

New NICE guidance on the diabetic foot

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Article points

1. Despite previous guidance, diabetic foot complications still carry high mortality rates and access to care is not always consistent.
2. New guidance from NICE expands on previous guidance and includes specific instructions on the diagnosis and management of Charcot arthropathy.
3. The guidance sets out clear care pathways for those at risk of diabetic foot complications.

Key words

- Diabetic foot
- Foot protection service
- Guidelines
- NICE

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NICE has published a new guideline entitled *Diabetic foot problems: prevention and management*. It combines the advice from previous NICE guidance with new evidence-based guidance on the timing of care, foot screening, referrals and protocols, investigating and managing diabetic foot ulcers, diabetic foot infections and how to diagnose and manage Charcot arthropathy. The guidance presents the evidence underpinning its recommendations with indications of how robust the studies are and it also points out where there are gaps in the evidence that need to be investigated. In this article, two members of the guideline development group describe how the guidance was created, drawing out key elements of the guidance for primary care clinicians in boxes. It is hoped that the guidance will result in equitable, cost-effective care for people at risk of diabetic foot complications, which will help to reduce the morbidity and mortality associated with the condition.

The number of people diagnosed with diabetes continues to rise at an alarming rate. It is estimated to reach over 5 million by 2025 (Diabetes UK, 2012). The National Diabetes Inpatient Audit (NaDIA) from 2013 showed that 15.8% of people in hospital have diabetes (Rayman, 2013). Diabetic foot problems are serious and have the potential to result in minor or major amputation or even death. Mortality rates after foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation and 50% dying within 5 years of having foot ulceration (Moulik et al, 2012)

Management of the diabetic foot has a significant financial impact on the NHS. The cost has been estimated at £650 million annually (Kerr et al, 2014). Appropriate risk assessment, early referral, adequate training and the provision of a foot protection service (FPS) and multidisciplinary foot care service (MDFS) has shown improvement in clinical outcomes for people with diabetes (Edmonds et al, 1986; Krishnan et al, 2008).

Despite the publication of many guidance documents – including NICE clinical guideline (CG) 10, *Type 2 diabetes foot problems: Prevention and management of foot problems* (2004), CG119, *Diabetic foot problems: Inpatient management of diabetic foot problems* (2011), and the Putting Feet First documents (Diabetes UK and NHS Diabetes,

2009; 2011) – there still remains a variation in the practice of preventing and managing diabetic foot problems. Amputation rates still vary considerably across the UK (Holman et al, 2012). It has been suggested that this variation may in part be accounted for by different levels of services and care for people with diabetes and associated foot problems.

The new guideline produced by NICE (2015), *Diabetic Foot Problems: Prevention and Management of Foot Problems in People with Diabetes*, replaces *Type 2 diabetes foot problems: Prevention and management of foot problems* (NICE, 2004). It incorporates the recommendations from *Diabetic Foot Problems: Inpatient Management of Diabetic Foot Problems* (NICE, 2011). The guideline aims to provide one cohesive document for the management of the diabetic foot and hopes to address the inequalities in care and outcomes highlighted by the literature.

Development of the guideline

During the scoping process for this guideline, feedback from stakeholders – such as social care practitioners, public sector providers, commissioners of care or services and national organisations that represent health and social care practitioners, as well as the general public – and the clinical members of the guideline development group (GDG) highlighted concerns that a key area was missing

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from the guideline, namely the diagnosis and management of Charcot arthropathy (CA).

CA is complicated to diagnose and manage effectively. If managed incorrectly the consequences can be limb-threatening. The need for guidance on this particularly complex element of diabetic foot disease was reported to the NICE guidelines commissioning team, which resulted in the inclusion of CA as part of the new guideline. After the scoping process, the agreed remit of the GDG was to assess the evidence and make recommendations on best practice for the management of diabetic foot problems in the following areas:

- Care within 24 hours.
- Care across all settings.
- Foot screening and risk assessment.
- Referral for diabetic foot problems.
- Investigating and managing diabetic foot ulcers.
- Diabetic foot infection.
- CA.

Topics already covered in previously published NICE guidelines, such as *Peripheral arterial disease: diagnosis and management* (NICE, 2012) and *Pressure ulcers: prevention and management* (NICE, 2014), were not addressed by the group, but were linked to the final guideline.

