

Diabetic foot problems: prevention and management

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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The application of the recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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This guideline replaces CG10 and CG119.

This guideline partially replaces CG15.

This guideline is the basis of QS6.

Introduction

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

Diabetes is 1 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. Peripheral arterial disease affects 1 in 3 people with diabetes over the age of 50, and can also increase the risk of heart attack and stroke. For more information, see the NICE guideline on <u>lower limb peripheral arterial disease</u>.

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. A foot ulcer can be defined as a localised injury to the skin and/or underlying tissue, below the ankle, in a person with diabetes.

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 and around 50% dying within 5 years of developing a diabetic foot ulcer. This high mortality rate is believed to be associated with cardiovascular disease, and emphasises the importance of good diabetic and cardiovascular risk management. 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 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 update

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.

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.

Safeguarding children

Remember that child maltreatment:

- is common
- can present anywhere
- may co-exist with other health problems, including diabetes.

See the NICE guideline on <u>child maltreatment</u> for clinical features that may be associated with maltreatment.

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 <u>NHS</u> <u>Constitution for England</u> – 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. If it is clear that the child or young person fully understands the treatment and does not want their family or carers to be involved, they can give their own consent. Healthcare professionals should follow the <u>Department of Health's advice on consent</u>. If someone does not have capacity to make decisions, healthcare professionals should follow the <u>code of practice that accompanies the Mental Capacity</u> <u>Act</u> and the supplementary <u>code of practice on deprivation of liberty safeguards</u>.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in <u>patient experience in adult NHS</u> <u>services</u>.

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 <u>Transition: getting it right for young people</u>.

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.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in <u>section 1</u>.

See <u>implementation: getting started</u> for information about putting the recommendations on dermoscopy, managing suboptimal vitamin D levels, sentinel lymph node biopsy and completion lymphadenectomy into practice.

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]

Care across all settings

- Commissioners and service providers should ensure that the following are in place:
 - A 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. This may also be known as an interdisciplinary foot care service.
 - Robust protocols and clear local pathways for the continued and integrated care of people across all 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 <u>National Diabetes</u> <u>Foot Care Audit</u>.

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, and at least annually thereafter (see recommendation 1.3.11).
- If any foot problems arise.
- On any admission to hospital, and if there is any change in their status while they are in hospital.
- When examining the feet of a person with diabetes, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following risk factors:
 - Neuropathy (use a 10 g monofilament as part of a foot sensory examination).
 - Limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease).
 - Ulceration.
 - Callus.
 - Infection and/or inflammation.
 - Deformity.
 - Gangrene.
 - Charcot arthropathy.
- Assess the person's current risk of developing a diabetic foot problem or needing an amputation using the following risk stratification:
 - Low risk:
 - ♦ no risk factors present except callus alone.
 - Moderate risk:
 - deformity or
 - \diamond neuropathy or
 - non-critical limb ischaemia.
 - High risk:
 - previous ulceration or

- ♦ previous amputation **or**
- on renal replacement therapy or
- oneuropathy and non-critical limb ischaemia together or
- oneuropathy in combination with callus and/or deformity or
- ♦ non-critical limb ischaemia in combination with callus and/or deformity.
- Active diabetic foot problem:
 - Ilceration or
 - spreading infection or
 - critical limb ischaemia or
 - ♦ gangrene **or**
 - suspicion of an acute Charcot arthropathy, or an unexplained hot, red, swollen foot with or without pain.

Diabetic foot problems

- If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to acute services and inform the multidisciplinary foot care service (according to local protocols and pathways; also see <u>recommendation 1.2.1</u>), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following:
 - Ulceration with fever or any signs of sepsis.
 - Ulceration with limb ischaemia (see the NICE guideline on <u>lower limb peripheral arterial</u> <u>disease</u>).
 - Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration).
 - Gangrene (with or without ulceration).
- For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see <u>recommendation 1.2.1</u>) for triage within 1 further working day.

Diabetic foot infection

• 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.

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.
- To confirm the diagnosis of acute Charcot arthropathy, refer the person within 1 working day to the multidisciplinary foot care service for triage within 1 further working day. Offer non-weight-bearing treatment until definitive treatment can be started by the multidisciplinary foot care service.

