NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

APPENDIX B: SCOPE

1 Guideline title

Diabetic foot problems: prevention and management of foot problems in people with diabetes

1.1 Short title

Diabetic foot problems

2 The remit

This is an update of Management of type 2 diabetes: prevention and management of foot problems (NICE clinical guideline 10, 2004) and a partial update (covering the recommendations on foot care only) of Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults (NICE clinical guideline 15, 2004). It will incorporate the recommendations on inpatient management of diabetic foot problems in adults from Diabetic foot problems: inpatient management (NICE clinical guideline 119, 2011). We will also carry out an editorial review of all recommendations to ensure that they comply with NICE's duties under equalities legislation.

This guideline will replace all of NICE clinical guidelines 10 and 119 and will replace the recommendations on foot care in NICE clinical guideline 15. This update is being undertaken to bring together all NICE diabetic foot guidance into one guideline. It will complement 4 other NICE clinical guidelines that are currently being updated that address diabetes care. These are listed below:

Guideline 1 – Diabetes in children and young people (developed by the National Collaborating Centre for Women's and Children's Health)

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This guideline will update Type 1 diabetes in children and young people (NICE clinical guideline 15). It will cover the diagnosis and management of type 1 and type 2 diabetes in children and young people (younger than 18 years). It will include: structured education programmes, behavioural interventions to improve adherence, glucose monitoring strategies, ketone monitoring, insulin regimens for type 1 diabetes and metformin monotherapy for type 2 diabetes.

Guideline 2 – Diabetes in pregnancy (developed by the National Collaborating Centre for Women's and Children's Health)
This guideline will update Diabetes in pregnancy (NICE clinical guideline 63). It will cover women of reproductive age who have pre-existing diabetes or who develop diabetes during pregnancy and it will also cover their newborn babies. It will include: target glucose ranges in the preconception period and during pregnancy, glucose monitoring strategies during pregnancy, screening, diagnosis and treatment of gestational diabetes, and postnatal testing for type 2 diabetes.

Guideline 3 – Type 1 diabetes in adults (developed by the National Clinical Guideline Centre)
This guideline will update Type 1 diabetes in children and young people (NICE clinical guideline 15). It will cover adults (18 years or older) with type 1 diabetes. It will include: tests to differentiate type 1 diabetes from type 2 diabetes, structured education programmes, clinical monitoring of glucose control, insulin regimens, ketone monitoring, dietary advice on carbohydrate counting and glycaemic index, and treatment and monitoring of specific complications.

Guideline 4 –Type 2 diabetes in adults (developed by the Internal Clinical Guidelines Programme, Centre for Clinical Practice, NICE)
This guideline will update Type 2 diabetes (NICE clinical guideline 66) and Type 2 diabetes: newer agents (NICE clinical guideline 87). It will cover adults (18 years or older) with type 2 diabetes. It will include: pharmacological management of blood glucose levels, target values for blood glucose control,

self-monitoring of blood glucose levels for blood glucose control, antithrombotic therapy and drug therapy for erectile dysfunction.

3 Clinical need for the guideline

3.1 Epidemiology

a) Diabetes mellitus is one of the most common chronic diseases in the UK and its prevalence is increasing. In 2011 there were 2.9 million people in the UK diagnosed with diabetes. By 2025 it is estimated that more than 5 million people in the UK will have diabetes. In England, the number of people diagnosed with diabetes has increased by 25% between 2006 and 2011, from 1.9 million to 2.5 million. The life expectancy of people with diabetes is shortened by up to 15 years, and 75% die of macrovascular complications.

b) Foot complications are common in people with diabetes. Overall, between 20 and 40% of people with diabetes are estimated to have neuropathy, and about 2.5% (approximately 61,000 people) are estimated to have a foot ulcer at any given time. The number of people with diabetic foot ulcers is expected to increase as the number of people with diabetes increases.

c) Diabetes is the most common cause of non-traumatic limb amputation, with diabetic foot ulcers preceding more than 80% of amputations in people with diabetes. After a first amputation, people with diabetes are twice as likely to have a subsequent amputation as people without diabetes. Mortality rates after diabetic foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation. 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

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subgroups than in the general population of people with diabetes in the UK.

d) The risk of foot problems in people with diabetes is increased, predominantly a result of either diabetic neuropathy (nerve damage or degeneration) or peripheral vascular disease (poor blood supply because of disease of the large and medium sized blood vessels in the legs) or a combination of both. Foot problems in people with diabetes have a significant financial impact on the NHS through primary care, community care, outpatient costs, increased bed occupancy and prolonged stays in hospital. A report published in 2012 by NHS Diabetes showed that around £650 million (or £1 in every £150 the NHS spends) is spent on foot ulcers or amputations each year.