Collecting evidence for the guidelines

The final recommendations were based on a trade-off between the benefit and harm of each intervention after examining the underpinning evidence. Search strategies were developed for 14 review questions, which covered care within 24 hours, care across all settings, foot screening and risk assessment, referral for diabetic foot problems, investigation and management of diabetic foot ulcers, diabetic foot infection and CA.

The wording in the guideline reflects the quality of the evidence on which the recommendation is made. For instance, the term “offer” was used when the GDG was confident that, for the vast majority of patients, an intervention will do more good than harm, as well as being cost-effective. However, the word “consider” was used when the GDG was confident that an intervention will do more good than harm for most patients and be cost-effective, although other options may be similarly cost-effective.

The new recommendations

The new guideline is a fully integrated document encompassing foot care for everyone with diabetes, irrespective of age and type of diabetes. It highlights the importance of clear local protocols and pathways for the continued and integrated care of people with diabetes and diabetic foot problems. Some key priorities for implementation are presented in *Box 1*.

A comprehensive care pathway

The whole of CG119 has been incorporated into NG19 to ensure a comprehensive pathway of care in one document. However, additions to the new document highlight that people with limb- or life-threatening diabetic foot problems should be referred immediately to acute services, informing the multidisciplinary team. It also emphasises the importance of assessing individuals’ risk of developing foot complications on admission to hospital and if there is any change in their status while in hospital. NG19 recommends that people in hospital who are at moderate or high risk of developing a foot problem should be given pressure-redistribution devices to offload the heels to reduce the risk of hospital-acquired pressure ulceration. Another development in this document is the need for patients identified as at risk to be referred to the foot protection service when they are discharged in order to provide ongoing care.

Referrals

The guideline recommends an integrated service from screening to the FPS and then a referral to the MDFS if necessary. It emphasises the need for clear local pathways across all settings, ensuring all clinicians know who, when and where to refer. It recommends that the FPS is led by a podiatrist with specialist training in diabetic foot problems, with access to other team members with skills in diabetes management, biomechanics, orthoses and wound care. The MDFS should have strong identifiable leadership and consist of clinicians with specialist skills and knowledge in managing complex diabetic foot complications.

Previous guidance for active foot problems that are not limb- or life-threatening was a referral within 24 hours. The new document is designed to be more appropriate and achievable, with a referral for an

Box 1. Key priorities for implementation (adapted from NICE [2015]).

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.

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
 - Robust protocols and clear local pathways for the continued and integrated care of people across all settings, including emergency care and general practice
 - Regular reviews of treatment and patient outcomes, in line with the National Diabetes Foot Care Audit.

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
 - 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
 - Moderate risk: 1 risk factor present
 - High risk: previous ulceration or amputation, on renal replacement therapy, or more than 1 risk factor present
 - 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
- 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.
- Refer people who are at moderate or high risk of developing a diabetic foot problem to the foot protection service.
- 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

- 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*

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), 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 lower limb peripheral arterial disease)
 - 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) 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.
- Do not offer antibiotics to prevent diabetic foot infections.
- 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.
- 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 one regimen is appropriate, select the regimen with the lowest acquisition cost.
- Decide the targeted antibiotic regimen for diabetic foot infections based on the clinical response to antibiotics and the results of the microbiological examination.
- Do not offer tetracycline to treat diabetic foot infections unless other antibiotics are not suitable.
- For mild diabetic foot infections, initially offer oral antibiotics with activity against gram-positive organisms.
- Do not use prolonged antibiotic treatment (more than 14 days) for the treatment of mild soft tissue diabetic foot infections.

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.

active foot problem required within 1 working day and triage by the FPS or MDFS within 1 further working day. It provides clear timelines for service providers on referral times and frequency of review for people referred to the FPS. The services should have the capacity to assess and treat new patients identified as being at moderate risk within 6–8 weeks and those at high risk within 2–4 weeks. Follow-up care should then be provided for moderate-risk patients every 3–6 months, depending on individual assessment. High-risk patients should be seen every 1–2 months if there is no immediate concern and every 1–2 weeks if there is immediate concern, such as pre-ulcerative changes.

Advice to commissioners

NG19 offers guidance to commissioners to enable them to calculate the level of investment in podiatry to meet the needs of the population based on risk assessment stratification. It reminds service providers and commissioners of the importance of providing foot care for people who have difficulty in accessing services, such as people in nursing homes, those with mental health problems and homeless people, ensuring equitable care for all.