1 Recommendations

The following guidance is based on the best available evidence. The <u>full guideline</u> gives details of the methods and the evidence used to develop the guidance.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation). See <u>about this guideline</u> for details.

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 service 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 service 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 service. [2011]

1.2 Care across all settings

- 1.2.1 Commissioners and service providers should ensure that the following are in place:
 - A 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. This may also be known as an interdisciplinary foot care service.
 - Robust protocols and clear local pathways for the continued and integrated care of people across all 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 <u>National Diabetes</u> <u>Foot Care Audit</u>.
- 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 and orthoses.
 - Wound care.
- 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.
- Biomechanics and orthoses.
- Interventional radiology.
- Casting.
- Wound care.
- 1.2.4 The multidisciplinary foot care service should have access to rehabilitation services, plastic surgery, psychological services and nutritional services.
- 1.2.5 Healthcare professionals may need to discuss, agree and make special arrangements for disabled people and people who are housebound or living in care settings, to ensure equality of access to foot care assessments and treatments for people with diabetes.
- 1.2.6 Take into account any disabilities, including visual impairment, when planning and delivering care for people with diabetes.

1.3 Assessing the risk of developing a diabetic foot problem

Frequency of assessments

- 1.3.1 For children with diabetes who are under 12 years, give them, and their family members or carers (as appropriate), basic foot care advice.
- 1.3.2 For young people with diabetes who are 12–17 years, the paediatric care team or the transitional care team should assess the young person's feet as part of their annual assessment, and provide information about foot care. If a diabetic foot problem is found or suspected, the paediatric care team or the transitional care team should refer the young person to an 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, and at least annually thereafter (see recommendation 1.3.11).

- If any foot problems arise.
- On any admission to hospital, and if there is any change in their status while they are in hospital.

Assessing the risk of developing a diabetic foot problem

- 1.3.4 When examining the feet of a person with diabetes, remove their shoes, socks, bandages and dressings, and examine both feet for evidence of the following risk factors:
 - Neuropathy (use a 10 g monofilament as part of a foot sensory examination).
 - Limb ischaemia (see the NICE guideline on lower limb peripheral arterial disease).
 - Ulceration.
 - Callus.
 - Infection and/or inflammation.
 - Deformity.
 - Gangrene.
 - Charcot arthropathy.
- 1.3.5 Use ankle brachial pressure index in line with the NICE guideline on <u>lower limb</u> <u>peripheral arterial disease</u>. Interpret results carefully in people with diabetes because calcified arteries may falsely elevate results.
- 1.3.6 Assess the person's current risk of developing a diabetic foot problem or needing an amputation using the following risk stratification:
 - Low risk:
 - no risk factors present except callus alone.
 - Moderate risk:
 - deformity or
 - neuropathy or

- non-critical limb ischaemia.
- High risk:
 - previous ulceration or
 - previous amputation or
 - on renal replacement therapy or
 - neuropathy and non-critical limb ischaemia together or
 - neuropathy in combination with callus and/or deformity or
 - non-critical limb ischaemia in combination with callus and/or deformity.
- Active diabetic foot problem:
 - ulceration or
 - spreading infection or
 - critical limb ischaemia or
 - gangrene **or**
 - 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.
- 1.3.8 Refer people who are at moderate or high risk of developing a diabetic foot problem to the foot protection service.
- 1.3.9 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.
- 1.3.10 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 orthoses.
 - 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 disease.
- 1.3.11 Depending on the person's risk of developing a diabetic foot problem, carry out reassessments at the following intervals:
 - 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, and for people who are unable to check their own feet.

1.3.12 People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service.

Patient information about the risk of developing a diabetic foot problem

- 1.3.13 Provide information and clear explanations to people with diabetes and/or their family members or carers (as appropriate) when diabetes is diagnosed, during assessments, and if problems arise. Information should be oral and written, and include the following:
 - Basic foot care advice and the importance of foot care.
 - Foot emergencies and who to contact.
 - Footwear advice.
 - The person's current individual risk of developing a foot problem.
 - Information about diabetes and the importance of blood glucose control (also see recommendation 1.3.14).
- 1.3.14 For guidance on education programmes and information about diabetes, see the <u>education and information</u> section in type 1 diabetes in adults: diagnosis and management (NICE guideline NG17), the <u>patient education</u> section in type 2 diabetes in adults: management (NICE guideline NG28) and the sections <u>education and information for children and young people with type 1 diabetes</u> and <u>education and information for children and young people with type 2</u> <u>diabetes</u> in diabetes (type 1 and type 2) in children and young people: diagnosis and management (NICE guideline NG18).

