





Diabetic foot problems: prevention and management

NICE guideline

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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 and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services 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 complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

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This guideline replaces CG10 and CG119.

This guideline partially replaces CG15.

This guideline is the basis of QS208 and QS209.

Overview

This guideline covers preventing and managing foot problems in children, young people and adults with diabetes. It aims to reduce variation in practice, including antibiotic prescribing for diabetic foot infections.

See a <u>3-page visual summary of the antimicrobial prescribing recommendations, including tables to support prescribing decisions.</u>

Who is it for?

- Healthcare professionals caring for people with diabetes
- Commissioners and providers of diabetes foot care services
- People with diabetes, and their families and carers

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.

1.1 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)

- 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</u> Diabetes Foot Care Audit. [2015]
- 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. [2015]
- 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. [2015]
- 1.2.4 The multidisciplinary foot care service should have access to rehabilitation services, plastic surgery, psychological services and nutritional services. [2015]
- 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. [2015]
- 1.2.6 Take into account any disabilities, including visual impairment, when planning and delivering care for people with diabetes. **[2015]**

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. [2023]
- 1.3.5 Use ankle brachial pressure index in line with the <u>NICE guideline on peripheral</u> 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
 - peripheral arterial disease.
- High risk:
 - previous ulceration or
 - previous amputation or
 - on renal replacement therapy or
 - neuropathy and peripheral arterial disease together or
 - neuropathy in combination with callus and/or deformity or
 - peripheral arterial disease in combination with callus and/or deformity.
- Active diabetic foot problem:
 - ulceration or
 - infection or
 - chronic limb-threatening ischaemia or
 - gangrene or
 - suspicion of an acute Charcot arthropathy, or an unexplained hot,
 swollen foot with a change in colour, with or without pain. [2023]

For a short explanation of why the committee did not change the recommendations that were reviewed in 2023, and how this might affect practice, see the <u>rationale and</u> impact section on assessing the risk of developing a diabetic foot problem.

Full details of the evidence and the committee's discussion are in <u>evidence review B:</u> <u>risk assessment models and tools for predicting the development of diabetic foot</u> 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 <u>section on patient</u> information about the risk of developing a diabetic foot problem)
 - advise them that they could progress to moderate or high risk. [2023]
- 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. [2023]
- 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 2023, and how this might affect practice, see the <u>rationale and</u> impact section on managing the risk of developing a diabetic foot problem.

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

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). [2015]
- 1.3.14 For guidance on education programmes and information about diabetes, see the education and information section in the NICE guideline on type 1 diabetes in adults, the education section in the NICE guideline on type 2 diabetes in adults, and the sections on education and information for children and young people with type 1 diabetes and education and information for children and young people with type 2 diabetes in the NICE guideline on diabetes (type 1 and type 2) in children and young people. [2015]

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 the <u>recommendation on services and protocols commissioners and service providers should ensure are in place</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 <u>NICE guideline on peripheral arterial</u> disease).
- Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration).
- Gangrene (with or without ulceration). [2015]
- 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 the recommendation on services and protocols commissioners and service providers should ensure are in place) for triage within 1 further working day. [2015]

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 the <u>recommendation on additional guidance on education programmes</u> and information about diabetes). [2015]

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 cardiovascular disease: risk assessment and reduction, including lipid modification. [2015]

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. [2015]
- 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. [2015]
- 1.5.3 Do not use the Wagner classification system to assess the severity of a diabetic foot ulcer. [2015]

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. [2015]
- 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. [2015]

- 1.5.6 In line with the <u>NICE guideline on pressure ulcers</u>, use pressure-redistributing devices and strategies to minimise the risk of pressure ulcers developing. **[2015]**
- 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. [2015]
- 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. [2015]
- 1.5.9 Consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service.