3.2 Current practice

a) Despite the publication of strategies on commissioning specialist services for preventing and managing diabetic foot problems ('Putting feet first: the national minimum skills framework for commissioning of footcare services for people with diabetes', Diabetes UK 2011; 'Putting feet first: commissioning specialist services for the management and prevention of diabetic foot disease in hospitals', Diabetes UK 2009; 'Improving emergency and inpatient care for people with diabetes', Department of Health 2008), there is variation in practice in preventing and managing diabetic foot problems across different NHS settings, and amputation rates still vary up to fourfold in the UK.

b) This variation in practice results from a wide variety of factors. These include the varying levels of organisation of care for people with diabetes and diabetic foot problems. This variability depends on geography, individual trusts, individual specialties (such as the organisation and access of the diabetic foot care services) and

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availability of healthcare professionals with expertise in the management of diabetic foot problems.

c) Furthermore, the implementation of footcare surveillance programmes is still varied across the UK, and there is currently a lack of guidance on foot surveillance strategies aimed at young people and children with diabetes. There is a need for a comprehensive guideline on foot care for people with diabetes that addresses all NHS settings.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Adults, young people and children with type 1 or type 2 diabetes.

b) Subgroups that need specific consideration will be considered during development.

4.1.2 Groups that will not be covered

a) Adults, young people and children without a diagnosis of diabetes.

4.2 Healthcare setting

a) All settings where NHS healthcare is commissioned or delivered (including a person's home).

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4.3 Clinical management

4.3.1 Key clinical issues that will be covered

Recommendations on the inpatient management of diabetic foot problems (NICE clinical guideline 119) will not be updated but will be incorporated into this guideline.

Organisation of care

a) The definition and composition of the foot protection team and the multidisciplinary foot care team.

b) Indications for referral to the foot protection and multidisciplinary foot care teams.

Surveillance and preventing foot problems

c) Foot examination and risk classification.

d) Prevention strategies for people with diabetes who are at risk of developing foot problems, including:

- frequency of review
- information, advice and education for adults, young people and children (including family members and carers, as appropriate) about self-monitoring and preventing foot problems
- footwear or foot orthoses
- skin and nail care.

Assessing and diagnosing foot problems (ulcers, soft tissue infections, osteomyelitis and gangrene) in people with diabetes

e) Assessing and diagnosing foot ulcer (including severity), soft tissue infection, osteomyelitis or gangrene in people with diabetes.

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Managing foot problems (ulcers, soft tissue infections, osteomyelitis and gangrene) resulting from diabetes

f) Management strategies for foot problems (ulcers, soft tissue infections, osteomyelitis or gangrene) resulting from diabetes, including:

- frequency of review
- information, advice and education for adults, young people and children (including family members and carers, as appropriate) about self-care and preventing further foot problems
- footwear or foot orthoses
- blood glucose management
- skin and nail care.

g) Clinical effectiveness of treatments for foot problems (ulcers, soft tissue infections, osteomyelitis or gangrene) resulting from diabetes, including:

- surgical or non-surgical debridement, wound dressings, off-loading (removal of weight bearing)
- antibiotic regimens and antimicrobial therapy for foot infection
- other adjunctive treatments, including dermal or skin substitutes, growth factors, hyperbaric oxygen therapy, bio-debridement, topical negative pressure therapy, electrical stimulation.

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

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Investigating orthopaedic and vascular complications and referring to specialist services

h) Signs and symptoms of:

- Charcot arthropathy
- lower limb ischaemia.

i) Indications for referral to other specialist services including:

- specialist investigative or interventional radiology
- orthopaedic services
- vascular services
- specialist pain management
- specialist orthotics.

Diagnosing and managing Charcot arthropathy

j) Diagnosing and managing Charcot arthropathy in people with diabetes

Clinical issues that will not be covered

a) Surgical procedures for amputation.

b) Postoperative rehabilitation following amputation.

c) Treating peripheral vascular disease.

d) Treating diabetic neuropathy.

e) General management of diabetes, comorbidities and complications other than diabetic foot problems.

4.4 Main outcomes

a) Rates and extent of amputation (major or minor).

b) Rates (and recurrent rates) of foot ulcerations, soft tissue infections, osteomyelitis and gangrene.

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c) Healing rates of foot ulcers.

d) Health-related quality of life of people with diabetic foot problems. Ideally this will include data from validated generic instruments such as the EQ-5D that are able to provide a single index value of health status (on a scale of 0 to 1). Generic health survey questionnaire data, such as from the Short Form 36, may also be appropriate.

e) Rates of hospital admission and re-admission.

f) Length of hospital stay.

g) Mortality.

h) Adverse events of treatment.

i) Resource use and costs.

j) Patient experience of care

4.5 Review questions

Review questions guide a systematic review of the literature. They address only the key clinical issues covered in the scope, and usually relate to interventions, diagnosis, prognosis, service delivery or patient experience. Please note that these review questions are draft versions and will be finalised with the Guideline Development Group.