1.4 Diabetic foot problems

Referral

- 1.4.1 If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to acute services and inform the multidisciplinary foot care service (according to local protocols and pathways; also see recommendation 1.2.1), so they can be assessed and an individualised treatment plan put in place. Examples of limb-threatening and life-threatening diabetic foot problems include the following:
 - Ulceration with fever or any signs of sepsis.

- Ulceration with limb ischaemia (see the NICE guideline on <u>lower limb peripheral</u> <u>arterial disease</u>).
- Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration).
- Gangrene (with or without ulceration).
- 1.4.2 For all other active diabetic foot problems, refer the person within 1 working day to the multidisciplinary foot care service or foot protection service (according to local protocols and pathways; also see recommendation 1.2.1) for triage within 1 further working day.

Patient information about diabetic foot problems

- 1.4.3 Provide information and clear explanations as part of the individualised treatment plan for people with a diabetic foot problem. Information should be oral and written, and 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 (also see recommendation 1.3.14).
- 1.4.4 If a person presents 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. For guidance on the primary prevention of cardiovascular disease, see the NICE guideline on <u>lipid</u> modification.

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.
- 1.5.2 Use a standardised system to document the severity of the foot ulcer, such as the SINBAD (Site, Ischaemia, Neuropathy, Bacterial Infection, Area 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 diabetic foot ulcer.

Treatment

- 1.5.4 Offer 1 or more of the following as standard care for treating diabetic foot ulcers:
 - Offloading.
 - Control of foot infection.
 - Control of ischaemia.
 - Wound debridement.
 - Wound dressings.
- 1.5.5 Offer non-removable casting to offload plantar neuropathic, non-ischaemic, uninfected forefoot and midfoot diabetic ulcers. Offer an alternative offloading device until casting can be provided.
- 1.5.6 In line with the NICE guideline on <u>pressure ulcers</u>, use pressure-redistributing devices and strategies to minimise the risk of pressure ulcers developing.
- 1.5.7 When treating diabetic foot ulcers, debridement in hospital should only be done by healthcare professionals from the multidisciplinary foot care service, 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 When treating diabetic foot ulcers, 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 Consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service.
- 1.5.10 When deciding about wound dressings and offloading when treating diabetic foot ulcers, 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 when treating diabetic foot ulcers, only when healing has not progressed and on the advice of the multidisciplinary foot care service.
- 1.5.12 Do not offer the following to treat diabetic foot ulcers, 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 with diabetes, 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 with diabetes 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 deep swab because it may provide useful information on the choice of antibiotic treatment.
- 1.6.2 Consider an X-ray of the person's affected foot (or feet) to determine the extent of the diabetic foot problem.
- 1.6.3 Think about osteomyelitis if the person with diabetes has a local infection, a deep foot wound or a chronic foot wound.
- 1.6.4 Be aware that osteomyelitis may be present in a person with diabetes despite normal inflammatory markers, X-rays or probe-to-bone testing.
- 1.6.5 If osteomyelitis is suspected in a person with diabetes but is not confirmed by initial X-ray, consider an 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 diabetic foot infections.
- 1.6.8 Start antibiotic treatment for suspected diabetic foot infection as soon as possible. Take cultures and samples before, or as close as possible to, the start of antibiotic treatment.
- 1.6.9 Choose the antibiotic treatment based on the severity of the diabetic foot infection, the care setting, and the person's preferences, clinical situation and medical history and, if more than 1 regimen is appropriate, select the regimen with the lowest acquisition cost.