 [2015]
- 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. [2015]
- 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. [2015]
- 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], plateletderived growth factor [PDGF], epidermal growth factor [EGF] and transforming growth factor beta [TGF-β]).
 - Hyperbaric oxygen therapy. [2015]

- 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. [2015]
- 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. [2015]

1.6 Diabetic foot infection

Investigation

- 1.6.1 If a <u>diabetic foot infection</u> 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. [2015]
- 1.6.2 Consider an X-ray of the person's affected foot (or feet) to determine the extent of the diabetic foot problem. [2015]
- 1.6.3 Think about osteomyelitis if the person with diabetes has a local infection, a deep foot wound or a chronic foot wound. [2015]
- 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. [2015]
- 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. [2015]

Treatment

1.6.6 Start antibiotic treatment for people with suspected diabetic foot infection as soon as possible. Take samples for microbiological testing before, or as close as possible to, the start of antibiotic treatment. [2019]

- 1.6.7 When choosing an antibiotic for people with a suspected diabetic foot infection (see recommendations 1.6.8 and 1.6.9), take account of:
 - the severity of diabetic foot infection (mild, moderate or severe)
 - the risk of developing complications
 - previous microbiological results
 - previous antibiotic use
 - patient preferences. [2019]

For a short explanation of why the committee made these 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on treatment</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> <u>diabetic foot infection: antimicrobial prescribing.</u>

Choice of antibiotic

- 1.6.8 When prescribing antibiotics for a suspected diabetic foot infection in adults aged 18 years and over, follow table 1 for a mild infection or table 2 for a moderate or severe infection. [2019]
- 1.6.9 Seek specialist advice when prescribing antibiotics for a suspected diabetic foot infection in children and young people under 18 years. [2019]
- Give oral antibiotics first line if the person can take oral medicines, and the severity of their condition does not require intravenous antibiotics. [2019]
- 1.6.11 If intravenous antibiotics are given, review by 48 hours and consider switching to oral antibiotics if possible. **[2019]**
- 1.6.12 Base antibiotic course length on the severity of the infection and a clinical assessment of response to treatment. Review the need for continued antibiotics regularly. [2019]

Table 1 Antibiotics for mild diabetic foot infection in adults aged 18 years and over

First-choice oral antibiotic

Antibiotic	Dosage and course length
See <u>BNF</u> for appropriate use and dosing in specific populations, for example, people with hepatic or renal impairment, or who are pregnant or breastfeeding.	Oral doses are for immediate-release medicines.
Flucloxacillin	500 mg to 1 g four times a day for 7 days. A longer course (up to a further 7 days) may be needed based on clinical assessment. However, skin does take some time to return to normal, and full resolution of symptoms at 7 days is not expected.
	In August 2015, the upper dose of 1 g four times a day was off label. See <u>NICE's information on prescribing medicines</u> .

Alternative oral antibiotics for penicillin allergy or if flucloxacillin unsuitable (guided by microbiological results when available)

Antibiotic	Dosage and course length
See <u>BNF</u> for appropriate use and dosing in specific populations, for example, people with hepatic or renal impairment, or who are pregnant or breastfeeding.	Oral doses are for immediate-release medicines.
Clarithromycin	500 mg twice a day for 7 days. A longer course (up to a further 7 days) may be needed based on clinical assessment. However, skin does take some time to return to normal, and full resolution of symptoms at 7 days is not expected.

Antibiotic	Dosage and course length
Erythromycin (in pregnancy)	500 mg four times a day for 7 days. A longer course (up to a further 7 days) may be needed based on clinical assessment. However, skin does take some time to return to normal, and full resolution of symptoms at 7 days is not expected.
Doxycycline	200 mg on first day, then 100 mg once a day (can be increased to 200 mg daily) for 7 days. A longer course (up to a further 7 days) may be needed based on clinical assessment. However, skin does take some time to return to normal, and full resolution of symptoms at 7 days is not expected.

Table 2 Antibiotics for moderate or severe diabetic foot infection in adults aged 18 years and over

First-choice antibiotics (guided by microbiological results when available); in severe infection, give intravenously for at least 48 hours (until stabilised)

Antibiotic	Dosage
See <u>BNF</u> for appropriate use and dosing in specific populations, for example, people with hepatic or renal impairment, or who are pregnant or breastfeeding, and administering intravenous (IV; or, where appropriate, intramuscular) antibiotics.	Oral doses are for immediate- release medicines.
Flucloxacillin with or without	1 g four times a day orally or 1 to 2 g four times a day IV. In August 2015, the dose of 1 g four times a day was off label. See NICE's information on prescribing medicines.

