



**National Institute for
Clinical Excellence**

**National Institute for
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Management of type 2 diabetes

*Management of blood pressure
and blood lipids*

Clinical Guideline H

Management of type 2 diabetes

Management of blood pressure and blood lipids

Issue date: October 2002

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Ordering Information

Copies of this guideline can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting ref. N0167. A patient version of this document, *Managing blood pressure and blood lipid levels*, can also be obtained by quoting ref. N0168 for an English version and N0169 for an English/Welsh version.

This document has been circulated to the following:

- PCT Chief Executives
- NHS Trust Chief Executives in England and Wales
- Local Health Group General Managers
- Medical and Nursing Directors in England and Wales
- GPs in England and Wales
- Consultant endocrinologists and diabetologists in England and Wales
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- Medical Director & Head of NHS Quality – Welsh Assembly Government
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- Representative bodies for health services, professional organisations and statutory bodies, Royal Colleges

This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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This guideline is a part of the Inherited Clinical Guidelines work programme. It was commissioned by the Department of Health before the Institute was formed in April 1999. It has followed closely the development brief that was agreed at the time of commissioning. The developers have worked with the Institute to ensure, in the time available, that the guideline has been subjected to validation and to consultation with stakeholders. However, it has not been possible to subject it to the full guideline development process that the Institute has now adopted.

1. Evidence

1.1 Evidence levels

The definitions of the type of evidence used in this guideline (Table 1) originate from the US Agency for Health Care Policy and Research.

Table 1 Levels of evidence

Level	Type of evidence
Ia	evidence from meta-analysis of randomised controlled trials
Ib	evidence from at least one randomised controlled trial
IIa	evidence from at least one controlled study without randomisation
IIb	evidence from at least one other type of quasi-experimental study
III	evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies
IV	evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Adapted from Agency for Health Care Policy and Research (1992) *Acute Pain Management: Operative or Medical Procedures and Trauma*. Rockville, MD, USA: Agency for Health Care Policy and Research/US Department of Health and Human Services, Public Health Service.

1.2 Derivation and grading of recommendations

The grading scheme used in this guideline (Table 2) is from Eccles M et al. (1998).

Table 2 Grading of recommendations

Grade	Evidence (see Table 1)
A	directly based on category I evidence
B	directly based on category II evidence, or extrapolated recommendation from category I evidence
C	directly based on category III evidence, or extrapolated recommendation from category I or II evidence
D	directly based on category IV evidence, or extrapolated recommendation from category I, II or III evidence

Eccles M et al. (1998) North of England Evidence Based Guideline Development Project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure. *British Medical Journal* 316:1369.

2. Background

2.1 This guideline

This guideline is one of a series on type 2 diabetes; others in the series cover:

- screening for retinopathy and early management of the condition (guidance was issued by the National Institute for Clinical Excellence in February 2002)
- the prevention and early management of renal disease (guidance was issued by the National Institute for Clinical Excellence in February 2002)
- the management of blood glucose (guidance was issued by the National Institute for Clinical Excellence in September 2002)
- foot care (the original guideline, published by the Royal College of General Practitioners in April 2000, will be updated by the National Institute for Clinical Excellence in 2003/04).

2.2 Diabetes

Type 2 diabetes is affecting increasing numbers of people in the UK and the burden of serious complications and their sequelae can be considerable both for the individual concerned and the health service in general. Many aspects of these complications can be limited, even prevented in some instances, with good management of the condition, including monitoring blood lipid levels and blood pressure and providing appropriate therapy. The aim of the guidelines in this series is to provide guidance about managing type 2 diabetes for people with diabetes and the whole range of clinical staff who work in primary and secondary care, in order to maximise the potential for reducing complications and improving the quality of life of people with the disease.

2.3 Cardiovascular risk

Cardiovascular disease is the major cause of morbidity and mortality in people with diabetes, and coronary heart disease is the most common cause of death among people with type 2 diabetes. Many people with type 2 diabetes have an increased coronary event risk even if they do not have manifest cardiovascular disease.

Hypertension is associated with an increased risk of many complications of diabetes, including cardiovascular disease, and the findings from the United Kingdom Prospective Diabetes Study (UKPDS) indicate that any reduction in a person's average blood pressure reduces the risk of complications.

Raised blood lipid levels are known to be a risk factor for coronary heart disease and studies have shown that lipid-regulating drugs can reduce the risk of coronary events. Management of blood lipid levels can contribute to the reduction in cardiovascular risk in people with type 2 diabetes.

3. Guidance

3.1 Assessment and management of overall cardiovascular disease risk for all people with type 2 diabetes

- At diagnosis, take a full clinical history, including any history of cardiovascular disease. **D**
- Arrange recall and at least annual review for all people with type 2 diabetes. **D**
- Estimate coronary heart disease risk at least annually for all people without manifest cardiovascular disease. **C**
- Use risk assessment charts (such as the Joint Societies Charts in the *British National Formulary*) to estimate 10-year coronary event risk. **D** (See Box 1)
- Classify people with manifest cardiovascular disease as being at higher 10-year coronary event risk. **C** (See Box 1)
- Maintain tight blood glucose control (haemoglobin A_{1c} below 6.5% to 7.5% according to an individual's target and level of coronary event risk) and manage according to the guideline in this series (see Section 2.1). **A**
- Screen for renal disease and manage according to the renal guideline in this series (see Section 2.1). **B**
- Measure blood pressure and manage according to Section 3.2. **B**
- Measure lipid profile and manage according to Section 3.3. **B**
- Review and discuss other modifiable risk factors, particularly smoking. **B**
- Offer smoking cessation advice where appropriate. **C**
- Offer lifestyle management advice. **C** (For further details of the evidence, see the blood glucose management guideline in this series.)
- For individuals who are overweight or obese, encourage weight loss and increased physical activity. **A** (For further details of the evidence, see the blood glucose management guideline in this series – see Section 2.1.)

Box 1 10-year coronary event risk

For the purposes of this guideline higher and lower 10-year coronary event risk are defined as follows.

A person at **higher risk** is one:

- who has manifest cardiovascular disease (a history or symptoms of coronary heart disease, stroke or peripheral vascular disease) **or**
- whose 10-year coronary event risk is assessed as above 15%, taking into account the known limitations of the risk assessment charts (see *British National Formulary* 2002; 44).