- 1.6.10 Decide the targeted antibiotic regimen for diabetic foot infections based on the clinical response to antibiotics and the results of the microbiological examination.
- 1.6.11 Do not offer tigecycline to treat diabetic foot infections unless other antibiotics are not suitable.
- 1.6.12 For mild diabetic foot infections, initially offer oral antibiotics with activity against gram-positive organisms.
- 1.6.13 Do not use prolonged antibiotic treatment (more than 14 days) for the treatment of mild soft tissue diabetic foot infections.
- 1.6.14 For moderate and severe diabetic foot infections, initially 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 situation.
- 1.6.15 Offer prolonged antibiotic treatment (usually 6 weeks) to 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 To confirm the diagnosis of acute Charcot arthropathy, refer the person within 1 working day to the multidisciplinary foot care service for triage within 1 further working day. Offer non-weight-bearing treatment until definitive treatment can be started by the multidisciplinary foot care service.
- 1.7.4 If acute Charcot arthropathy is suspected, arrange a weight-bearing X-ray of the affected foot and ankle. Consider an MRI if the X-ray is normal but Charcot arthropathy is still suspected.

Treatment

- 1.7.5 If the multidisciplinary foot care service suspects acute Charcot arthropathy, offer treatment with a non-removable offloading device. If a non-removable device is not advisable because of the clinical, or the person's, circumstances, consider treatment with a removable offloading device.
- 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 Intensive monitoring for people at risk of diabetic foot problems

Does intensive monitoring of people at risk of diabetic foot disease reduce the morbidity associated with developing the disease and is such monitoring cost effective?

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 or cohort study 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.

2.2 Referral criteria for the foot protection service and the multidisciplinary foot care service

When and with what criteria should people with diabetes be referred to the foot protection service or the multidisciplinary foot care service?

Why this is important

The evidence surrounding different referral criteria for those at risk of, or who have developed diabetic foot problems was limited. It is proposed that a prospective cohort study is undertaken to explore this question. The proposed study would monitor and evaluate the rates (and recurrent rates) of foot ulceration, infection and gangrene resulting from diabetes, resource use and costs (including referral rates), rates of hospital admission for foot problems resulting from diabetes, length of hospital stay, and the health-related quality of life as a result of different referral criteria to these teams.

2.3 Education and psycho-behavioural interventions for prevention

What is the role of educational models and psycho-behavioural interventions in prevention of diabetic foot complications?

Why this is important

The evidence surrounding the role of educational measures for those at risk of diabetic foot problems was limited and inconclusive. It is proposed that new interventions are developed that target psychological and behavioural factors. The proposed study would monitor and evaluate the rates (and recurrent rates) of foot ulceration, infection and gangrene resulting from diabetes, rates and extent of amputation, rates of hospital admission for foot problems resulting from diabetes, length of hospital stay, and resource use and cost as a result of applying these interventions.

2.4 Prevention strategies for Charcot arthropathy

What strategies may be useful in the prevention of Charcot arthropathy?

Why this is important

The evidence surrounding Charcot arthropathy was limited and of low quality. It is proposed that a prospective cohort study is undertaken to explore this question. The proposed study would monitor and evaluate the rates of Charcot arthropathy resulting from diabetes, rates and extent of amputation (major or minor), rates and extent of deformity, health-related quality of life, and hospital admission rates following strategies for the prevention of Charcot arthropathy or its sequelae.

2.5 Diabetic ulcer dressings

What is the clinical effectiveness of different dressing types 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.

3 Other information

3.1 Scope and how this guideline was developed

NICE guidelines are developed in accordance with a <u>scope</u> 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 <u>section 4</u>), 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 publication of the guideline (August 2015). Further information is available on the <u>NICE website</u>.

Published

General

- Drug allergy (2014) NICE guideline CG183
- Patient experience in adult NHS services (2012) NICE guideline CG138
- <u>Medicines adherence</u> (2009) NICE guideline CG76

Condition-specific

- Type 2 diabetes in adults: management (2015) NICE guideline NG28
- Type 1 diabetes in adults: diagnosis and management (2015) NICE guideline NG17
- <u>Diabetes (type 1 and type 2) in children and young people: diagnosis and management</u> (2015) NICE guideline NG18
- Antimicrobial stewardship (2015) NICE guideline NG15

