------|---|---|-------------------------|
| Rachel Berrington | Chair of local Casting Consensus Group. The aim of the group is to standardise how casting is performed, with competencies attached | Personal non-pecuniary interest | Declare and participate |
| Issak Bhojani | Presented a talk to local GPs on fasting (Ramadan) and hypoglycaemia. The educational session was sponsored by Merck and Co. | Non-specific personal pecuniary interest | Declare and participate |
| Issak Bhojani | GP surgery is being paid to take part in a randomised controlled trial 'QSAC: Oral Steroids for Acute Cough'. The trial is being funded through the National School for Primary Care Research (National Institute for Health Research) | Non-specific, non-personal pecuniary interest | Declare and participate |
| Catherine Gooday | Manages a foot clinic currently involved in the following research trials for which the clinic is being reimbursed: <ul style="list-style-type: none"> • Evaluation of lightweight fibreglass heel casts in the management of heel ulcers in diabetes. Sponsored by Nottingham University. CRN adopted trial • Comparing sampling methods in diabetic foot infections (CODIFI). Sponsored by University Leeds. CRN adopted trial • Assessment of the efficacy and safety of a new wound dressing in the local treatment of diabetic foot ulcers (EXPLORER). CRN adopted trial Proposed future involvement in studies <ul style="list-style-type: none"> • LeucoPatch Study. Sponsor Nottingham University | Non-personal pecuniary interests | Declare and participate |

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|-------------------|--|---------------------------------|--|
| | <ul style="list-style-type: none"> • Molnlycke Dressing Study. • Authorship on - Putting feet first: national minimum skills framework. The national minimum skills framework for commissioning of foot care services for people with diabetes. Revised 2011 • Member of Diabetes UK – Putting Feet First Implementation Group | | |
| Catherine Gooday | Member of a Casting Consensus Group | Personal non-pecuniary interest | Declare and participate |
| Stephen Hutchings | <p>Co-author of a published article:</p> <p>Chapman JD, Preece S, Braunstein B, Höhne A, Nester CJ, Brueggemann P, Hutchins S (2013) Effect of rocker shoe design features on forefoot plantar pressures in people with and without diabetes. Clin Biomech (Bristol, Avon) 28(6): 679–85</p> <p>This was an output of an EU-funded project: Special Shoe Movement (SSHOES) EC (Framework) project award, University of Salford. Principal investigator: C Nester (50%). Co-investigators: A Williams (15%), D Howard (20%), S Hutchins (15%)</p> | Personal non-pecuniary interest | Declare and participate |
| Laurie King | Research interest in the Ektona, a 3D camera | Personal non-pecuniary interest | Declare and participate |
| Fania Pagnamenta | Reimbursement for study leave and travel by URGO Medical to attend Wound UK conference in November 2012 | Personal pecuniary interest | Declare and participate on a co-opted expert basis (not able to participate in making recommendations) |

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| Fania Pagnamenta | Reimbursement by DirectHealthCare for travel and accommodation to attend a study day on pressure ulcer and measuring improvement | Personal pecuniary interest | Declare and participate on a co-opted expert basis (not able to participate in making recommendations) |
| Fania Pagnamenta | Fully sponsored by ArjoHuntleigh to attend the European Pressure Ulcer Advisory Panel Conference in August 2013 | Personal pecuniary interest | Declare and participate on a co-opted expert basis (not able to participate in making recommendations) |
| Gerry Rayman | Receives reimbursement from Owen Mumford who manufacture the neuropen, a monofilament and neurotip device designed by Gerry Rayman about 10 years ago | Personal pecuniary interest | Declare and withdraw from related discussions |
| Gerry Rayman | Principal investigator on research conducted by his department. Research grants have been received from Eli Lilly, Boehringer Ingelheim, Novo Nordisk, Sanofi, Abbott Diabetes Care, Medtronic Diabetes Care and Pfizer. These trials are related to insulin testing, blood glucose meter testing, glucose sensor testing and educational tools | Non-personal pecuniary interest | Declare and participate |
| Gerry Rayman | National Lead on the inpatient diabetes audit | Personal non-pecuniary interest | Declare and participate |
| Gerry Rayman | Works a clinical adviser on the 'Putting feet first' campaign with Diabetes UK | Personal non-pecuniary interest | Declare and participate |
| Gerry Rayman | Developed the Ipswich Touch Test for detecting sensory loss in the feet | Personal non-pecuniary interest | Declare and participate |
| Gerry Rayman | Developed the LDI flare technique | Personal non-pecuniary interest | Declare and participate |