Antibiotic	Dosage
Gentamicin and/or	Initially 5 to 7 mg/kg once a day IV, subsequent doses adjusted according to serum gentamicin concentration. See BNF for information on therapeutic drug monitoring and monitoring of patient parameters.
Metronidazole	400 mg three times a day orally or 500 mg three times a day IV.
Co-amoxiclav with or without	500/125 mg three times a day orally or 1.2 g three times a day IV
Gentamicin	Initially 5 to 7 mg/kg once a day IV, subsequent doses adjusted according to serum gentamicin concentration. See BNF for information on therapeutic drug monitoring and monitoring of patient parameters.
Co-trimoxazole (in penicillin allergy) with or without	960 mg twice a day orally or 960 mg twice a day IV (can be increased to 1.44 g twice a day). See BNF for information on monitoring of patient parameters. In August 2015, this was not licensed for diabetic foot infection, so was off-label.
	See NICE's information on prescribing medicines.

Antibiotic	Dosage
Gentamicin and/or	Initially 5 to 7 mg/kg once a day IV, subsequent doses adjusted according to serum gentamicin concentration. See BNF for information on therapeutic drug monitoring and monitoring of patient parameters.
Metronidazole	400 mg three times a day orally or 500 mg three times a day IV.
Ceftriaxone with	2 g once a day IV.
Metronidazole	400 mg three times a day orally or 500 mg three times a day IV.

Notes:

Course length is based on clinical assessment: minimum of 7 days and up to 6 weeks for osteomyelitis (use oral antibiotics for prolonged treatment).

Give oral antibiotics first line if the person can take oral medicines, and the severity of their condition does not require intravenous antibiotics.

Review intravenous antibiotics by 48 hours and consider switching to oral antibiotics if possible.

Other antibiotics may be appropriate based on microbiological results and specialist advice.

Skin takes some time to return to normal, and full resolution of symptoms after a course of antibiotics is not expected. Review the need for continued antibiotics regularly.

Additional antibiotic choices if Pseudomonas aeruginosa suspected or confirmed (guided by microbiological results when available)

Antibiotic	Dosage
See BNF for appropriate use and dosing in specific populations, for example, people with hepatic or renal impairment, or who are pregnant or breastfeeding, and administering intravenous (IV; or, where appropriate, intramuscular) antibiotics.	Oral doses are for immediate-release medicines.
Piperacillin with tazobactam	4.5 g three times a day IV (can be increased to 4.5 g four times a day).
Clindamycin with	150 to 300 mg four times a day orally (can be increased to 450 mg four times a day) or 600 mg to 2.7 g daily IV in two to four divided doses, increased if necessary in lifethreatening infection to 4.8 g daily (maximum per dose 1.2 g).
Ciprofloxacin (consider safety issues) and/or	500 mg twice a day orally or 400 mg two or three times a day IV. See Medicines and Healthcare products Regulatory Agency (MHRA) advice for restrictions and precautions for using fluoroquinolone antibiotics due to very rare reports of disabling and potentially long-lasting or irreversible side effects affecting musculoskeletal and nervous systems. Warnings include: stopping treatment at first signs of serious adverse reaction (such as tendonitis), prescribing with special caution in people over 60 years and avoiding coadministration with a corticosteroid (March 2019).
Gentamicin	Initially 5 to 7 mg/kg once a day IV, subsequent doses adjusted according to serum gentamicin concentration. See BNF for information on therapeutic drug monitoring and monitoring of patient parameters.

Notes:

Course length is based on clinical assessment: minimum of 7 days and up to 6 weeks for osteomyelitis (use oral antibiotics for prolonged treatment).

Give oral antibiotics first line if the person can take oral medicines, and the severity of their condition does not require intravenous antibiotics.

Review intravenous antibiotics by 48 hours and consider switching to oral antibiotics if possible.

Other antibiotics may be appropriate based on microbiological results and specialist advice.