A person at **lower risk** is one:

- who does not have manifest cardiovascular disease **and**
- whose 10-year coronary event risk is 15% or below, taking into account the known limitations of the risk assessment charts (see *British National Formulary* 2002; 44).

3.2 Management of blood pressure

3.2.1 Assessing blood pressure

- Measure blood pressure according to standard practice. **D***

*The accepted methods for the measurement of blood pressure are set out in the guidelines of the British Hypertension Society – see Ramsay L, et al. (1999) Guidelines for management of hypertension: report of the third working party of the British Hypertension Society. *Journal of Human Hypertension*; 13: 569–592.

3.2.2 Management for people with blood pressure below 140/80 mmHg

- Monitor blood pressure on an annual basis. **D**
- If blood pressure is raised, at or above 140/80 mmHg, take two further readings over a period of 2 months, or sooner if clinical circumstances dictate. **D**
- If blood pressure is subsequently persistently raised, at or above 140/80 mmHg, manage according to the recommendations in Section 3.2.3. **B**

3.2.3 Management for people with blood pressure of 140/80 mmHg and above

For all people with blood pressure of 140/80 mmHg and above:

- offer lifestyle management advice to minimise subsequent blood pressure increase, **D**
- use an average of three blood pressure recordings to determine baseline blood pressure measurement, **D**
- monitor blood pressure every 6 months, or more frequently according to an individual's requirements. **D**

Table 3 shows the recommendations for pharmacological management for people with raised blood pressure (140/80 mmHg and above) with or without a higher 10-year coronary event risk or microalbuminuria/proteinuria.

Note

Prescribers are advised to consult the *British National Formulary* for precautions and contraindications before initiating the drug treatment referred to in this guidance. Full information on individual drugs is available in the Summary of Product Characteristics.

Table 3 Recommendations for pharmacological management of raised blood pressure in people with type 2 diabetes

Blood pressure	10-year coronary event risk (see Box 1 page 5)	Concomitant micro-albuminuria or proteinuria	Recommendations
1 $\geq 140/80$ mmHg and $< 160/100$ mmHg	Lower (no history of CVD and 10-year coronary event risk $\leq 15\%$)	No	<ul style="list-style-type: none"> • Monitor blood pressure every 6 months or more frequently if necessary. D • If 10-year coronary event risk is subsequently found to have increased to the higher risk level, treat according to (2) below. C • If blood pressure rises to a level persistently equal to or greater than 160/100 mmHg, treat according to (3) below. C
2 $\geq 140/80$ mmHg and $< 160/100$ mmHg	Higher (history of CVD or 10-year coronary event risk $> 15\%$)	No	<ul style="list-style-type: none"> • Offer pharmacological treatment to reduce blood pressure. B (See Box 2) • Aim for a target blood pressure below 140/80 mmHg. B
3 $\geq 160/100$ mmHg	Higher or lower	No	<ul style="list-style-type: none"> • Offer pharmacological treatment to reduce blood pressure. B (See Box 2) • Aim for a target blood pressure below 140/80 mmHg. B
4* $\geq 140/80$ mmHg	Higher or lower	Yes	<ul style="list-style-type: none"> • Offer pharmacological treatment to achieve a target blood pressure equal to or less than 135/75 mmHg. B • Use ACE inhibitors as the class of first choice to treat people with microalbuminuria or proteinuria. A (See Box 2) • Where ACE inhibitors are unsuitable or are contraindicated in people with microalbuminuria or proteinuria, then angiotensin II receptor antagonists may be considered as alternative first-line therapy. B (See Box 2) • Drug classes that may be used in combination therapy with ACE inhibitors or angiotensin II receptor antagonists include beta blockers, long-acting calcium channel blockers or thiazide diuretics. B
* The recommendations in (4) are from the guideline on renal care in this series (see Section 2.1)			
See Section 3.4 for recommendations on anti-platelet therapy			

Box 2 Recommendations on choice of pharmacological therapy to reduce blood pressure

- Use ACE inhibitors (see Box 3), angiotensin II receptor antagonists, beta blockers or thiazide diuretics as first-line treatments in people who do not have microalbuminuria. **A**
- Long-acting dihydropyridine and non-dihydropyridine calcium-channel blockers have an important role in treating blood pressure, but on current evidence should be prescribed as second-line treatment or as part of combination therapy. **B**
- Do not prescribe short-acting calcium-channel blockers. **D**
- Anticipate that combination therapy with any or all of these drug classes will be required to meet treatment targets in the majority of people. **C**
- Assess the response to treatment frequently (every 3 to 6 months when stabilised, more frequently when titrating treatment). **D**

Box 3 Starting ACE inhibitor therapy for patients*:

- caution in patients with peripheral vascular disease/renovascular disease
- caution in patients with raised serum creatinine.

In all patients, measure serum creatinine and electrolytes 1 week after:

- initiating ACE inhibitor therapy
- each increase in dose.

* Some ACE inhibitors are not licensed for use at the blood pressure levels at which they are recommended in this guideline. See cautions in the *British National Formulary*.

3.3 Management of blood lipids

3.3.1 Assessing lipid profile at diagnosis

- When type 2 diabetes is diagnosed, measure total cholesterol (TC), low-density lipoprotein (LDL-C), high-density lipoprotein (HDL-C) and triglycerides (TG). **C**
- Use fasting measurement of lipids if feasible. **C**

3.3.2 For people with normal lipid profile

For people with total cholesterol less than 5.0 mmol/litre (or LDL-C less than 3.0 mmol/litre) **and** triglycerides less than 2.3 mmol/litre:

- annually measure total cholesterol and HDL-C and – if fasting measurements are feasible – LDL-C and triglycerides, **D**
- no pharmacological treatment is recommended. **B**

3.3.3 Initial assessment and general management for people with an adverse lipid profile

Initial assessment should be as follows for people with total cholesterol 5.0 mmol/litre or higher (or LDL-C 3.0 mmol/litre or higher) **or** triglycerides 2.3 mmol/litre or higher.

- On first assessment, to identify people with an adverse lipid profile secondary to conditions other than diabetes mellitus:
 - ask about alcohol consumption and manage accordingly, **C**
 - check thyroid function tests to exclude hypothyroidism, **C**
 - check liver function tests to exclude liver disease, **C**
 - check serum creatinine and urine protein to exclude renal disease. **C**
(This is a standard part of assessment, together with testing for urine protein – see the renal disease guideline in this series.)

General management for people with an adverse lipid profile should be as follows.