Organisation of care

a) In UK current practice, are there existing definitions and compositional models (including skills and specialisms) for foot protection teams and multidisciplinary foot care teams?

b) When and with what criteria should people be referred to the foot protection team or the multidisciplinary foot care team?

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Surveillance and preventing foot problems

c) What are the clinical utilities of assessment and risk stratification tools for examining the feet of people with diabetes and classifying risk of foot problems?

d) How often should people with diabetes at risk of developing foot problems be reviewed?

e) What is the effectiveness of different prevention strategies for people with diabetes at risk of developing foot problems? This includes information, advice and education about self-monitoring and preventing foot problems, appropriate footwear, provision of foot orthoses, and skin and nail care.

Assessing and diagnosing foot problems (ulcers, soft tissue infections, osteomyelitis and gangrene) in people with diabetes

f) What are the clinical utilities and accuracy of tools for assessing and diagnosing:

- foot ulcers (including severity)
- soft tissue infections
- osteomyelitis
- gangrene?

Managing foot problems (ulcers, soft tissue infections, osteomyelitis and gangrene) resulting from diabetes

g) How often should people with diabetes who have foot ulcers, soft tissue infections, osteomyelitis or gangrene be reviewed?

h) What is the effectiveness of different management strategies for people with diabetes who have foot ulcers, soft tissue infections, osteomyelitis or gangrene? This includes information, advice and education about self-care and preventing further foot problems, appropriate footwear, blood glucose management, provision of foot orthoses, and skin and nail care.

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i) What is the clinical effectiveness of surgical or non-surgical debridement, wound dressings and off-loading?

j) What is the clinical effectiveness of different antibiotic regimens and antimicrobial therapies for foot infection?

k) What is the clinical effectiveness of adjunctive treatments including:

- dermal or skin substitutes
- growth factors
- hyperbaric oxygen therapy
- bio-debridement
- topical negative pressure therapy
- electrical stimulation?

Investigating orthopaedic and vascular complications and referring to specialist services

l) What signs and symptoms or risk factors should prompt healthcare professionals to suspect Charcot arthropathy and lower limb ischaemia?

m) What are the indicators for referral to specialist services, such as investigative or interventional radiology, orthopaedic or vascular services, specialist pain management and specialist orthotics?

Diagnosing and managing Charcot arthropathy

n) What are the clinical utilities and accuracy of tools for assessing and diagnosing Charcot arthropathy in people with diabetes?

o) What is the effectiveness of different management strategies for people with diabetes who have Charcot arthropathy?

4.6 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative

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interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually only be from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.7 Status

4.7.1 Scope

This is the final scope.

4.7.2 Timing

The development of the guideline recommendations will begin in July 2013.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be updated

This guideline will update and replace the following NICE guidance.

- Type 1 diabetes (recommendations on foot care only). NICE clinical guideline 15 (2004).
- Management of type 2 diabetes: foot care. NICE clinical guideline 10 (2004).

5.1.2 NICE guidance to be incorporated

This guideline will incorporate the following NICE guidance.

- Diabetic foot problems: inpatient management. NICE clinical guideline 119 (2011).

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5.1.3 Other related NICE guidance

- Physical activity: brief advice for adults in primary care. NICE public health guidance 44 (2013).
- Lower limb peripheral arterial disease. NICE clinical guideline 147 (2012).
- Walking and cycling. NICE public health guidance 41 (2012).
- Preventing type 2 diabetes: risk identification and interventions for individuals at high risk. NICE public health guidance 38 (2012).
- Hypertension. NICE clinical guideline 127 (2011).
- Preventing type 2 diabetes: population and community interventions. NICE public health guidance 35 (2011).
- Venous thromboembolism: reducing the risk. NICE clinical guideline 92 (2010).
- Depression with a chronic physical health problem. NICE clinical guideline 91 (2009).
- Smoking cessation services. NICE public health guidance 10 (2008).
- Brief interventions and referral for smoking cessation. NICE public health guidance 1 (2006).
- Guidance on the use of patient-education models for diabetes. NICE technology appraisal guidance 60 (2003).

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website).

- Neuropathic pain – pharmacological management (update). NICE clinical guideline. Publication expected October 2013.
- Pressure ulcers (update). NICE clinical guideline. Publication expected May 2014.
- Lipid modification (update). NICE clinical guideline. Publication expected July 2014.
- Exercise referral schemes. NICE public health guidance. Publication expected September 2014.

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- Diabetes in children and young people. NICE clinical guideline. Publication date to be confirmed.
- Diabetes in pregnancy (update). NICE clinical guideline. Publication date to be confirmed.
- Type 1 diabetes (update). NICE clinical guideline. Publication date to be confirmed.
- Type 2 diabetes (update). NICE clinical guideline. Publication date to be confirmed.

6 Further information

Information on the guideline development process is provided in:

- How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS
- The guidelines manual.

Information on the progress of the guideline will also be available from the NICE website.

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