- <u>Maintaining a healthy weight and preventing excess weight gain among adults and children</u> (2015) NICE guideline NG7
- Diabetes in pregnancy (2015) NICE guideline NG3
- <u>Obesity: identification, assessment and management of overweight and obesity in children,</u> young people and adults (2014) NICE guideline CG189
- Exercise referral schemes to promote physical activity (2014) NICE guideline PH54
- Lipid modification (2014) NICE guideline CG181
- <u>Pressure ulcers</u> (2014) NICE guideline CG179
- <u>VibraTip for testing vibration perception to detect diabetic peripheral neuropathy</u> (2014) NICE medical technology guidance 22
- <u>Neuropathic pain pharmacological management</u> (2013) NICE guideline CG173
- 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
- <u>Preventing type 2 diabetes: risk identification and interventions for individuals at high risk</u> (2012) NICE guideline PH38
- <u>Preventing type 2 diabetes: population and community-level interventions</u> (2011) NICE guideline PH35
- <u>Hypertension</u> (2011) NICE guideline CG127
- <u>Venous thromboembolism: reducing the risk</u> (2010) NICE guideline CG92
- Depression in adults with a chronic physical health problem (2009) NICE guideline CG91
- Depression in adults (2009) NICE guideline CG90
- <u>Obesity: guidance on the prevention of overweight and obesity in adults and children</u> (2006) NICE guideline CG43
- Brief interventions and referral for smoking cessation (2006) NICE guideline PH1

• <u>Guidance on the use of patient-education models for diabetes</u> (2003) NICE technology appraisal guidance 60

Under development

NICE is developing the following guidance:

• <u>Sepsis: the recognition, diagnosis and management of severe sepsis</u>. NICE guideline (publication expected July 2016)

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 Group, see the <u>full guideline</u>.

Damien Longson (Chair) Consultant Liaison Psychiatrist, Manchester Mental Health and Social Care Trust

Chizo Agwu

Consultant Paediatrician/Clinical Director, Sandwell & Birmingham NHS Trust/ Honorary Senior Clinical Lecturer, University of Birmingham

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

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

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

Susan Ellerby Clinical Adviser

Nicole Elliott (until June 2014) Associate Director

Vicky Gillis (from November 2013 to June 2014) Technical Analyst Craig Grime (from March 2013 to November 2013) Technical Analyst

Chris Gibbons Health Economist

Michael Heath (until October 2014) Programme Manager

Hugh McGuire (from April 2014) Technical Adviser

Stephanie Mills Project Manager

Gabriel Rogers Technical Adviser

Susan Spiers (from June 2014) Associate Director

Toni Tan (until April 2014) Technical Adviser

4.3 NICE project team

Christine Carson Guideline Lead

Phil Alderson Clinical Adviser

Claire Ruiz (until August 2013) Guideline Commissioning Manager

Oliver Bailey (from August 2013 to February 2015) Guideline Commissioning Manager Sarah Stephenson (from February 2015) Guideline Commissioning Manager

Laura Donegani (until March 2013) Guideline Coordinator

Anthony Gildea (March 2013 to November 2014) Guideline Coordinator

Besma Nash (from November 2013 to April 2015) Guideline Coordinator

James Povah (from April 2015 to June 2015) Guideline Coordinator

Trudie Willingham (from June 2015) 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

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 Deci interest	ision taken
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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 interest	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 interest	Declare and participate
Chizo Agwu	Member of the Royal College of Paediatrics and Children's Health	Specific personal non-pecuniary interest	Declare and participate
Chizo Agwu	Member of the European Society of Paediatric Endocrinology	Specific personal non-pecuniary interest	Declare and participate
Chizo Agwu	Member of the British Society for Paediatric Endocrinology and Diabetes	Specific personal non-pecuniary interest	Declare and participate
Chizo Agwu	Member of the International Society for Pediatric and Adolescent Diabetes	Specific personal non-pecuniary interest	Declare and participate
Chizo Agwu	On the editorial board of the journal, Diabetes Digest	Specific personal non-pecuniary interest	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 of 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
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
lssak 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: Evaluation of lightweight fibreglass heel casts in the management of heel ulcers in diabetes. Sponsored by Nottingham University. CRN adopted trial 	Non-personal pecuniary interest	Declare and participate
	• 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		
	• LeucoPatch Study. Sponsor Nottingham University		
	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	Co-author of a published article: 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 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%)	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)
Fania Pagnamenta	Reimbursement by Direct Healthcare 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 as 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

Implementation: getting started

This section highlights 3 areas of the diabetic foot problems guideline that could have a big impact on practice and be challenging to implement, along with the reasons why change is happening in these areas (given in the box at the start of each area). We identified these with the help of stakeholders and GDG members (see <u>section 9.4 of the manual</u>).

