NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease

1.1 Short title

Lipid modification

2 The remit

This is a partial update of:

- Lipid modification (NICE clinical guideline 67, 2008)
- Statins for the prevention of cardiovascular events (NICE technology appraisal guidance 94, 2006).

See section 4.3.1 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICE's duties under equalities legislation.

This update is being undertaken as part of the guideline review cycle.

3 Clinical need for the guideline

3.1 Epidemiology

a) Cardiovascular disease (CVD) is defined for epidemiological and trial purposes as fatal and non-fatal coronary heart disease, stroke and peripheral arterial disease that need intervention.

b) CVD is 1 of a number of diseases associated with atherosclerosis (hardening and narrowing of the arteries). Other diseases

associated with atherosclerosis include aortic aneurysm, acute onset heart failure after myocardial infarction, chronic heart failure, and cardiac arrhythmias. Although they share common risk factors, their disease processes and management differ.

c) CVD has significant cost implications.

d) CVD is a major cause of morbidity in England, with a prevalence of 13.6% in men and 13.0% in women.

e) CVD is the leading cause of death in the UK. In 2008 diseases of the circulatory system caused 190,857deaths in the UK, of which 88,236 were due to coronary heart disease and 43,142 to stroke. The death rate varies with age, gender, socioeconomic status, ethnicity and geographic location. Death rates for CVD have been falling in the UK since the 1970s. About 58% of this decline during the 1980s and 1990s is attributable to reductions in major risk factors, principally smoking. Treatment of people at risk, including secondary prevention, accounts for the remaining 42%.

3.2 Current practice

a) Strategies for the primary prevention of CVD have focused on interventions to reduce risk factors for CVD and on identifying, assessing and treating people who are at high risk of developing CVD but currently have no symptoms. The risk assessment stage of the NHS Health Check (formerly known as the Vascular Check Programme) uses a risk engine for people aged 40–74 years to calculate their 10-year risk of CVD. In both primary and secondary prevention, the focus is on dealing with modifiable risk factors such as smoking, high blood pressure, blood lipids, physical inactivity and obesity.

b) Blood lipids, including cholesterol, are a modifiable risk factor for CVD. The risk of CVD is directly related to blood cholesterol levels and it is estimated that more than 50% of CVD in developed

countries is a result of blood cholesterol levels higher than 3.8 mmol/litre. Blood cholesterol and other lipid components can be modified by drugs, physical activity and dietary changes; a multifactorial approach is likely to yield most benefit.

c) Drug therapy, although important, must be seen in the context of other interventions to reduce absolute risk of CVD. The use of lipid-lowering drugs in primary and secondary prevention has major cost implications. The net ingredient cost of lipid-lowering drugs dispensed in the community in 2011 was £544,187,400.

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 scope is based on the referral from the Department of Health.

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 (aged 18 years and older) without established CVD.

b) Adults with type 1 diabetes (not covered in the original guideline).

c) Adults with type 2 diabetes (not covered in the original guideline).

d) Adults with chronic kidney disease (CKD) (not covered in the original guideline).

e) Adults (aged 18 and older) with established CVD.

f) The following special groups will be considered:

- people from black and minority ethnic groups
- people with a family history of CVD
- people from low socioeconomic groups
- people older than 75
- women
- people with autoimmune disease
- people with serious mental illness.

4.1.2 Groups that will not be covered

a) People with familial hypercholesterolaemia.

b) People with familial clotting disorders that increase cardiovascular risk.

c) People with other genetic disorders that increase cardiovascular risk.

d) People at high risk of CVD or abnormalities of lipid metabolism as a result of endocrine or other secondary disease processes other than diabetes.

e) People receiving renal replacement therapy.

