NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline

Diabetic foot problems: prevention and management

Draft for consultation, September 2022

This is an update to NICE guideline NG19 (published August 2015). We have:

- reviewed the evidence on risk assessment tools for diabetic foot problems and frequency of diabetic foot reviews
- made no new recommendations
- updated the existing research recommendation on frequency of diabetic foot checks and made a new research recommendation on digital and emerging technologies for assessing the risk of diabetic foot problems.

Who is it for?

- Healthcare professionals
- Commissioners and providers
- People with diabetes, and their families and carers

What does it include?

- the recommendations covered by the evidence review
- related recommendations that were not part of the evidence review but are included here for context (shaded in grey and marked **[2015]**)
- recommendations for research

- rationale and impact sections that explain why the committee did not change the 2015 recommendations, and how this might affect practice
- the guideline context.

Information about how the guideline was developed is on the guideline's webpage. This includes the evidence reviews, the scope, details of the committee and any declarations of interest.

Commenting on this update

We have reviewed the evidence on risk assessment tools for diabetic foot problems and the frequency of diabetic foot reviews (we have not changed the recommendations). You are invited to comment on the recommendations. These are marked as **[2022]**.

We have not reviewed the evidence for the recommendations marked **[2015]** (shaded in grey) and cannot accept comments on them.

Sections of the guideline that have had no changes at all have been temporarily removed for this consultation and will be re-instated when the final guideline is published. See the current version of the guideline.

See update information for a full explanation of what is being updated.

Full details of the evidence and the committee's discussion on the recommendations that were reviewed in 2022 are in the evidence review. Evidence for the 2015 recommendations is in the full version of the 2015 guideline.

Contents

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

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. **[2015]**

1.3.2 For young people with diabetes who are 12 to 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. **[2015]**

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 the recommendation on carrying out reassessments at intervals, depending on the person's risk of developing a diabetic foot problem).

- If any foot problems arise.
- On any admission to hospital, and if there is any change in their status while they are in hospital. **[2015]**

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 peripheral arterial disease)
- ulceration
- callus
- infection and/or inflammation
- deformity
- gangrene
- Charcot arthropathy. **[2022]**

1.3.5 Use ankle brachial pressure index in line with the NICE guideline on peripheral arterial disease. Interpret results carefully in people with diabetes because calcified arteries may falsely elevate results. **[2015]**

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. **[2022]**

For a short explanation of why the committee did not change the recommendations that were reviewed in 2022, and how this might affect practice, see the rationale and impact section on assessing the risk of developing a diabetic foot problem.

Full details of the evidence and the committee's discussion are in evidence review B: risk assessment models and tools for predicting the development of diabetic foot problems and foot review frequency.

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 foot assessments at their annual diabetes review

- emphasise the importance of foot care (see the section on patient information about the risk of developing a diabetic foot problem)
- advise them that they could progress to moderate or high risk. **[2022]**

1.3.8 Refer people who are at moderate or high risk of developing a diabetic foot problem to the foot protection service. **[2015]**

1.3.9 The foot protection service should assess newly referred people as follows:

- Within 2 to 4 weeks for people who are at high risk of developing a diabetic foot problem.
- Within 6 to 8 weeks for people who are at moderate risk of developing a diabetic foot problem. **[2015]**

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. **[2015]**

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, as part of their annual diabetes review.
- Frequently (for example, every 3 to 6 months) for people who are at moderate risk.

- More frequently (for example, every 1 to 2 months) for people who are at high risk, if there is no immediate concern.
- Very frequently (for example, every 1 to 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. **[2022]**

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. **[2015]**

For a short explanation of why the committee did not change the recommendations that were reviewed in 2022, and how this might affect practice, see the rationale and impact section on managing the risk of developing a diabetic foot problem.