- Optimise glycaemic control (preferably to haemoglobin A_{1c} below 6.5%). **C**
- Offer intensive advice on diet and physical activity to all patients and advice on weight loss to those who are overweight or obese. **B**
- Before starting any pharmacological treatment for abnormal lipid profile, measure fasting levels of total cholesterol, HDL-C, LDL-C and triglycerides as a baseline. **C**
- If the lipid profile remains abnormal, consider pharmacological therapy. **D**
(See Section 3.3.4)
- Monitoring of lipids after treatment starts should preferably be done with fasting blood samples to measure total cholesterol, HDL-C, LDL-C and triglycerides, but when it is not feasible to obtain fasting samples it is acceptable to monitor using total cholesterol and HDL-C levels in non-fasting samples. **D**

See Section 3.3.4 for recommendations for pharmacological therapy for people with an adverse lipid profile.

3.3.4 Recommendations for pharmacological therapy for people with an adverse lipid profile

Table 4 shows the recommendations for pharmacological management for people with an adverse lipid profile with or without a higher 10-year coronary event risk.

There is evidence from clinical studies of benefits of pharmacological intervention for patients aged up to 69 years for primary prevention and up to 75 years for secondary prevention. However, these guidelines do not recommend age-related restrictions on the use of pharmacological therapy.

Table 4 Recommendations for pharmacological management of adverse blood lipid profiles in people with type 2 diabetes

	Blood lipid profile at start of therapy	10-year coronary event risk (see Box 1, page 5)	Recommendations
1	TC ≥ 5.0 mmol/litre (or LDL-C ≥ 3.0 mmol/litre) or TG ≥ 2.3 mmol/litre and < 10 mmol/litre	Lower (no history of CVD and 10-year coronary event risk ≤ 15%)	<ul style="list-style-type: none"> • Discuss CHD risk with the patient, and consider whether treatment is appropriate at the time when type 2 diabetes is diagnosed. D • Consider offering drug therapy at higher levels of cholesterol or triglyceride. D • Following a decision to start treatment: <ul style="list-style-type: none"> - offer a statin, B - assess the effect of statin therapy within 3 months and titrate the dose if required, D - monitor the effect of therapy annually. D • If a decision is made not to start pharmacological therapy, monitor lipid profile and cardiovascular risk annually, to consider the need for therapy. D
2	TC ≥ 5.0 mmol/litre (or LDL-C ≥ 3.0 mmol/litre) or TG ≥ 2.3 mmol/litre and <10 mmol/litre	Higher: 10-year coronary event risk >15% but no history of CVD	<p>Primary prevention</p> <ul style="list-style-type: none"> • Offer a statin. B • Assess the effect of statin therapy within 3 months and titrate the dose if required. D • Monitor the effect of therapy annually. D
3	TC ≥ 5.0 mmol/litre (or LDL-C ≥ 3.0 mmol/litre) or TG ≥ 2.3 mmol/litre and < 10 mmol/litre	Higher: manifest CVD	<p>Secondary prevention</p> <ul style="list-style-type: none"> • Offer a statin. B • Assess the effect of statin therapy within 3 months and titrate the dose if required. D • Consider adding a fibrate after 6 months if triglyceride remains ≥ 2.3 mmol/litre. D • Ensure there is no evidence of drug interaction between the proposed choices of fibrate and statin preparation. C* • Monitor the effect of therapy annually. D
4	TC < 5.0 mmol/litre (or LDL-C < 3.0 mmol/litre) and TG ≥ 2.3 mmol/litre and <10 mmol/litre	Higher: manifest CVD	<p>Secondary prevention</p> <ul style="list-style-type: none"> • Offer a statin B or a fibrate. C • Assess the effect of statin therapy within 3 months and titrate the dose if required. D • Monitor the effect of therapy annually. D
5	Fasting TG ≥ 10 mmol/litre	Higher or lower	<ul style="list-style-type: none"> • Offer fibrate therapy and consider referral to a diabetes or lipid clinic. D

CHD, coronary heart disease; CVD, cardiovascular disease; LDL-C, low-density lipoprotein; TC, total cholesterol; TG, triglycerides

* Use of a statin and fibrate together increases the likelihood of adverse effects (see *British National Formulary* 2002; 44)

Target thresholds for pharmacological treatment: the target threshold for cholesterol should be, at a minimum, to reduce total cholesterol to below 5.0 mmol/litre or by 20–25%, whichever is lower **or** to reduce LDL-C to below 3.0 mmol/litre or by 30%, whichever is lower, although benefit increases with further reduction.

3.4 Anti-platelet therapy for people with higher 10-year coronary risk

The recommendations for anti-platelet therapy for people with higher 10-year coronary risk, regardless of blood pressure or blood lipid levels, are as follows.

- Secondary prevention
 - For people with manifest cardiovascular disease, offer 75 mg aspirin daily. **B**
- Primary prevention
 - For people with a 10-year coronary risk of greater than 15%, offer 75 mg aspirin daily. **A**
 - Before starting aspirin therapy for this group of people, reduce systolic blood pressure to 145 mmHg or below and maintain while taking aspirin for primary prevention. **B**
- Prescribe aspirin according to the recognised cautions and contraindications given in the *British National Formulary*. **D**

4 Full guideline

- 4.1 These recommendations are derived from the guidelines entitled *Clinical Guidelines for Type 2 Diabetes: Blood Pressure Management* and *Clinical Guidelines for Type 2 Diabetes: Lipids Management* commissioned from a collaboration between the Royal College of General Practitioners, the Royal College of Physicians, the Royal College of Nursing and Diabetes UK. *Clinical Guidelines for Type 2 Diabetes: Blood Pressure Management* and *Clinical Guidelines for Type 2 Diabetes: Lipids Management* are available on the NICE website, www.nice.org.uk, and on the National Electronic Library for Health's website, www.nelh.nhs.uk. The guideline developers are listed in Appendix A.
- 4.2 These guidelines were commissioned by the Department of Health before the National Institute for Clinical Excellence (NICE or 'the Institute') was formed in April 1999. The developers have followed closely the development brief that was agreed at the time of commissioning. The developers have worked with the Institute to ensure, in the time available, that the guidelines have been the subject of validation and consultation with stakeholders. However, it has not been possible to subject them to the full guideline development process that the Institute has now adopted.

