NHS
National Institute for Health and Clinical Excellence

Quick reference guide

Issue date: May 2008 (reissued March 2010)

Lipid modification

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

NICE clinical guideline 67
Developed by the National Collaborating Centre for Primary Care

Abbreviations

BMI body mass index

CVD cardiovascular disease

CHD coronary heart disease

HDL high density lipoprotein

HIV human immunodeficiency virus

LDL low density lipoprotein

SLE systemic lupus erythematosus

TIA transient ischaemic attack

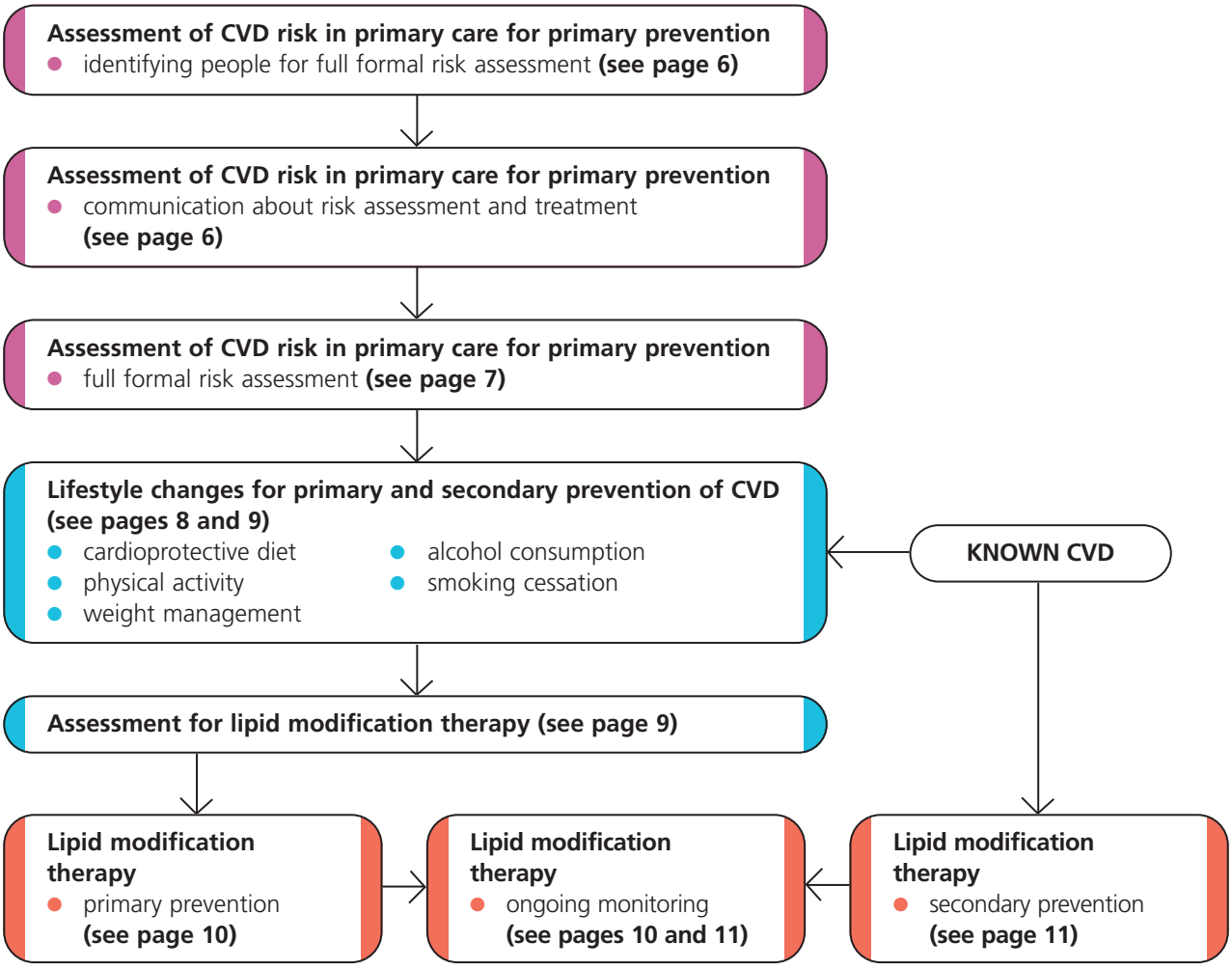
In February 2010 NICE agreed to withdraw the recommendation that the Framingham risk equation should be the equation of choice for assessment of CVD risk, but agreed that it should be considered as one of the possible equations to use. Recommendations relating specifically to the use and modification of the Framingham risk equation have been moved to a box on page 13 and to appendix D of the NICE guideline. These recommendations should be considered when using the Framingham risk equation for assessment of CVD risk.