These antibiotics may also be appropriate in other situations based on microbiological results and specialist advice.

Antibiotics to be added if MRSA infection suspected or confirmed (combination therapy with an antibiotic listed above)

Antibiotic	Dosage
See <u>BNF</u> for appropriate use and dosing in specific populations, for example, people with hepatic or renal impairment, or who are pregnant or breastfeeding, and administering intravenous (IV; or, where appropriate, intramuscular) antibiotics.	Oral doses are for immediate-release medicines.
Vancomycin	15 to 20 mg/kg two or three times a day IV (maximum 2 g per dose), adjusted according to serum vancomycin concentration.
	See <u>BNF</u> for information on therapeutic drug monitoring and monitoring of patient parameters.

Antibiotic	Dosage
	Initially 6 mg/kg every 12 hours for three doses, then 6 mg/kg once a day IV.
Teicoplanin	See <u>BNF</u> for information on therapeutic drug monitoring and monitoring of patient parameters.
Linezolid (if vancomycin or teicoplanin cannot be used; specialist use only)	600 mg twice a day orally. 600 mg twice a day IV. See <u>BNF</u> for information on monitoring of patient parameters.

Notes:

Course length is based on clinical assessment: minimum of 7 days and up to 6 weeks for osteomyelitis (use oral antibiotics for prolonged treatment).

Review intravenous antibiotics by 48 hours and consider switching to oral antibiotics if possible.

Other antibiotics may be appropriate based on microbiological results and specialist advice.

For a short explanation of why the committee made these 2019 recommendations and how they might affect practice, see the <u>rationale and impact section on choice of</u> antibiotic, dose frequency, route of administration and course length.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> <u>diabetic foot infection: antimicrobial prescribing.</u>

Advice

1.6.13 When prescribing antibiotics for a diabetic foot infection, give advice about:

- possible adverse effects of the antibiotic(s)
- seeking medical help if symptoms worsen rapidly or significantly at any time, or do not start to improve within 1 to 2 days. [2019]

For a short explanation of why the committee made this 2019 recommendation and how it might affect practice, see the rationale and impact section on advice.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> diabetic foot infection: antimicrobial prescribing.

Reassessment.

- 1.6.14 When microbiological results are available:
 - review the choice of antibiotic and
 - change the antibiotic according to results, using a narrow-spectrum antibiotic, if appropriate. [2019]
- 1.6.15 Reassess people with a suspected diabetic foot infection if symptoms worsen rapidly or significantly at any time, do not start to improve within 1 to 2 days, or the person becomes systemically very unwell or has severe pain out of proportion to the infection. Take account of:
 - other possible diagnoses, such as pressure sores, gout or non-infected ulcers
 - any symptoms or signs suggesting a more serious illness or condition, such as limb ischaemia, osteomyelitis, necrotising fasciitis or sepsis
 - previous antibiotic use. [2019]

For a short explanation of why the committee made these 2019 recommendations and how they might affect practice, see the rationale and impact section on reassessment.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> diabetic foot infection: antimicrobial prescribing.

Prevention

Do not offer antibiotics to prevent diabetic foot infections. Give advice about seeking medical help if symptoms of a diabetic foot infection develop. [2019]

For a short explanation of why the committee made this 2019 recommendation and how it might affect practice, see the rationale and impact section on prevention.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> diabetic foot infection: antimicrobial prescribing.

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. **[2015]**
- 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. [2015]
- 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. [2015]

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. [2015]

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. [2015]
- 1.7.6 Do not offer bisphosphonates to treat acute Charcot arthropathy, unless as part of a clinical trial. [2015]
- 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. [2015]
- 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. [2015]

Terms used in this guideline

Diabetic foot infection

Diabetic foot infection is defined by the presence of at least 2 of the following:

- local swelling or induration
- erythema
- local tenderness or pain

- local warmth
- purulent discharge.

Mild diabetic foot infection

Local infection involving only the skin and subcutaneous tissue; if erythema, must be 0.5 cm to less than 2 cm around the ulcer (exclude other causes of inflammatory response, such as trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis and venous stasis).