5 Scope

- 5.1 This part of the national guideline for type 2 diabetes is aimed primarily at all healthcare professionals involved in the measurement and management of blood pressure and blood lipid levels in people with diagnosed type 2 diabetes in primary and secondary care, irrespective of location. Depending on the type, stage and severity of the clinical problem, the guideline may also be valuable to those who work in diabetes care in the tertiary sector.
- 5.2 This guideline has been developed to advise on the care of adults with type 2 diabetes, but it may also help inform the care of those with type 1 diabetes.
- 5.3 The scope of the guideline covers:
- definitions and epidemiology of acceptable and unacceptable blood pressure levels in people with type 2 diabetes

- definitions and epidemiology of acceptable and unacceptable levels of lipids (total cholesterol, LDL-C, HDL-C and triglycerides) in people with type 2 diabetes
- the beneficial effects of reducing lipid levels and blood pressure
- the measurement of blood lipids and blood pressure
- pharmacological interventions
- lifestyle interventions.

5.4 Matters outside the scope of the guideline include the following:

- the care of children
- the identification of undiagnosed diabetes
- the general management of people with type 2 diabetes (other than aspects that relate to the management of dyslipidaemia and raised blood pressure)
- questions about the organisation and delivery of population-based or service-wide responses to the needs of people with diabetes.

6 Implementation in the NHS

This guideline is published as part of a range of clinical resources to support the Diabetes National Service Framework. Its implementation should take place as part of the health improvement plans for each local health community.

- 6.1 Local health communities will need to review existing service provision against this guidance. This review should result in a strategy that identifies the resources required to implement fully the guidance set out in Section 3, the people and processes involved and the timeline over which full implementation is envisaged.
- 6.2 Relevant local clinical guidelines and protocols should be reviewed in the light of this guidance and revised accordingly.
- 6.3 To enable clinicians to audit their own compliance with this guideline it is recommended that, if not already in place, management plans are recorded for each patient. This information should be incorporated into local clinical audit data recording systems and consideration given (if not already in place) to the establishment of appropriate categories in electronic record systems.
- 6.4 Prospective clinical audit programmes should record the proportion of patients whose care adheres to the guidance. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's formal clinical governance arrangements and where they are linked to specific postgraduate activities.
- 6.5 Selected key audit review criteria are shown in Box 4.

Box 4 Selected key audit criteria

Both lipids and blood pressure

- The percentage of patients without manifest cardiovascular disease who have had their coronary heart disease risk estimated.
- The percentage of patients who have had their modifiable coronary heart disease factors reviewed.
- The percentage of patients with higher coronary heart disease risk who have been offered anti-platelet therapy (aspirin).

Blood pressure management

- The percentage of patients who have had their blood pressure measured in the previous 12 months.
- The percentage of patients with blood pressure 140/80 mmHg or above who have had their blood pressure measured in the previous 6 months or more frequently if required by their condition.
- The percentage of patients with blood pressure 160/100 mmHg or above who have been offered pharmacological therapy.
- For patients with blood pressure 140/80 mmHg or above **and either** manifest cardiovascular disease (history of or symptoms of coronary heart disease, stroke or peripheral vascular disease) **or** a 10-year coronary event risk greater than 15%:
 - the percentage who have been offered pharmacological therapy.
- For those patients receiving pharmacological therapy and who do not have microalbuminuria or proteinuria, the percentage of patients whose blood pressure is below 140/80 mmHg.
- For those patients receiving pharmacological therapy and who have microalbuminuria or proteinuria, the percentage of patients whose blood pressure is equal to or below 135/75 mmHg.

Blood lipids management

- The percentage of patients with normal lipid levels and no history of cardiovascular disease who have had the following measured in the previous 12 months (fasting if possible):
 - total cholesterol
 - LDL-C
 - HDL-C
 - triglycerides.
- For patients who do not have manifest cardiovascular disease, whose 10-year risk of a coronary event is more than 15% and where total cholesterol is 5.0 mmol/litre or higher or LDL-C is 3.0 mmol/litre or higher **or** triglycerides level is equal to or greater than 2.3 mmol/litre and less than 10 mmol/litre:
 - the percentage who have been offered a statin.
- For patients with manifest cardiovascular disease (history of or symptoms of coronary heart disease, stroke or peripheral vascular disease) whose total cholesterol is equal to or greater than 5.0 mmol/litre or LDL-C is equal to or greater than 3.0 mmol/litre **or** triglycerides level is equal to or greater than 2.3 mmol/litre and less than 10 mmol/litre:
 - the percentage who have been offered a statin.
- For patients with manifest cardiovascular disease (history of or symptoms of coronary heart disease, stroke or peripheral vascular disease) whose total cholesterol is less than 5.0 mmol/litre or LDL-C is less than 3.0 mmol/litre **and** whose triglycerides level is equal to or greater than 2.3 mmol/litre and less than 10 mmol/litre:
 - the percentage who have been offered a statin or a fibrate.
- The percentage of patients whose fasting triglycerides level is 10 mmol/litre or more who have been offered fibrate therapy.

7 Future research recommendations

In the course of developing the recommendations, the guideline developers considered that research in the following areas would be of value.

7.1 Blood pressure management

- Is there an optimal screening interval for blood pressure in people with type 2 diabetes and if so, what is it?
- Does the screening interval vary by group (for example, severity of diabetes, age, life expectancy, ethnicity, current treatment)? Does it differ for screening versus monitoring?
- Are there any advantages for automated (including 24-hour ambulatory patient self-testing) over standard blood pressure measurement?
- What thresholds versus risks should be used for deciding on therapy?
- Do adequate UK data exist to define risk based on ethnic groups, age, sex, smoking habit, and other cardiovascular risks (for example, left ventricular hypertrophy)?

7.2 Lipids management

- How often should lipid profile be measured in patients on lipid-modifying treatment?
- Should any biochemical monitoring for adverse effects of lipid-modifying treatment be undertaken?
- Should HDL-C be a criterion for statin or fibrate treatment?
- Do fibrates decrease mortality and coronary events in patients with diabetes and dyslipidaemia? If they do, are they effective in patients without a history of cardiovascular disease?
- In which patients is combined statin and fibrate therapy effective? What are the short- and long-term adverse effects of combination therapy?
- What behavioural interventions in patients with type 2 diabetes can reduce coronary heart disease risk?
- How can coronary heart disease risk be predicted more accurately in people with type 2 diabetes in the UK, taking into account recently identified risk factors (e.g. microalbuminuria) and differences in risk between ethnic groups?