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Contents



Introduction

Cardiovascular disease (CVD) is the leading cause of death in England and Wales. CVD predominantly affects people older than 50. Apart from age and sex, three modifiable risk factors – smoking, raised blood pressure and raised cholesterol – make a major contribution to CVD risk, particularly in combination. The risk of a future CVD event can be calculated from these risk factors, and people at higher risk can be identified. Blood cholesterol has a log–linear relationship to the risk of coronary heart disease (CHD) and is a key modifiable risk factor. Blood cholesterol can be reduced by dietary change, physical activity and drugs. This guideline addresses the identification of those at higher risk of CVD and the modification of lipids in these people and people with established CVD[1]. The care of people with conditions that may predispose them to higher risk of CVD, such as diabetes, chronic kidney disease and familial hypercholesterolaemia, is outside the scope of this guideline.

Patient-centred care

Healthcare professionals should use everyday, jargon-free language when discussing risk of CVD, lifestyle modifications and treatments with patients.

Adequate time should be set aside for the consultation to allow questions to be answered, and further consultation may be needed.

Discussions with patients about CVD risk should be documented.

Treatment and care should take into account:

- a person's needs and preferences
- a person's culture and any physical, sensory or learning disabilities
- the need to ensure effective communication of information if a person does not speak or read English.

Follow Department of Health advice on seeking consent if needed (available from **www.dh.gov.uk**).

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

[1] This guideline only addresses lipid modification, but modification of other risk factors such as high blood pressure and obesity are important in people at higher risk of CVD and those with established CVD. See 'Hypertension' (NICE clinical guideline 34) and 'Obesity' (NICE clinical guideline 43) for advice on managing these conditions.