Full details of the evidence and the committee's discussion are in evidence review B: risk assessment models and tools for predicting the development of diabetic foot problems and foot review frequency.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Frequency of diabetic foot checks

Based on clinical trial data and routinely collected real-world data, what is the clinical and cost effectiveness of annual foot checks for people categorised as low-risk, compared with checks every 2 years, in reducing diabetic foot problems (including ulcer, amputation and death)? **[2022]**

2 Digital and emerging technologies for assessing the risk of developing diabetic foot problems

What is the effectiveness, cost-effectiveness and acceptability of digital and emerging technologies for assessing the risk of developing a diabetic foot problem (for example laser Doppler flowmetry, infrared thermography, and devices to assess plantar pressure)? **[2022]**

3 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? **[2015]**

4 Education and psycho-behavioural interventions for prevention

What is the role of educational models and psycho-behavioural interventions in prevention of diabetic foot complications? **[2015]**

5 Prevention strategies for Charcot arthropathy

What strategies may be useful in the prevention of Charcot arthropathy? **[2015]**

6 Diabetic ulcer dressings

What is the clinical effectiveness of different dressing types in treating diabetic foot problems? **[2015]**

Other recommendations for research

Referral of people who have diabetic foot problems

Within the hospital multidisciplinary team, when is it appropriate and effective to refer people with diabetes who have foot problems to specialist services such as investigative or interventional radiology, orthopaedic or vascular services, specialist pain management and specialist orthotics? **[2015]**

Prevention of diabetic foot problems

What is the effectiveness of different footwear, insoles and orthoses in the prevention of foot problems? **[2015]**

Review of people with diabetic foot problems

How often should people with diabetic foot problems (foot ulcers, soft tissue infections, osteomyelitis or gangrene) be reviewed? **[2022]**

Negative pressure wound therapy for treating diabetic foot ulcers

What is the clinical effectiveness of negative pressure wound therapy in the treatment of diabetic foot ulcers? **[2015]**

Maggot debridement therapy for treating diabetic foot ulcers

What is the clinical effectiveness of maggot debridement therapy in the debridement of diabetic foot ulcers? **[2015]**

Risk stratification tools for predicting Charcot arthropathy

Which risk stratification tools can be used to predict the likelihood of Charcot arthropathy? **[2015]**

When to stop contact casting for acute Charcot arthropathy

When is it safe to stop contact casting in the treatment of acute Charcot arthropathy? **[2015]**

Rationale and impact

These sections briefly explain why the committee kept the existing recommendations, and how this might affect practice.

Assessing the risk of a diabetic foot problem

Recommendations 1.3.4 and 1.3.6

Why the committee made the recommendations

All the risk assessment tools reviewed by the committee were able to predict ulcer occurrence with acceptable accuracy. There were no significant differences in classification accuracy (assessed using c-statistics) between the different risk assessment tools. The PODUS and SIGN systems showed the best overall sensitivity and specificity.

The committee agreed that the most important factor for an assessment tool was the ability to accurately identify people who are at high risk of developing a diabetic foot ulcer. Accurate identification allows people to be referred to appropriate services, where monitoring and preventative treatment can be started. A focus on high sensitivity over high specificity may lead to more false positives, with more people incorrectly receiving increased monitoring and referral to specialist services. However, the committee believe that this is preferable to using a system with lower sensitivity, because an increased risk of ulcer, infection and amputation is much worse than wasted resources from unnecessary monitoring or referrals. Overall, the SIGN system showed the highest sensitivity for both high-risk and combined high- and moderate-risk groups.

The committee considered recommending the PODUS clinical prediction rule because:

- it has higher classification accuracy than the SIGN system, and
- it is a short and simple assessment with only 3 items, and it could be completed by healthcare assistants or practice nurses in primary care.