The challenge: competently undertaking routine assessments to determine the risk of diabetic foot problems developing

See recommendations 1.3.3-1.3.7.

Ensuring that all assessments and, where necessary, referrals to foot care services, are undertaken by skilled and trained healthcare professionals will reduce the risk of complications associated with diabetic foot problems (such as ulceration, infection, amputation and death) and their associated costs.

Ensuring that staff are competent in carrying out routine foot assessment for people with diabetes

It is important that healthcare professionals responsible for undertaking routine assessments to determine a person's risk of diabetic foot problems have the skills and knowledge to meet the requirements for examining people's feet and take the recommended actions described (see <u>recommendation 1.3.4</u>). This may be particularly challenging for healthcare professionals working in general practice who are responsible for caring for people with a wide variety of conditions and who therefore may not have expertise in this area.

To do this, managers of services responsible for carrying out routine annual foot assessments could:

- Increase staff awareness of locally available diabetic foot problems services, by making links to:
 - Foot protection service.
 - Multidisciplinary foot care service.
 - Other practices carrying out routine annual foot assessments.

• Support staff to develop and maintain the necessary skills. This could include regular training events with the local diabetic foot problems service.

To do this, commissioners could:

- Review their incentive systems for annual diabetic reviews to support staff to carry out foot assessments in line with the recommendations, and to take appropriate actions with the results.
- Establish an 'integrated interdisciplinary foot care service' for people with diabetes, incorporating the foot protection service and multidisciplinary foot care service, in order to support the skills of those carrying out routine assessments.
- Use service specifications to ensure that assessments are standardised across all the integrated services.

The challenge: establishing a foot protection service

See recommendations <u>1.2.1, 1.2.2, 1.3.8–1.3.12, 1.4.2, 1.7.8</u>.

Improved patient outcomes (such as reduced rates of foot ulceration, infection, gangrene, hospital admissions, amputation and length of hospital stay) and significant cost savings are likely to be achieved in the long term across all care settings where there is access to a foot protection service or multidisciplinary foot care service.

Ensuring healthcare professionals have the appropriate skills and competencies to deliver the foot protection service:

It may be challenging to ensure that staff in the foot protection service have the necessary skills and competencies because:

- Staff working in some foot protection services may need extra training if the remit of their current foot protection service differs from what is recommended in this guideline.
- Complex, active foot problems are managed by the multidisciplinary foot care service, therefore staff in the foot protection service may find it challenging to maintain their skills and competency in assessing and triaging more complex cases.
- It could be difficult to recruit and retain skilled podiatrists to lead this service at this level.

To do this, lead podiatrists and managers of foot protection services could:

- Invest in long-term development of podiatrists with the relevant skills and competencies by:
 - providing learning placements and opportunities to undergraduate and postgraduate podiatrists
 - liaising with the multidisciplinary foot care service to establish a programme of secondments and rotational placements for qualified podiatrists between services.

What could commissioners do to help?

• Support members of the multidisciplinary foot care service to be flexible, and provide access to their skills for the foot protection service. This would promote shared learning and training, and increase service capacity.

Ensuring timely access to the service for eligible patients

Achieving the recommended timeframes for triaging, assessing and reassessing people with diabetes may be a change to current practice for some areas (see recommendations 1.3.9, 1.3.11 and 1.4.2) and may increase demand on capacity.

To do this, lead podiatrists and managers of the footprotection services could:

- Review people under the care of the (diabetic) foot protection service and ensure that they meet the criteria identified within this guideline. See the QIPP example <u>podiatry education to</u> <u>empower patients to self-care</u>.
- Use the NICE <u>costing report and template</u> to develop a business case for local commissioners to secure support for development or enhancement of a foot protection service with capacity to meet demand.

What can commissioners do to help?

- Be flexible with resources when establishing a foot protection service to maximise patient access to healthcare professionals with skills in diabetology, biomechanics, orthoses and wound care when clinically required.
- Ensure that service specifications about which patients should be cared for within this service meet those recommended in this guideline.