Key priorities for implementation

Primary prevention of CVD

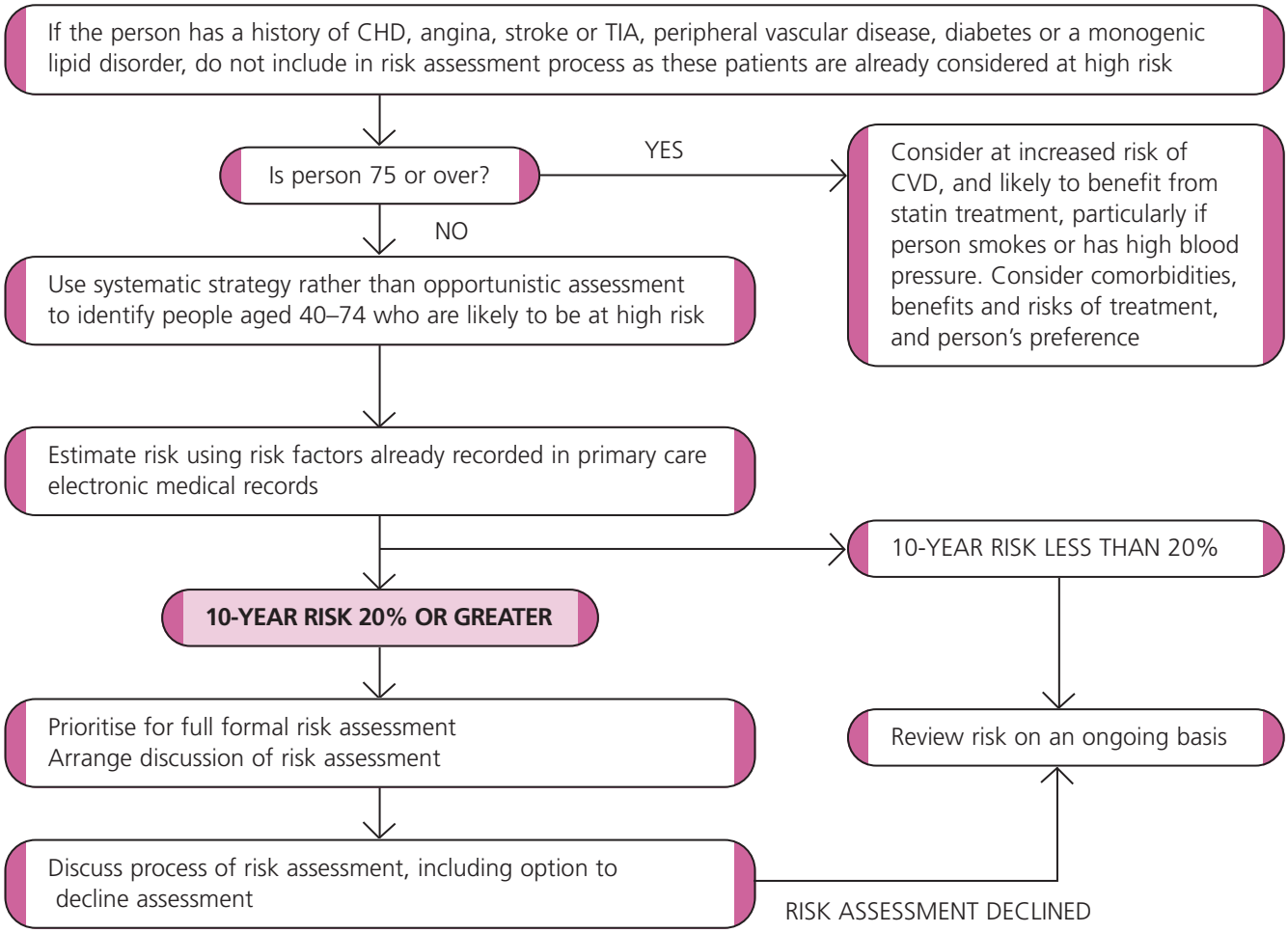
- For the primary prevention of CVD in primary care, a systematic strategy should be used to identify people aged 40–74 who are likely to be at high risk.
- People should be prioritised on the basis of an estimate of their CVD risk before a full formal risk assessment. Their CVD risk should be estimated using CVD risk factors already recorded in primary care electronic medical records.
- Risk equations should be used to assess CVD risk.
- People should be offered information about their absolute risk of CVD and about the absolute benefits and harms of an intervention over a 10-year period. This information should be in a form that:
  - presents individualised risk and benefit scenarios
  - presents the absolute risk of events numerically
  - uses appropriate diagrams and text.

  (See **www.npci.org.uk**)
- Before offering lipid modification therapy for primary prevention, all other modifiable CVD risk factors should be considered and their management optimised if possible. Baseline blood tests and clinical assessment should be performed, and comorbidities and secondary causes of dyslipidaemia should be treated. Assessment should include:
  - smoking status
  - alcohol consumption
  - blood pressure (see 'Hypertension', NICE clinical guideline 34)
  - body mass index or other measure of obesity (see 'Obesity', NICE clinical guideline 43)
  - fasting total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides (if fasting levels are not already available)
  - fasting blood glucose
  - renal function
  - liver function (transaminases)
  - thyroid-stimulating hormone (TSH) if dyslipidaemia is present.
- Statin therapy is recommended as part of the management strategy for the primary prevention of CVD for adults who have a 20% or greater 10-year risk of developing CVD. This level of risk should be estimated using an appropriate risk calculator, or by clinical assessment for people for whom an appropriate risk calculator is not available or appropriate (for example, older people, people with diabetes or people in high-risk ethnic groups).