4.2 Healthcare setting

a) All settings in which NHS care is delivered.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) The most appropriate risk tool system to estimate a person's absolute risk of developing CVD for:

- people without diabetes – for example, age alone, QRISK and Framingham risk assessment tools (10-year or lifetime risk)

- people with diabetes – for example, age alone, QRISK and UKPDS Risk Engine tools (not covered in the original guideline).

b) Lipid modification strategy: for example, fixed dose or treating to a target lipid level.

c) Pharmacological interventions (1) to reduce the risk of developing CVD (primary prevention) and (2) for secondary prevention in people with established CVD:

- First-line treatment:
  - statins.
- Second-line treatment (alone or in combination with statins):
  - fibrates
  - anion-exchange resins
  - nicotinic acid group
  - omega-3 fatty acids.

d) Cardioprotective diet, including plant stanols and sterols.

e) Assessment of blood lipids: which fractions of blood lipids should be measured and in what circumstances (for example, fasting).

f) Identifying subgroups at increased risk of adverse events, and strategies to maintain and improve adherence to individual agents, for example coenzyme $Q_{10.}$

g) Monitoring lipid-lowering treatment, for example, blood lipids, liver function test, creatine kinase and glycaemia.

h) Criteria for referral to specialist assessment and management for people found to have lipid disorders, for example familial lipid disorders.

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.

4.3.2 Clinical issues that will not be covered

a) Identifying and assessing prediabetes or metabolic syndrome, and their management beyond the lipid abnormalities present in this condition.

b) The identification and management of people with Type 1 diabetes, Type 2 diabetes and Chronic Kidney Disease other than in relation to risk assessment for cardiovascular disease and lipid modification.

c) Assessment and clinical management of modifiable risk factors for cardiovascular disease other than lipid modification such as raised blood pressure or hypertension, smoking, obesity and blood clotting abnormalities.

d) Self-medication with lipid-regulating drugs, specifically over-the-counter drugs, including statins.

e) Clinical management of lipid disorders considered to merit referral to secondary care for specialist assessment and follow-up.

f) Secondary prevention of myocardial infarction other than lipid modification.

4.4 Main outcomes

a) Morbidity and mortality.

b) Hospitalisation.

c) 10-year risk of developing CVD.

d) Lifetime risk of developing CVD.

e) Adverse events.

f) Quality of life outcomes.

g) Adherence.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative 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 be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in September 2012.

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:

- Lipid modification. NICE clinical guideline 67 (2008).
- Statins for the prevention of cardiovascular events. NICE technology appraisal guidance 94 (2006).

5.1.2 Other related NICE guidance

- Hypertension. NICE clinical guideline 127 (2011)

- Type 2 diabetes – newer agents. NICE clinical guideline 87 (2009)
- Medicines adherence. NICE clinical guideline 76 (2009)
- Familial hypercholesterolaemia. NICE clinical guideline 71 (2008)
- Stroke. NICE clinical guideline 68 (2008)
- MI: secondary prevention. NICE clinical guideline 48 (2007)
- Prevention of cardiovascular disease at the population level. NICE public health guidance 25 (2011)
- Identifying and supporting people most at risk of dying prematurely. NICE public health guidance 15 (2008)
- Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events. NICE technology appraisal guidance 210 (2010)
- Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia. NICE technology appraisal guidance 132 (2007).

5.2 Guidance under development

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

- Lower limb peripheral arterial disease. NICE clinical guideline. Publication expected August 2012.
- Preventing type 2 diabetes – risk identification and interventions for individuals at high risk. NICE public health guidance. Publication expected June 2012.
- Myocardial infarction: secondary prevention in primary and secondary care for patients following a myocardial infarction. NICE clinical guideline. Publication expected July 2013.
- Myocardial infarction with ST-segment-elevation. NICE clinical guideline. Publication expected July 2013.
- Chronic kidney disease. NICE clinical guideline. Publication expected July 2014.
- Type 1 diabetes: the diagnosis and management of type 1diabetes in adults (update). NICE clinical guideline. Publication expected July 2014

- Type 2 diabetes. NICE clinical guideline. Publication expected TBC.

6 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- 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.