

# The new NICE guidance on the diabetic foot: a summary from members of the guideline development group

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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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The National Institute for Health and Care Excellence (NICE) has published a new guideline entitled *Diabetic Foot Problems: Prevention and Management of Foot Problems in People with Diabetes*. 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. 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 mortality rate associated with the condition.

The number of people diagnosed with diabetes continues to rise at an alarming rate. The number 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 National Institute for

Health and Care Excellence (NICE) Clinical Guideline (CG) 10, *Type 2 — Diabetes Foot Problems: Prevention and Management of Foot Problems* (2004) and CG119 *Diabetic Foot Problems: Inpatient Management of Diabetic Foot Problems* (2011), Diabetes UK and NHS *Putting Feet First* (2009), and *Putting Feet First: National Minimum Skills Framework* (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 *Management of Type 2 Diabetes: Prevention and Management of Foot Problems* (NICE, 2004). It incorporates the recommendations from *Diabetic Foot Problems: Inpatient Management* (NICE, 2011). It aims to provide one cohesive document for the management of the diabetic foot and hopes

**“The new guideline is a fully integrated document encompassing foot care for everyone with diabetes irrespective of age and type of diabetes.”**

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 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 care 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 the *Lower Limb Peripheral Arterial Disease: Diagnosis and Management* (NICE, 2012) and *Pressure Ulcers: Prevention and Management of Pressure Ulcers* (NICE, 2014), were not addressed by the group, but were linked to the final guideline.

The GDGs have also been working on four other topics:

- Type 1 diabetes in adults
- Type 2 diabetes in adults
- Diabetes in children and young people
- Diabetes in pregnancy.

This standardising of high-quality, evidence-based care should result in better outcomes for people with diabetes.

In order to ensure representation from all stakeholders, there were places on the GDG for key members of the diabetic foot service and service users. Alongside the clinical and patients representatives appointed to the group there were many members from the NICE project team. These people included commissioners, a technical analyst, technical advisors, clinical advisors, a health economist, a project manager and medical editors.

### 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 structured questions were developed using the population, intervention, comparison and outcome (PICO) model (Counsell, 1997). The papers were graded according to relevance, quality of study design, evidence, statistical analysis and the risk of bias by the NICE team. Initial searches identified thousands of articles, but after appraisal by the NICE technical team, the GDG was often presented with just a handful of papers that were relevant to the topic.

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.

**“The new guidance advises clinicians on the typical presentation of Charcot arthropathy and to suspect it even if pain or deformity is not reported.”**

**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 patients 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 patients’ risk of developing foot complications on admission to hospital and if there is any change in their status while in hospital. NICE Guideline 19 (NG19) recommends that people in hospital who are 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 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 patients referred to the FPS. The services should have the capacity to assess and treat new patients identified as 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 the homeless, 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 (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, not 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

Counsell C (1997) Formulating questions and locating primary studies for inclusion in systematic reviews. *Ann Intern Med* **127**: 380–7

Diabetes UK, NHS (2009) *Putting Feet First*. Available at: <http://bit.ly/1MOTOoe> (accessed on 19.10.2015)

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Edmonds ME, Blundell MP, Morris ME et al (1986) Improved survival of the diabetic foot: the role of a specialized foot clinic. *QJ Med* **60**: 763–71

Health and Social Care Information Centre (2015) *National Diabetes Foot Care Audit*. Available at: <http://bit.ly/1LZS5Ht> (accessed 19.10.2015)

Holman N, Young R, Jeffcoate W (2012) Variation in the recorded incidence of amputation of the lower limb in England. *Diabetologia* **55**: 1919–25

Ince P, Abbas Z, Lutale JK et al (2008) Use of SINBAD classification system and score in comparing outcome of foot ulcer management on three continents. *Diabetes Care* **31**: 964–7

Kerr M, Rayman G, Jeffcoate W (2014) Cost of diabetic foot disease to the National Health Service in England. *Diabet Med* **31**: 1498–504

Krishnan S, Nash F, Baker N et al (2008) Reduction in diabetic

on CA is urgent referral to the MDFS within 1 working day. Clinicians who suspect a diagnosis of CA should, where possible, offer non-weight-bearing treatment until definitive treatment with a non-removable device, such as a cast, is provided by the MDFS. The guidance also provides advice on the diagnosis, assessment and ongoing management of acute and then chronic CA.

### 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 patients. If the cost is £671–859, 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.

### Implementing the guidance

Many practitioners 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 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 medium 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 a 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 patients to ensure they are receiving high quality care and hopefully go some way to address the current inequalities in the outcome of diabetic foot complications. ■

The new guidance is available at [www.nice.org.uk/guidance/ng19](http://www.nice.org.uk/guidance/ng19)

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