Continued on page 12

Assessment of CVD risk in primary care for primary prevention

Identifying people for full formal risk assessment



Communication about risk assessment and treatment

Encourage the person to work with you to reduce their CVD risk:

- find out what they have been told about their risk and how they feel about it
- explore what they believe determines future health
- assess readiness to change lifestyle, undergo tests and take medication
- tell them about possible future management options
- develop a shared management plan
- check that they have understood what has been discussed.

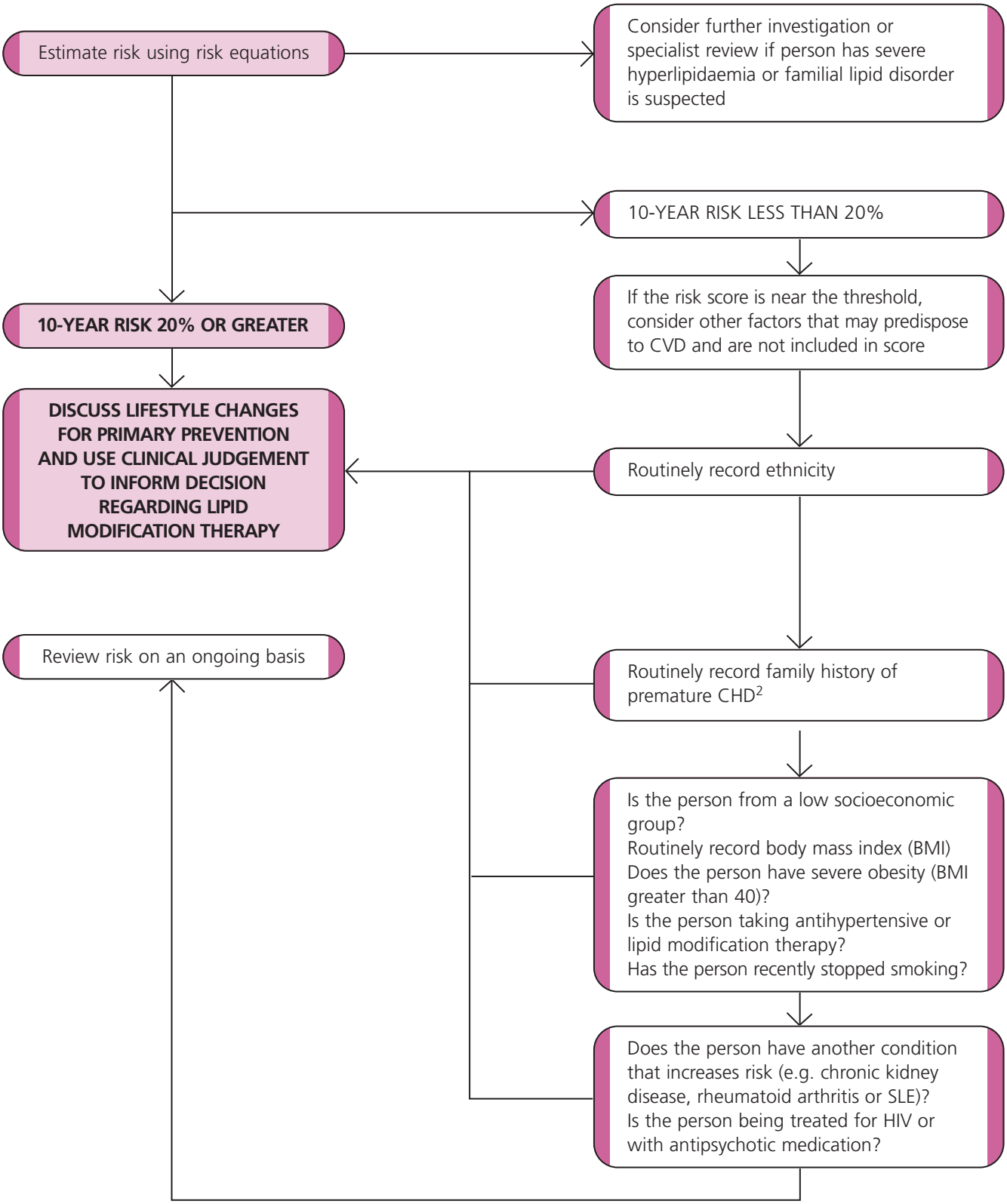
Inform people that risk is estimated, but is more likely to be accurate if over 20%.