8.1 Guidelines

This guideline is one of a series of guidelines on type 2 diabetes. Guidelines covering the screening for and early management of retinopathy and the prevention and early management of renal disease were published in February 2002. A guideline on the management of blood glucose was published in September 2002. A guideline on foot care was published by the Royal College of General Practitioners in April 2000; this will be updated by the National Institute for Clinical Excellence in 2003/04.

- Hutchinson A, McIntosh A, Feder G et al. (April 2000) *Clinical Guidelines and Evidence Review for Type 2 Diabetes: Prevention and Management of Foot Problems*. London: Royal College of General Practitioners. Available from www.rcgp.org.uk.
- National Institute for Clinical Excellence (February 2002) Management of type 2 diabetes: retinopathy – early management and screening. *NICE Inherited Clinical Guideline E*. London: NICE. (Ref. no. N0058.) Available from www.nice.org.uk.
- National Institute for Clinical Excellence (February 2002) Management of type 2 diabetes: renal disease – prevention and early management. *NICE Inherited Clinical Guideline F*. London: NICE. (Ref. no. N0061.) Available from www.nice.org.uk.
- National Institute for Clinical Excellence (September 2002) Managing blood glucose levels. *NICE Inherited Clinical Guideline G*. London: NICE. (Ref. no. N0128.) Available from www.nice.org.uk.

Guidelines on the management of type 1 diabetes are being developed by the Institute and will be available in late 2003/early 2004.

8.2 Technology appraisals

The Institute has published the following technology appraisals that may be relevant to the treatment of a person with type 2 diabetes. The guidance is available from the NICE website, www.nice.org.uk, and paper copies can be ordered from the NHS Response Line, phone 08701 555 455.

- National Institute for Clinical Excellence (August 2000) Guidance on the use of rosiglitazone for type 2 diabetes mellitus. *Technology Appraisal Guidance No. 9*. London: NICE. (Ref. no. 22181.*)
- National Institute for Clinical Excellence (March 2001) Guidance on the use of pioglitazone for type 2 diabetes mellitus. *Technology Appraisal Guidance No. 21*. London: NICE. (Ref. no. 23357.*)
- National Institute for Clinical Excellence (March 2001) Guidance on the use of orlistat for the treatment of obesity in adults. *Technology Appraisal Guidance No. 22*. London: NICE. (Ref. no. 23358.)
- National Institute for Clinical Excellence (October 2001) Guidance on the use of sibutramine for obesity in adults. *Technology Appraisal Guidance No. 31*. London: NICE. (Ref. no. N0033.)
- National Institute for Clinical Excellence (March 2002) Guidance on the use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. *Technology Appraisal Guidance No. 38*. London: NICE. (Ref. no. N0082.)

- National Institute for Clinical Excellence (July 2002) Guidance on the use of surgery to aid weight reduction for people with morbid obesity. *Technology Appraisal Guidance* No. 46. London: NICE. (Ref. no. N0119.)

*Currently under review (see below).

The following technology appraisals are part of the Institute's ongoing work programme.

- Long-acting insulin analogues for diabetes: due to be issued December 2002.
- The clinical effectiveness and cost effectiveness of insulin pump therapy: due to be issued February 2003.
- Glitazones in the treatment of type 2 diabetes (review of current guidance no. 9 and no. 21): due to be issued March 2003.
- Patient education models for diabetes: due to be issued March 2003.

9. Review date

The Institute's Guidance Executive will consider changes in the evidence base for this guideline in October 2005. At that time a decision will be made as to the need for and the extent of any update.

APPENDIX A

Guideline Development Groups and Recommendations Panel

Guideline Development Groups

The Guideline Development Groups are multiprofessional teams brought together on a project basis to consider the evidence of clinical and cost effectiveness and develop the guidelines. The members of the Blood Pressure Management Guideline Development Group and the Lipids Management Guideline Development Group are listed below.

Membership of the Blood Pressure Management Guideline Development Group

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Recommendations Panel

The production of the guidelines for type 2 diabetes is overseen by a Recommendations Panel, which has ultimate responsibility for ensuring that a valid, relevant, rigorous national clinical guideline is produced as the result of the guideline development process. The Panel is also responsible for the final grading of recommendations. Membership details of the Recommendations Panel are listed in the full guideline.

APPENDIX B

Guidelines Advisory Committee

The Guidelines Advisory Committee (GAC) is a standing committee of the Institute. It has responsibility for agreeing the scope and commissioning brief for clinical guidelines and for monitoring progress and methodological soundness. The GAC considers responses from stakeholders and advises the Institute on the acceptability of the guidelines it has commissioned. The members of the GAC are listed below.

Professor Stephanie A Amiel

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Royal College of Surgeons

Mrs Joyce Cormie

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Assistant Director
Contact a Family

Appendix C

Managing blood pressure and blood lipid levels – a guide for adults with type 2 diabetes, and carers

The patient information in this appendix has been designed to support the production of your own information leaflets. You can download it from our website at www.nice.org.uk where it is available in English and Welsh. If you would like printed copies of the leaflets please ring the NHS Response Line on 0870 1555 455 and quote reference number N0168 for the English patient leaflet and N0169 for the bi-lingual patient leaflet.

About this information

This information:

- is for adults with type 2 diabetes and their relatives and carers
- describes the advice, treatment and care you should receive to control your blood pressure and your blood lipid levels
- is based on national evidence-based clinical guidelines on the management of blood pressure and blood lipid levels for people with type 2 diabetes

About clinical guidelines

Clinical guidelines exist to help healthcare teams and patients make the best decisions about healthcare. They are developed by teams of healthcare professionals (such as doctors, nurses and therapists), lay people and researchers who look at the best evidence about care for a particular condition. (In the remaining sections we talk about ‘doctors and nurses’ rather than ‘healthcare professionals’, as these are the healthcare professionals that most people with type 2 diabetes see on a regular basis; however, in some instances, it may be another healthcare professional, such as a dietitian, who gives the advice or support.)

Guidelines are recommendations for good practice – they’re not intended to be a complete description of a medical condition or disorder. And they are not a substitute for patient preference or clinical judgement. There may be good reasons why your treatment may differ from the recommendations in this booklet.

What is diabetes?

Diabetes mellitus is a common condition in which the amount of glucose (a type of sugar) in the blood is too high because the body is unable to use it properly. Normally, a person’s pancreas (an organ in the body) produces a natural hormone called insulin, which controls the levels of glucose in the blood. Diabetes occurs when the body does not produce enough insulin, or produces insulin but cannot use it properly. There are two types of diabetes.