Reducing the mortality rate

The guideline attempts to address the high mortality rate associated with diabetic foot complications by reminding clinicians to assess patients for the risk of cardiovascular disease.

Classification, negative-pressure wound therapy and removable casts

In line with the National Diabetes Foot Care Audit (Health and Social Care Information Centre, 2015), the guideline recommends the use of a standardised classification system, such as SINBAD (site, ischaemia, neuropathy, bacterial infection, area and depth; Ince et al, 2008). It also supports the use of negative pressure after surgical debridement if advised by members of the MDFS.

This is the first NICE guideline on the diabetic foot that recommends the use of a non-removable cast as the first-line treatment in the management of plantar neuropathic, non-infected, non-ischaemic forefoot and midfoot ulceration. The use of casting has not been widely adopted, partly because of lack of training and mentorship and fear of associated

complications (Prompers et al, 2008; Wu et al, 2008). Greater use of casting will improve healing rates for appropriately assessed diabetic foot ulceration and reduce the economic and social burden of diabetic foot complications.

Charcot arthropathy

The new guidance advises clinicians on the typical presentation of CA and to suspect it even if pain or deformity is not reported. The recommendation on CA is urgent referral to the MDFS within 1 working day.

Renal disease and risk levels

In the guideline, people with diabetes on renal replacement therapy have automatically been considered as at high risk of foot complications. Renal disease increases the likelihood of ischaemia, foot ulceration, CA and amputation.

Orthotics

The NICE health economist looked at the cost-effectiveness of providing custom orthotic footwear. This would attempt to solve the question of whether providing footwear is cost-effective in the prevention of primary ulceration and re-ulceration in the diabetic foot. The results have shown that footwear that costs between £82 and £671 is cost-effective when provided to moderate- and high-risk people. If the cost is £671 to £859, footwear is only cost-effective for high-risk patients. Although the benefits of footwear are clear, the financial investment needed to provide this footwear would have a huge impact on the NHS, given the current budget constraints. However, this work should support the diabetic foot MDFS and FPS in maintaining and developing their orthotic services.

Patient education

Some key elements of the guidance on patient education are presented in *Box 2*.

Implementing the guidance

Many members of the primary care team undertaking foot screening have not received any formal training on how to assess the diabetic foot. The new guideline recommends that all people who screen for complications are competent in carrying out routine foot assessments. The challenge will be

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Box 2. Key elements of the guidance on patient education (NICE, 2015).

From the primary care team

- 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

From the primary care team, multidisciplinary foot care service or foot protection service

- 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

developing and funding local training programmes with agreed measures of competence.

NG19 highlights the importance of ensuring clinicians within the FPS have the necessary skills and competencies to identify complex diabetic foot problems and refer appropriately to the MDFs. It will support managers in developing a programme of placements or secondments for clinicians. Podiatrists and other healthcare professionals could rotate through the MDFs to expand their clinical knowledge and build inter-professional relationships.

There may be an increased demand on the FPS if it is to meet the recommendations on waiting times and frequency of assessment for people with diabetes identified as being at high or moderate risk. This will need to be discussed with and addressed by commissioners through the development of business cases to support service redesign or expansion. This guideline continues to recommend that an MDFs foot clinic manages diabetic foot complications. However, despite this being a recommendation in CG10, the NaDIA data from 2013 show that only 71.8% of acute hospitals had access to an MDFs (Rayman, 2013). Service providers and commissioners need to work together to meet this recommendation.

Conclusion

The most challenging aspect for the GDG was the lack of high-quality, robust evidence to support the recommendations. There is a real need for research to confirm what is accepted as current best practice in diabetic foot care. However, the authors acknowledge the difficulties in developing and running these types of complex studies, which require large numbers of patients in order to reach statistical significance.

The guideline has made specific recommendations on future research priorities including: evaluating the role of foot screening in the prevention of diabetic foot complications; who should be referred to the FPS and MDFs and when; the use of dressings and advanced wound modalities; the prevention and management of CA; and the role of educational models and psycho-behavioural interventions in the prevention of diabetic foot complications.

This guideline brings together all aspects of diabetic foot disease and it will support commissioners and service providers in developing integrated pathways. It advises healthcare professionals on the evidence-based management of diabetic foot disease. It will empower individuals to ensure they are receiving high-quality care and hopefully go some way to addressing the current inequalities in the outcome of diabetic foot complications. ■

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