Offer people information about their absolute risk of CVD and treatment (including benefits and harms) over a 10-year period. The information should:

- present individualised risk and benefit scenarios
- present the absolute risk of events numerically
- use appropriate diagrams and text.

Full formal risk assessment

Healthcare professionals should always be aware that all CVD risk estimation tools can provide only an approximation of CVD risk. Interpretation of CVD risk scores should always reflect informed clinical judgement



[2] Age at onset younger than 55 in fathers, sons or brothers or younger than 65 in mothers, daughters or sisters.

Lifestyle changes for primary and secondary prevention of CVD

Cardioprotective diet

- Advise people to eat a diet in which:
  - total fat intake is 30% or less of total energy intake
  - saturated fats are 10% or less of total energy intake
  - dietary cholesterol is less than 300 mg/day
  - saturated fats are replaced by monounsaturated and polyunsaturated fats.
- Advise eating at least:
  - five portions of fruit and vegetables per day
  - two portions of fish per week, including a portion of oily fish.
- Advise pregnant women to limit their intake of oily fish to two portions a week.
- Recommend looking at **www.eatwell.gov.uk/healthydiet** and **www.5aday.nhs.uk** for advice on healthy eating and portion size.
- Do not routinely recommend omega-3 fatty acid supplements or plant sterols and stanols for primary prevention.

Physical activity

- Advise people to take 30 minutes of at least moderate intensity exercise a day at least 5 days a week.
- Encourage people who cannot manage this to exercise at their maximum safe capacity.
- Recommend exercise that can be incorporated into everyday life, such as brisk walking, using stairs and cycling.
- Tell people that they can exercise in bouts of 10 minutes or more throughout the day.
- Take into account the person's needs, preferences and circumstances.
- Agree goals and provide written information about the benefits of activity and local opportunities to be active.

Weight management

- Offer people who are overweight or obese advice and support to work towards achieving and maintaining a healthy weight. Follow 'Obesity' (NICE clinical guideline 43).

Alcohol consumption

- Advise men to limit their alcohol intake to 3–4 units a day.
- Advise women to limit their alcohol intake to 2–3 units a day.
- Advise everyone to avoid binge drinking.
- Recommend looking at **www.eatwell.gov.uk/healthydiet** for information on alcohol units.

Smoking cessation

- Advise all people who smoke to stop.
- If people want to stop:
  - offer support and advice
  - offer referral to an intensive support service (for example, NHS Stop Smoking Services)
  - if they do not or cannot take up the referral for intensive support, offer pharmacotherapy in line with 'Smoking cessation services' (NICE public health programme guidance 10) and 'Varenicline for smoking cessation' (NICE technology appraisal guidance 123).

Assessment for lipid modification therapy

Before offering lipid modification therapy for **primary prevention**, optimise the management of other modifiable risk factors if possible. Assess:

- smoking status
- alcohol consumption
- blood pressure
- body mass index or other measure of obesity
- fasting total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides (if fasting levels not already available)
- fasting blood glucose
- renal function
- liver function (transaminases)
- TSH if dyslipidaemia is present.

For **secondary prevention**, offer lipid modification therapy. Carry out blood tests and clinical assessment as for primary prevention. Treat comorbidities and secondary causes of dyslipidaemia.

Do not routinely exclude from statin therapy people with transaminases that are raised but are less than 3 times the upper limit of normal.

If statin treatment is appropriate for primary prevention, offer as soon as possible after full risk assessment and discussion about the risks and benefits, taking into account comorbidities and life expectancy.