Type 1 diabetes (also called insulin-dependent diabetes) occurs when there is a severe lack of insulin in the body because most or all of the cells in the pancreas that produce it have been destroyed. This type of diabetes usually appears in people under the age of 40, often in childhood, and is treated by insulin injections and diet.

Type 2 diabetes (also called non-insulin-dependent diabetes) develops when the body can still make some insulin, but not enough for its needs, or when the insulin that is produced does not work properly (known as insulin resistance). This type of diabetes usually appears in people over the age of 40, though it can appear in younger people.

Diabetes can cause a number of problems, which may affect:

- blood glucose (sugar) levels
- blood pressure levels
- the feet
- the eyes (diabetic retinopathy)
- the levels of certain substances in the blood (for example, lipids such as cholesterol)
- the kidneys (kidney problems are sometimes called nephropathy or renal disease).

This information describes the advice, treatment and care that adults with type 2 diabetes should receive to control their blood pressure and blood lipid levels and to help to reduce their risk of developing problems with their heart, blood vessels or blood circulation.

Other patient information from guidelines in the series covers:

- the prevention and management of kidney (renal) problems
- screening for retinopathy and early management of this eye condition
- the management of blood glucose (sugar) levels.

Diabetes-related problems

One of the effects of type 1 and type 2 diabetes is that blood vessels in the body can become damaged. Damage to the small blood vessels can cause problems in the eyes, kidneys and nerves, while damage to the larger blood vessels can cause heart problems (such as heart attack) and stroke. The ‘umbrella’ term for problems affecting the heart, blood vessels or blood circulation is ‘cardiovascular disease’.

Research shows that people with diabetes can reduce the risk of developing these problems by:

- controlling blood pressure, blood glucose and blood lipid levels (your doctor or nurse will advise you on the levels you should be aiming to maintain)
- managing their weight (your doctor or nurse can advise you on an appropriate weight for your height)
- maintaining good levels of physical activity (your doctor or nurse can advise you on appropriate exercise or fitness plans).

You are at increased risk of having complications the longer you have had diabetes and if you:

- have high blood glucose (sugar) levels*
- have high blood pressure levels*
- are older
- have high levels of certain lipids, such as cholesterol*

- are a man (but the other risk factors still apply to women)
- smoke
- have a family history of kidney problems
- are South Asian or African-Caribbean
- have high levels of protein in your urine.

* Levels that are high for you – levels that are considered high for one person may be normal for another.

Cardiovascular disease

Because ‘cardiovascular disease’ (disorders of the heart, blood vessels or blood circulation) is a particular risk for people with diabetes, NICE has made recommendations about:

- how your doctor should estimate how much at risk you are from cardiovascular disease (that is, what are the chances of developing cardiovascular disease, or of existing cardiovascular problems getting worse)
- ways in which your doctor can help to reduce your risk from cardiovascular disease.

And, because raised blood pressure and higher than normal levels of certain lipids (fats) in the blood are known to increase the risk of having cardiovascular disease, NICE has also made recommendations about monitoring and managing blood pressure and blood lipid levels.

Details of these recommendations are given in the sections that follow.

Checking for cardiovascular disease

The NICE recommendations about estimating your level of risk of cardiovascular disease are as follows.

- When you are diagnosed with type 2 diabetes your doctor should find out about any problems you have had with your health in the past. This will include checking whether you have had cardiovascular problems. He or she should check whether you have symptoms of cardiovascular disease now.
- At least once a year you should have a review of your level of risk of cardiovascular problems; this means that the doctor will carry out a number of tests and measurements, including measuring your blood pressure and taking a sample of blood so that the level of blood glucose (sugar) and lipids (fats) in it can be measured in a laboratory; he or she will also weigh you and ask you questions about your lifestyle, including your diet, how much exercise you take, and whether you smoke.
- If you do not have obvious symptoms of cardiovascular disease, at least once a year your doctor should estimate how much at risk you are of having a coronary event, which means the chance of having a heart attack or a first attack of angina some time in the next 10 years. (See the box on page 21 for more information.) He or she should estimate the risk using standard charts that combine information about your blood pressure, levels of certain lipids (fats) in your blood, your age and whether you smoke.
- If you do have obvious symptoms of cardiovascular disease your doctor should consider you to be in the group of people who are at higher risk of having a ‘coronary event’. (See the box on page 21 for more information.)

What is 'higher 10-year coronary event risk'?

For this guideline, a person who is at 'higher 10-year coronary event risk' is considered to be someone:

- who has symptoms of cardiovascular disease (coronary heart disease, stroke or peripheral vascular disease) or has had cardiovascular disease in the past
- or**
- whose 10-year coronary event risk is estimated to be more than 15%, according to standard charts. (Your doctor or nurse will explain what this means.)

What is 'lower 10-year coronary event risk'?

For this guideline, a person who is at 'lower 10-year coronary event risk' is considered to be someone:

- who does not have symptoms of or a history of cardiovascular disease
- and**
- whose 10-year coronary event risk is estimated to be 15% or less, according to standard charts.

Reducing the risk of cardiovascular disease

NICE has also made some general recommendations about ways in which your doctor can help you to reduce the risks of problems with cardiovascular disease. These recommendations are that the doctor should:

- help you to control your blood glucose levels using the methods described in a separate guideline in this series
- help you to control your blood pressure according to the recommendations in this NICE guideline (these are described later)
- help you to control your blood lipid levels according to the recommendations in this NICE guideline (these are described later)
- check how your kidneys are working and offer you treatment according to the recommendations in a separate guideline in this series
- discuss ways in which you could help to reduce your risks of problems from cardiovascular disease – for example, by losing weight, taking more exercise, changing what you eat, or giving up smoking. (If you are a smoker, your doctor should offer you advice on ways to give up.)

Managing blood pressure

'Blood pressure' is the force at which your heart pumps blood through your arteries. High blood pressure (which is also known as 'hypertension') increases the risk of diabetes-related problems, including cardiovascular disease, so it's important to monitor and manage your blood pressure.