Moderate diabetic foot infection

Local infection with erythema more than 2 cm around the ulcer or involving structures deeper than skin and subcutaneous tissues (such as abscess, osteomyelitis, septic arthritis or fasciitis), and no systemic inflammatory response signs.

Severe diabetic foot infection

Local infection with signs of systemic inflammatory response (such as temperature of more than 38°C or less than 36°C, increased heart rate or increased respiratory rate).

Diabetic foot problem

'Diabetic foot problem' refers to any problem affecting the feet in people with diabetes that is caused by loss of sensation (peripheral sensory neuropathy) and/or circulation problems (peripheral arterial disease).

Diabetic foot problems include:

- diabetic foot ulcers
- soft tissue infection
- destruction of the deep tissues such as heel pressure sores
- osteomyelitis (bone infection)
- Charcot arthropathy.

This guideline uses 'diabetic foot problem' throughout, because this is the term healthcare professionals will most commonly recognise for foot problems in people with diabetes. We do not mean to imply that people with diabetes should be blamed for their foot problems, and they should still be treated as individuals with their own needs, preferences and values.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Frequency of diabetic foot assessments

Based on clinical trial data and routinely collected real-world data, what is the clinical and cost effectiveness of annual foot assessments for people categorised as low risk, compared with checks every 2 years, in reducing diabetic foot problems (including ulcer, amputation and death)? [2023]

For a short explanation of why the committee made this recommendation for research, see the <u>rationale section on managing the risk of developing a diabetic foot problem</u>.

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

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
- helping to prevent diabetic foot problems from developing.

For example, laser doppler flowmetry, infrared thermography, and devices for measuring and providing feedback on plantar pressure. [2023]

For a short explanation of why the committee made this recommendation for research, see the <u>rationale section on managing the risk of developing a diabetic foot</u> problem.

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

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

7 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]

8 Prevention of diabetic foot problems

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

9 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? [2023]

For a short explanation of why the committee made this recommendation for research, see the <u>rationale section on managing the risk of developing a diabetic foot problem</u>.

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

10 Negative pressure wound therapy for treating diabetic foot ulcers

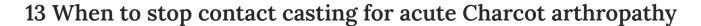
What is the clinical effectiveness of negative pressure wound therapy in the treatment of diabetic foot ulcers? [2015]

11 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]

12 Risk stratification tools for predicting Charcot arthropathy

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



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 made the recommendations and how they 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. When considering classification accuracy, sensitivity and specificity together, the PODUS and SIGN systems were the best. PODUS had a higher c-statistic than SIGN, but it did not report sensitivity or specificity. SIGN had 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:

- evidence from the prospective cohort study was high quality
- 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

primary care professionals who do not have specialist knowledge of diabetic foot care.

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

- SIGN had good sensitivity and specificity (although this assessment was based on a study with a high risk of bias).
- PODUS did not include an assessment of foot deformity in its final model (in an earlier systematic review to identify the factors that most accurately predicted foot ulceration, foot deformity was rejected for being inconsistently defined). Based on their experience and knowledge of established research, the committee believe that this is an important clinical risk factor and disagreed with it being left out of the final PODUS model.
- 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 think that assessments
 using SIGN would only take slightly longer than assessments using PODUS, and could
 also be completed by primary care professionals who do not have specialist
 knowledge of diabetic foot care.
- SIGN is recommended by the 2015 guideline. It is well established in clinical practice, and widely recognised and understood by practitioners. If the committee recommended SIGN, existing processes could be used without issue and there would be no risk of a disruptive change to practice.
- If the committee recommended PODUS, staff would need training on how to use the new system. Several free online training courses for primary care professionals would need changing. Primary care electronic patient record systems would also need to be modified.
- There is no evidence assessing the use of PODUS in NHS practice. Given the
 difficulties the NHS and primary care are currently facing, the committee did not want
 to introduce a potentially expensive and time-consuming change in practice without
 clear evidence of a significant benefit. They were particularly concerned about the
 impact because of current low staffing levels and the time staff will need for retraining.
- NHS organisations and diabetes specialists were broadly supportive of retaining the 2015 recommendations.