Lipid modification therapy

Primary prevention

Consider drugs for primary and secondary prevention effect on CVD morbidity

Offer 40 mg simvastatin (or drug of similar efficacy and acquisition cost) as part of the management strategy for adults over 40 who have a 20% or greater 10-year risk of developing CVD, based on risk equations and clinical judgement

If there are potential drug interactions or 40 mg simvastatin is contraindicated, offer a lower dose of simvastatin or pravastatin

Do not routinely offer:

- higher intensity statins
- fibrates
- anion exchange resins

Do not offer nicotinic acid or the combination of an anion exchange resin, fibrate or a fish oil supplement with a statin

There is no target level for total or LDL cholesterol for primary prevention

Review drug therapy in line with good clinical practice

Repeat lipid profile is not necessary but review management according to clinical judgement and patient preference

Ongoing

Measure liver function within 3 months and at 12 months, but not again unless clinically indicated

If drugs that interfere with statin metabolism are introduced for another illness, consider reducing the statin dose or temporarily or permanently stopping it

Advise people to seek medical advice if they develop muscle pain, tenderness or weakness

If statins are not tolerated for primary prevention, consider:

- fibrates
- anion exchange resins
- ezetimibe[3]

[3] See 'Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia' (NICE technology appraisal guidance 132).

Secondary prevention

for which there is evidence in clinical trials of a beneficial and mortality outcomes

Offer lipid modification therapy as soon as possible

Offer 40 mg simvastatin (or drug of similar efficacy and acquisition cost) to all adults with clinical evidence of CVD

If there are potential drug interactions or 40 mg simvastatin is contraindicated, offer a lower dose of simvastatin or pravastatin

Offer a higher intensity statin to people with acute coronary syndrome. Do not delay until lipid levels are available. Take into account:

- informed preference
- comorbidities
- other drug therapy
- benefits and risks

Consider increasing dose to 80 mg simvastatin or drug of similar efficacy and cost if the total cholesterol does not fall below 4 mmol/litre or the LDL cholesterol does not fall below 2 mmol/litre. Take into account:

- informed preference
- comorbidities
- other drug therapy
- benefits and risks

Use an 'audit' level of total cholesterol of 5 mmol/litre to assess progress in groups with CVD. Recognise that less than half will achieve total cholesterol less than 4 mmol/litre or LDL cholesterol less than 2 mmol/litre

Measure fasting lipid levels about 3 months after the start of treatment

monitoring

Do not routinely monitor creatine kinase in people without adverse events, but do measure it in people with muscle symptoms

Stop statins and seek specialist advice if unexplained peripheral neuropathy develops

If statins are not tolerated for secondary prevention, consider:

- fibrates
- anion exchange resins
- nicotinic acid
- ezetimibe[4]

[4] See 'Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia' (NICE technology appraisal guidance 132).

Key priorities for implementation *continued*

- Treatment for the primary prevention of CVD should be initiated with simvastatin 40 mg. If there are potential drug interactions, or simvastatin 40 mg is contraindicated, a lower dose or alternative preparation such as pravastatin may be chosen.

Secondary prevention of CVD

- For secondary prevention, lipid modification therapy should be offered and should not be delayed by management of modifiable risk factors. Blood tests and clinical assessment should be performed, and comorbidities and secondary causes of dyslipidaemia should be treated. Assessment should include:
  - smoking status
  - alcohol consumption
  - blood pressure (see 'Hypertension', NICE clinical guideline 34)
  - body mass index or other measure of obesity (see 'Obesity', NICE clinical guideline 43)
  - fasting total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides (if fasting levels are not already available)
  - fasting blood glucose
  - renal function
  - liver function (transaminases)
  - thyroid-stimulating hormone (TSH) if dyslipidaemia is present.
- Statin therapy is recommended for adults with clinical evidence of CVD.
- People with acute coronary syndrome should be treated with a higher intensity statin. Any decision to offer a higher intensity statin should take into account the patient's informed preference, comorbidities, multiple drug therapy, and the benefits and risks of treatment.
- Treatment for the secondary prevention of CVD should be initiated with simvastatin 40 mg. If there are potential drug interactions, or simvastatin 40 mg is contraindicated, a lower dose or alternative preparation such as pravastatin may be chosen.
- In people taking statins for secondary prevention, consider increasing to simvastatin 80 mg or a drug of similar efficacy and acquisition cost if a total cholesterol of less than 4 mmol/litre or an LDL cholesterol of less than 2 mmol/litre is not attained. Any decision to offer a higher intensity statin should take into account informed preference, comorbidities, multiple drug therapy, and the benefit and risks of treatment.