Measuring blood pressure

If you have type 2 diabetes, you should expect to have your blood pressure checked when you are diagnosed and then at least once a year. Blood pressure is measured in millimetres of mercury (abbreviated to 'mmHg') and blood pressure readings show the pressure when the heart contracts and pushes blood into the arteries (this is known as the systolic blood pressure) and the pressure when the heart relaxes (this is known as the diastolic blood pressure). So, a reading of '140/80 mmHg' means that the systolic blood pressure is 140 millimetres of mercury and the diastolic blood pressure is 80 millimetres of mercury.

NICE recommends that:

- your doctor or nurse should measure your blood pressure according to standard methods that are described in guidelines from the British Hypertension Society.

If your blood pressure is below 140/80 mmHg

NICE recommends that:

- you should have your blood pressure checked once a year
- if the check finds that your blood pressure is 140/80 mmHg or higher, you should have it checked again twice over the next 2 months, or sooner if your doctor thinks it necessary – these extra checks are made because sometimes blood pressure is raised for only a short time and then returns to normal
- if your blood pressure continues to be 140/80 mmHg or higher, your doctor should follow the recommendations in this guideline, which are described in the following section.

If your blood pressure is 140/80 mmHg or higher

Some people can reduce their blood pressure or prevent further rises by making changes to their lifestyle (for example, by taking particular care over what they eat, losing some weight, taking more exercise or giving up smoking). Others may need to take one or more medicines. Whichever course of action you and your doctor or nurse decide on, it's important that you understand why you are taking that approach and the benefits that might occur as a result. Your doctor or nurse should discuss how he or she can best help you to understand what is happening in your body and how you can try to control your blood pressure.

For people who have blood pressure 140/80 mmHg or higher, NICE recommends that your doctor or nurse should:

- offer advice on how you could change your lifestyle to help prevent further rises in your blood pressure
- take three blood pressure readings so that the average can be used as a baseline against which later measurements can be compared
- check your blood pressure at least once every 6 months.

Using medicines to help lower blood pressure

Table 1 summarises the NICE recommendations about when medicines should be used to help lower blood pressure. Whether treatment with a medicine is recommended depends on how high a person's blood pressure is and whether or not they have other medical problems. These other problems include whether they have a higher 'coronary event risk'. What 'coronary event risk' means according to this NICE guideline is explained in the box on page 21.

Table 1 NICE recommendations about when to use medicines to help lower blood pressure		
1	If someone has: blood pressure equal to or greater than 140/80 mmHg and less than 160/100 mmHg	and a lower 10-year coronary event risk
		Medicine is not recommended unless: <ul style="list-style-type: none"> coronary event risk increases to the higher level, or several measurements show blood pressure increases to 160 mmHg or above. (If either of these occurs, the treatment should be according to recommendations 2 or 3 below.)
2	If someone has: blood pressure equal to or greater than 140/80 mmHg and less than 160/100 mmHg	and a higher 10-year coronary event risk
		NICE recommends that the doctor should: <ul style="list-style-type: none"> offer treatment with medicine* to help to reduce blood pressure aim for treatment to reduce blood pressure to below 140/80 mmHg.
3	If someone has: blood pressure of 160/100 mmHg or higher	–
		NICE recommends that the doctor should: <ul style="list-style-type: none"> offer treatment with medicine* to help to reduce blood pressure aim for treatment to reduce blood pressure to below 140/80 mmHg.
4	If someone has: blood pressure of 140/80 mmHg or higher	and has albumin or protein in their urine (these are signs of kidney problems)
		NICE recommends that the doctor should: <ul style="list-style-type: none"> offer treatment with medicine* with the aim of lowering blood pressure to 135/75 mmHg or lower.
*See the next section for the recommendations on the types of medicines to use		

The medicines available to help lower blood pressure

Several types of medicine are used to help lower blood pressure.

ACE inhibitors affect the way in which enzymes work in the blood so that blood vessels stay as wide open as possible. Blood flows more freely and this reduces the workload on the heart.

Angiotensin II receptor antagonists work in a similar way to ACE inhibitors.

Beta blockers reduce the force of the heart beat, which reduces the force at which blood is pumped around the body. They reduce the workload on the heart.

Thiazide diuretics act on the kidneys to increase the amount of urine passed and reduce the amount of fluid in the body. The workload on the heart is reduced because less blood has to be pumped around the body.

Calcium channel blockers act to relax the muscles in the walls of the blood vessels so that the blood vessels are kept as wide open as possible. Some calcium channel blockers are made so that their effects do not wear off quickly: these are called long-acting calcium channel blockers.

A note on proprietary names

Like most of the items on a supermarket shelf, medicines can have two names – the brand name, which can also be referred to as the proprietary name, and the general, or non-proprietary, name. On a medicine's packaging, the brand name may be printed in large coloured type, while the non-proprietary name is smaller and in black type. In this information, we refer to medicines by their non-proprietary names only; if you're not sure what your medicine's non-proprietary name is, ask your pharmacist or doctor.

If you are prescribed a medicine to help lower your blood pressure, it's important that you take it according to the directions of your doctor, nurse or pharmacist. You'll have your blood pressure taken again after you've been taking the medicine for a while so you and your doctor or nurse can see if the medicine is bringing your blood pressure down.

Most people with type 2 diabetes need more than one medicine to control blood pressure. Using more than one medicine is called 'combination therapy'. Some medicines aren't suitable for use by themselves and so they can only be used in combination with another medicine. Others aren't suitable for combining with other medicines. Your doctor or nurse can give you more information about this.

The NICE recommendations on the use of the different types of medicine to help lower blood pressure are shown in the box on page 25.

NICE recommendations on the choice of medicine to reduce blood pressure

- The doctor should be aware that most people will need combination therapy to control blood pressure adequately.
- The doctor or nurse should assess a person's response to treatment every 3 to 6 months. But someone who is trying different doses of medicine to find out what works best needs to have their blood pressure measured more frequently than this.

For people who have raised blood pressure but don't have kidney problems

- First choice of medicine: ACE inhibitors*, angiotensin II receptor antagonists, beta blockers or thiazide diuretics.
- Long-acting calcium channel blockers should not be the first choice of treatment, but they may be used if the first choices of treatment have not worked, or as part of combination therapy. Short-acting calcium channel blockers should not be used.

For people who have raised blood pressure and who have kidney problems indicated by high levels of albumin or protein in their urine

- First choice of medicine: ACE inhibitors*. If they are unsuitable, angiotensin II receptor antagonists may be an alternative.
- Long-acting calcium channel blockers should not be the first choice of treatment, but they may be used if the first choices of treatment have not worked, or as part of combination therapy. Short-acting calcium channel blockers should not be used.
- If combination therapy is needed, ACE inhibitors* or angiotensin II receptor antagonists can be combined with other medicines including beta blockers, long-acting calcium channel blockers, or thiazide diuretics.