• Consider creating an integrated interdisciplinary foot care service that starts at the point of diagnosis of diabetes and continues indefinitely. This will streamline the service and allow for rapid referrals, fewer delays and better communication. Service specifications could be used to develop robust protocols and local pathways clearly defining the relationships between services.

The challenge: establishing a multidisciplinary foot care service, which consists of specialists with skills in the recommended areas

See recommendations <u>1.1.3, 1.2.1, 1.2.3, 1.4.1, 1.4.2.</u>

The presence of multidisciplinary care with a well-designed team reduces rates of amputation and the length of hospital stay.

A culture of sharing of information, skills and abilities will be created by integrating the multidisciplinary foot care service with other services responsible for caring for people at risk of, or with, diabetic foot problems. This could lead to people with diabetes becoming better informed, having faster access to treatment, and fewer mistakes being made.

Ensuring that people with diabetic foot problems have access to the multidisciplinary foot care service

There are variations in availability and access to this service across the country. Centralisation of vascular services may mean that some hospitals do not have on-site access to vascular specialists.

To do this hospital managers and the named healthcare professional could:

- Work creatively to provide a flexible approach that focuses on core membership and achieving access to services when clinically needed, for example, through a network or vascular hub. One idea could be a weekly multidisciplinary foot care service meeting where members of the surgical and radiological teams are present.
- Use the <u>NICE costing report and template</u> to develop a business case for trust senior management and local commissioners to secure support for establishing or developing the multidisciplinary foot care service. This should include recognition that likely savings will be to the wider health economy.

To do this, commissioners could:

- Support the development of a multidisciplinary foot care service through commissioning arrangements. Ensuring access to high-quality vascular services and support from those services will be an important part of this.
- Use service specification to support integration of the multidisciplinary foot care service with the foot protection team and services responsible for the routine annual assessment of the risk of diabetic foot problems.

Need more help?

<u>Further resources</u> are available from NICE to support implementation of this guideline.

- <u>The National Diabetes Audit</u> is a major national clinical audit that measures the effectiveness of diabetes healthcare against NICE Clinical Guidelines and NICE Quality Standards in England and Wales. Within the overarching audit there are sub audits. The following are particularly relevant to diabetic foot problems:
 - The National Diabetes Core Audit collates data about foot examinations.
 - The <u>National Diabetes Foot Care Audit</u> allows all diabetes foot care services to measure their performance against NICE Clinical Guidelines and peer units, and to monitor adverse outcomes for people with diabetes who develop diabetic foot disease.
- A Clinical Knowledge Summary for <u>assessing and managing diabetic foot problems in type 2</u> <u>diabetes</u> (Scenario: Managing foot problems) is currently being updated.
- NICE produces indicators annually for use in the Quality and Outcomes Framework for the UK. The process for this and the NICE menu are available.
- NICE <u>uptake data</u> about guideline recommendations and quality standard measures are available on the NICE website.

Changes after publication

January 2016: Recommendation 1.3.6 has been updated to clarify the risk factors for and stratification of risk of developing a diabetic foot problem.

December 2015: Recommendation 1.3.14 and related NICE guidance section amended to refer to updated NICE guideline on type 2 diabetes in adults.

About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions.

NICE guidelines are developed in accordance with a <u>scope</u> that defines what the guideline will and will not cover.

This guideline was developed by the NICE Internal Clinical Guidelines Programme. The Internal Clinical Guidelines Programme worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in the <u>guidelines</u> <u>manual</u>.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

Update information

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

Recommendations marked [2011] indicates that the evidence has not been reviewed since 2011.

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 <u>patient-centred care</u>).

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

Recommendation wording in guideline updates

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of the <u>guidelines manual</u> (January 2009).

Other versions of this guideline

The full guideline, <u>diabetic foot problems: prevention and management</u>, contains details of the methods and evidence used to develop the guideline. It is published by the Internal Clinical Guidelines Programme.

The recommendations from this guideline have been incorporated into a <u>NICE pathway</u>.

We have produced information for the public about this guideline.

Implementation

Implementation tools and resources to help you put the guideline into practice are also available.

Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summaries of product characteristics of any drugs.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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