Implementation tools

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (**www.nice.org.uk/CG067**).

- Slides highlighting key messages for local discussion.
- Costing tools:
  - costing report to estimate the national savings and costs associated with implementation
  - costing template to estimate the local costs and savings involved.
- Audit support for monitoring local practice.

When using the Framingham risk equation for assessing CVD risk, increase the risk:

- by a factor of 1.4 for men with a South Asian background
- by a factor of 1.5 if one first-degree relative has a history of premature CHD
- by a factor of up to 2.0 if more than one first-degree relative has a history of premature CHD

Be aware that the Framingham risk equation may overestimate risk in UK populations.

Further information

Ordering information

You can download the following documents from **www.nice.org.uk/CG067**

- A quick reference guide (this document) – a summary of the recommendations for healthcare professionals.
- The NICE guideline – all the recommendations.
- 'Understanding NICE guidance' – information for patients and carers.
- The full guideline – all the recommendations, details of how they were developed, and reviews of the evidence they were based on.

For printed copies of the quick reference guide or 'Understanding NICE guidance', phone NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N1574 (quick reference guide)
- N1575 ('Understanding NICE guidance').

Related NICE guidance

For information about NICE guidance that has been issued or is in development, see the website (**www.nice.org.uk**).

Published

- Familial hypercholesterolaemia: identification and management of familial hypercholesterolaemia. NICE clinical guideline 71 (2008). Available from **www.nice.org.uk/CG071**
- Type 2 diabetes: the management of type 2 diabetes (update). NICE clinical guideline 66 (2008). Available from **www.nice.org.uk/CG066**
- Reducing the rate of premature deaths from cardiovascular disease and other smoking-related diseases: finding and supporting those most at risk and improving access to services. NICE public health guidance 15 (2008). Available from **www.nice.org.uk/PH015**
- Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities. NICE public health guidance 10 (2008). Available from **www.nice.org.uk/PH010**
- Ezetimibe for the treatment of primary (heterozygous-familial and non-familial) hypercholesterolaemia. NICE technology appraisal guidance 132 (2007). Available from **www.nice.org.uk/TA132**
- Varenicline for smoking cessation. NICE technology appraisal guidance 123 (2007). Available from **www.nice.org.uk/TA123**
- MI: secondary prevention in primary and secondary care for patients following a myocardial infarction. NICE clinical guideline 48 (2007). Available from **www.nice.org.uk/CG048**
- Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. NICE clinical guideline 43 (2006). Available from **www.nice.org.uk/CG043**
- Hypertension: management of hypertension in adults in primary care. NICE clinical guideline 34 (2006). Available from **www.nice.org.uk/CG034**

- Statins for the prevention of cardiovascular events. NICE technology appraisal guidance 94 (2006). Available from **www.nice.org.uk/TA094**
- Brief interventions and referral for smoking cessation in primary care and other settings. NICE public health intervention guidance 1 (2006). Available from **www.nice.org.uk/PHI001**
- Four commonly used methods to increase physical activity: brief interventions in primary care, exercise referral schemes, pedometers and community-based exercise programmes for walking and cycling. NICE public health intervention guidance 2 (2006). Available from **www.nice.org.uk/PHI002**

Updating the guideline

This guideline will be updated as needed, and information about the progress of any update will be posted on the NICE website (**www.nice.org.uk/CG067**).

About this booklet

This is a quick reference guide that summarises the recommendations NICE has made to the NHS in 'Lipid modification' (NICE clinical guideline 67).

Who should read this booklet?

The quick reference guide is for doctors, nurses and other staff who care for people with or at higher risk of cardiovascular disease.

Who wrote the guideline?

The guideline was developed by the National Collaborating Centre for Primary Care, which is based at the Royal College of General Practitioners. The Collaborating Centre worked with a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

For more information on how NICE clinical guidelines are developed, go to **www.nice.org.uk**

Where can I get more information about the guideline?

The NICE website has the recommendations in full, reviews of the evidence they are based on, a summary of the guideline for patients and carers, and tools to support implementation (see page 13 for more details).

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