Despite the good evidence for the PODUS system, the committee decided not to change the 2015 recommendations, because:

- SIGN had higher sensitivity than PODUS (although this assessment was based on a study with a high risk of bias).
- PODUS did not include an assessment of foot deformity. Based on their experience and knowledge of established research, the committee believe that this is an important clinical risk factor.
- The SIGN system is also relatively simple. It uses the same 3 items as PODUS, but also includes an assessment of foot deformity. The committee do not think it will take any longer to complete than the PODUS system.
- SIGN is recommended by the 2015 guideline and is well established in clinical practice. Switching to PODUS would be a potentially disruptive change to practice, and the committee did not believe that PODUS had enough advantages over SIGN to justify this.

The 2015 guideline recommended a modified version of SIGN that includes a check for renal disease. The committee agreed that this modification is useful and should be retained, because renal disease is a known risk factor for diabetic foot problems.

How the recommendations might affect practice

The recommendations have not changed, so no resource impact is expected.

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Managing the risk of developing a diabetic foot problem

Recommendations 1.3.7 and 1.3.11

Why the committee made the recommendations

The evidence showed that 95.5% of people assessed as low risk at their first clinical assessment remained in the low-risk group at their final assessment 8 years later. The ulceration rate in the low-risk group is also very low. Given this evidence, the committee discussed reducing the frequency of foot risk assessments to once every 2 years. However, they were concerned about the impact this may have on patient care.

The annual foot assessment is not just a foot examination and risk assessment. It is also a chance to teach people how to look after their feet, and to emphasise the importance of doing so. Many people with diabetes do not have good foot care routines, or do not have foot care routines at all. They may not know what to do if they have a foot problem, or who to contact. And they may benefit from regular advice about risk factors for foot problems. Reducing the frequency of foot assessments would mean reducing the number of chances to encourage good foot care and direct people to sources of support.

The committee discussed options for providing education and support outside of foot assessments (for example remote appointments). However, it was not clear how feasible it would be to run these extra appointments in practice. Foot assessments are currently part of the annual diabetes review, so it

makes sense to continue to include the foot check and risk assessment in that appointment. There are also Quality and Outcomes Framework (QOF) indicators for annual foot examination and risk classification, which further justify retaining the current system.

Given the risk of reducing access to education and support, the committee agreed to continue recommending annual foot assessments. They agreed that, for the recommendations to change, better evidence would be needed comparing annual and 2-yearly foot assessments. The committee therefore made research recommendations on:

- frequency of diabetic foot checks
- frequency of review for people with diabetic foot problems
- whether access to new technologies can improve diabetic foot checks.

How the recommendations might affect practice

The recommendations have not changed, so no resource impact is expected.

Return to recommendations

Context

Diabetes is one of the most common chronic diseases in the UK and its prevalence is increasing. More than 4.9 million people in the UK have diabetes. Around 90% of these people have type 2 diabetes, around 8% have type 1 diabetes, and about 2% have rarer types of diabetes. By 2030, it is estimated that more than 5.5 million people in the UK will have diabetes. In England, the number of people diagnosed with diabetes increased between 2006 and 2019 from 1.9 million to 3.3 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 peripheral arterial disease.

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. More than 7000 diabetes-related amputations are reported in the UK per year. People are at higher risk of diabetes-related major and minor limb amputations if they are male, from the most deprived areas, aged over 65, or of white European family background. 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. The NHS spends at least £10 billion a year on diabetes, equivalent to 10% of its budget. 80% of this is spent on treating complications, and diabetic foot care is estimated to cost the NHS in England over £1 billion per year. Diabetic foot care accounts for more healthcare costs in England than breast, prostate and lung cancer combined. Much of these costs come from treating prolonged and severe ulceration.

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE webpage on diabetes.

For details of the guideline committee see the committee member list.

Update information

October 2022: This guideline is an update of NICE guideline NG19 (published August 2015) and will replace it. We have reviewed the evidence on risk assessment tools for diabetic foot problems and frequency of diabetic foot reviews. We have made no new recommendations.

Recommendations are marked **[2022]** if the evidence has been reviewed.

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