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.

Return to recommendations

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 <u>recommendations for research</u> on:

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

How the recommendations might affect practice

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

Return to recommendations

Treatment

Recommendations 1.6.6 and 1.6.7

Why the committee made the recommendations

The committee agreed that in people with diabetes, all foot wounds are likely to be colonised with bacteria. However, for people with a diabetic foot infection, prompt treatment of the infection is important to prevent complications, including limb-threatening infections.

The committee agreed to retain the recommendation from the 2015 guideline that antibiotics should be started as soon as possible if a diabetic foot infection is suspected. The choice of antibiotic would depend on the severity of infection, although the committee acknowledged that the studies they looked at did not always differentiate between severities. The committee accepted the Infectious Diseases Society of America's definitions of mild, moderate and severe infection, and recommended that this should be taken into account when choosing an antibiotic.

The committee retained the 2015 recommendation that samples should be taken for

microbiological testing before, or as close as possible to, the start of antibiotic treatment. This would allow empirical antibiotic treatment to be changed if needed when results are available.

How the recommendations might affect practice

These recommendations are consistent with current practice.

Return to recommendations

Choice of antibiotic, dose frequency, route of administration and course length

Recommendations 1.6.8 to 1.6.12

Why the committee made the recommendations

The committee agreed that in their experience, the incidence of diabetic foot infections in children and young people is rare. The mean age of participants in the evidence considered ranged from 54 to 64 years. Based on these factors, the committee included an antibiotic prescribing table for adults, but not for children and young people. They recommended that if a diabetic foot infection is suspected or confirmed in children or young people, specialist advice should be sought regarding antibiotic choice and regimen.

The evidence showed no difference in clinical outcomes for most antibiotics. But the antibiotics used in the studies were not wholly representative of UK practice, with some not being available in the UK and others not widely used. There were no differences in adverse events for many antibiotic comparisons. However, there were differences between some antibiotic classes, with lower rates of adverse effects generally for beta-lactam antibiotics.

The committee agreed that the choice of antibiotic in adults should be based on severity of infection (mild, moderate or severe) and the risk of complications, while minimising adverse effects and antibiotic resistance. This means using narrow-spectrum antibiotics first where possible, and using microbiological results, when available, to guide treatment.

The antibiotics recommended have good activity against many of the pathogens that

cause diabetic foot infection, have good penetration for skin and soft tissue infections, and can be used in the different settings where treatment may take place, including ambulatory care. Based on evidence, their experience and resistance data, the committee agreed that flucloxacillin is an effective empirical antibiotic for mild diabetic foot infections (with dosing taking account of a person's body weight and renal function). The committee agreed that flucloxacillin has poor oral bioavailability and in people with diabetes who could have impaired circulation, a higher (off-label dose) of up to 1 g four times a day may be needed to adequately treat diabetic foot infection.

For adults with a moderate or severe diabetic foot infection, a choice of antibiotics (or combinations of antibiotics) should be available. This enables selection based on individual patient factors, likely pathogens, and guided by microbiological results where available. In moderate and severe infection (which includes osteomyelitis), broader cover is needed because aerobic and anaerobic bacteria may be present. Severe infections can become limb-threatening quickly so antibiotic choices with the broadest spectrum of cover are appropriate; this can be changed to a narrower-spectrum antibiotic based on microbiological results when available, in line with principles of good antimicrobial stewardship. For moderate or severe infection, the committee recommended flucloxacillin at a dose of 1 g four times a day.

Patient preference is also important, particularly for treatment that will involve a hospital stay or be prolonged. Diabetes is a chronic condition and people may have had previous foot infections, with previous courses of antibiotics, that will influence their preferences.

No evidence was identified comparing antibiotic dose, frequency or route of administration. However, the committee acknowledged that a person with a diabetic foot infection may already be on a number of other medications, and this should be taken into account when deciding on dose, frequency and route of administration of an antibiotic.

In line with the <u>NICE guideline on antimicrobial stewardship</u> and <u>Public Health England's Start smart – then focus</u>, the committee agreed that oral antibiotics should be used in preference to intravenous antibiotics where possible. Intravenous antibiotics should only be used for people who are severely ill, unable to tolerate oral treatment, or where oral treatment would not provide adequate coverage or tissue penetration. The use of intravenous antibiotics should be reviewed by 48 hours (taking into account the person's response to treatment and any microbiological results) and switched to oral treatment where possible.

The committee agreed that a shorter course was generally as effective as a longer course for adults with a mild diabetic foot infection, and a 7-day course was sufficient for most people. However, it agreed that a longer course (up to a further 7 days) may be needed for some people based on a clinical assessment of their symptoms and history. They discussed the limited evidence on antibiotic course length, which compared 6 weeks with 12 weeks in adults with diabetic foot osteomyelitis. The committee agreed that for adults with a moderate or severe diabetic foot infection (which includes osteomyelitis), a 7-day course would be a minimum, with antibiotic treatment for up to 6 weeks if they have osteomyelitis. When prolonged antibiotic treatment is given, oral options should be used and treatment should be reviewed regularly, taking into account the need for continued antibiotics. The committee discussed antibiotic choices for osteomyelitis and agreed that the empirical choices for moderate and severe diabetic foot infection are also effective empirical choices for osteomyelitis.

How the recommendations might affect practice

The recommendations aim to optimise antibiotic use and reduce antibiotic resistance.

Return to recommendations

Advice

Recommendation 1.6.13

Why the committee made the recommendation

The committee based the recommendation on their experience and safety netting advice from the <u>NICE guideline on antimicrobial stewardship</u>. They agreed that if symptoms worsened rapidly or significantly at any time, or did not improve within 1 to 2 days, people with a diabetic foot infection should be advised to seek medical help.

How the recommendation might affect practice

The recommendation should ensure that appropriate safety netting is in place.

Return to recommendation

Reassessment

Recommendations 1.6.14 and 1.6.15

Why the committee made the recommendations

The committee agreed that when microbiological results are available, they should be used to guide antibiotic choice. The committee recognised the complexity around interpreting microbiological results, and agreed that the quality and type of specimen should be taken into account when making decisions around whether to change an antibiotic. The committee also discussed factors that would indicate that a person with a diabetic foot infection would need to be reassessed. These included if an infection was rapidly or significantly worsening or not improving, if other diagnoses were possible, or symptoms suggested a more serious illness or condition.

How the recommendations might affect practice

These recommendations should ensure that appropriate reassessment is in place.

Return to recommendations

Prevention

Recommendation 1.6.16

Why the committee made the recommendation

The committee agreed to retain the 2015 recommendation that antibiotics should not be given to prevent diabetic foot infections. No evidence was identified for antibiotic prophylaxis and the committee agreed that antibiotic prophylaxis is not appropriate because of concerns about antimicrobial resistance. People should be advised to seek medical help if symptoms of a diabetic foot infection develop.

How the recommendation might affect practice

This recommendation is consistent with current practice.

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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 7,000 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. Of this, 80% 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 <u>NICE</u> topic page on diabetes.

For full details of the evidence and the guideline committee's discussions, see the <u>evidence reviews and the full guideline</u>. You can also find information about <u>how the guideline was developed</u>, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting NICE guidelines into practice, see <u>resources to help</u> you put guidance into practice.

Update information

October 2019: We have reviewed the evidence and made new recommendations on antimicrobial prescribing for adults with a diabetic foot infection. These recommendations are marked [2019].

Recommendations marked [2015] last had an evidence review in 2015. In some cases, minor changes have been made to the wording to bring the language and style up to date, without changing the meaning.

August 2015: This guidance updates and replaces NICE guidelines CG10 (published January 2004) and CG119 (published March 2011).

Recommendations marked [2011] last had an evidence review in 2011.

Minor changes since publication

January 2023: We reviewed recent evidence and decided that no changes were needed to our guidance on risk assessment tools for diabetic foot problems and frequency of diabetic foot reviews. Recommendations are marked **[2023]** if the evidence was reviewed.

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 has been amended to refer to the updated <u>NICE</u> guideline on type 2 diabetes in adults.

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