*ACE inhibitors should be prescribed with caution for people who have some kinds of kidney disease or peripheral vascular disease (narrowing of the blood vessels in the legs or arms).

Everyone who takes an ACE inhibitor should have a blood sample taken after 1 week's treatment or 1 week after any change in dose. The sample is sent to a laboratory so that certain substances in the blood can be measured to find out how well the kidneys are working.

The doctor should note that some ACE inhibitors are not licensed for use at some blood pressure levels dealt with in this guideline. He or she should check the cautions for use of ACE inhibitors in the *British National Formulary* (a book that gives key information about prescribing medicines).

There may be medical reasons why you shouldn't take a certain sort of medicine. Your doctor should discuss the options for treatment with you and explain the effects and side effects a medicine may have.

Managing blood lipid levels

High levels of some lipids (fats) in the blood are known to increase the risk of heart problems and so to help prevent these problems, it is important to monitor and manage your blood lipid (fat) levels.

Measuring blood lipid levels

If you have type 2 diabetes, you should expect to have your blood lipid levels checked when you are diagnosed and then at least once a year. A sample of blood will be taken and sent to the laboratory where the amounts of different fats and 'lipoproteins' will be measured. (Lipoproteins are made up of a mixture of lipid and protein; some carry cholesterol around the body.)

The most accurate measurements can be made in blood samples that are taken after you have not eaten for some time – these are called ‘fasting blood samples’. (Your doctor or nurse will tell you how long you should go without food before you have the blood sample taken to measure your blood lipids levels.)

The measurements most commonly made are of:

- cholesterol
- low-density lipoprotein carrying cholesterol (usually referred to as LDL-C)
- high-density lipoprotein carrying cholesterol (usually referred to as HDL-C)
- triglycerides (simple fats).

The results of the tests are given in the form of a concentration for each of the lipids, in units called millimoles per litre (abbreviated to mmol/litre). Your doctor will not just look at the results for individual lipids and lipoproteins, but will also consider the levels of two or more of the results together. The results of all the measurements together are referred to as the ‘blood lipid profile’.

NICE recommends that:

- when someone is diagnosed with type 2 diabetes, their levels of total cholesterol, LDL-C, HDL-C and triglycerides should be measured
- the measurements should be made in fasting blood samples if possible.

If you have quite low lipid levels

If:

your total cholesterol level is less than 5.0 mmol/litre

(or your LDL-C is less than 3.0 mmol/litre)

and your triglyceride level is less than 2.3 mmol/litre

NICE recommends that:

- you should have your blood lipid levels checked once a year (using fasting blood samples if possible)
- you do not need medicines to lower your blood lipid level.

If your lipid profile is different

Some people can improve their blood lipid profile or prevent further rises in blood lipid levels by making changes to their lifestyle (for example, by taking particular care over what they eat, losing some weight, or taking more exercise). Others may need to take one or more medicines. Whichever course of action you and your doctor or nurse decide on, it’s important that you understand why you are taking the approach and the benefits that might occur as a result. Your doctor or nurse should discuss how he or she can best help you to understand what is happening in your body and how you can try to control your blood lipid levels.

If:

your total cholesterol level is 5.0 mmol/litre or more

(or your LDL-C is 3.0 mmol/litre or more)

or your triglyceride level is 2.3 mmol/litre or more

NICE recommends that your doctor should:

- check whether the high lipid level is related to a disease other than your diabetes – this check will include taking blood samples and urine samples to send to the laboratory for tests and asking you how much alcohol you drink
- make sure your blood glucose levels are being controlled as well as possible
- offer you advice on how you could help to reduce your blood lipid levels, for example by losing weight, changing what you eat, or increasing the amount of exercise you take
- measure your blood lipid levels again before considering whether using a medicine would be an appropriate way to help to lower your blood lipid levels – any treatment with a medicine should only start if the new measurements show that lipid levels are still high
- continue to measure blood lipid levels (preferably with fasting blood samples) during any treatment with medicines.

Using medicines to help lower some blood lipid levels

Table 2 summarises the NICE recommendations about when medicines should be used to help lower some blood lipid levels. Whether treatment with a medicine is recommended depends on a person's blood lipid profile and whether or not they have a higher 'coronary event risk'. What 'coronary event risk' means in this NICE guideline is explained in the box on page 21.

There are minimum targets to be achieved by the treatments:

- to reduce total cholesterol to below 5.0 mmol/litre or to 75–80% of the level before treatment, whichever is lower, **or**
- to reduce LDL-C to below 3.0 mmol/litre or to 70% of the level before treatment, whichever is lower.

So, for example, if your blood cholesterol level was 8 mmol/litre before treatment started, your doctor would be aiming for treatment to lower it to less than 5 mmol/litre. If it was 6 mmol/litre before treatment, your doctor would be aiming for treatment to lower it to between 4.5 and 4.8 mmol/litre (these levels are 75% and 80% of the level before treatment).

The medicines available to help lower blood lipid levels

Statins and fibrates are two types of medicine that are used to help lower some blood lipid levels.

Statins are medicines that reduce the amount of cholesterol made by the body and so lower the amount of cholesterol in the blood. They help to prevent heart problems because high levels of cholesterol in the blood can gradually build up on the walls of the arteries and cause blockage.

Fibrates are medicines that reduce the amount of triglycerides and cholesterol that the liver produces and so lower the levels of these lipids in the blood.

Depending on your level of blood lipids, your doctor might recommend treatment using both a statin and a fibrate. If so, he or she should check the information on the two medicines to find out whether the drugs will work together without problems. You should be aware that taking both a statin and a fibrate increases the likelihood of experiencing adverse effects from the medicines. Your doctor should discuss these with you.

Table 2 NICE recommendations about when to use medicines to help lower lipid levels

<p>1 If someone: has a level of total cholesterol of 5.0 mmol/litre or more (or a level of LDL-C of 3.0 mmol/litre or more) or a triglyceride level of 2.3 mmol/litre or more but less than 10 mmol/litre</p>	<p>and has a lower 10-year coronary event risk</p>	<p>NICE recommends that the doctor should:</p> <ul style="list-style-type: none"> • discuss the risks of heart disease with the person and consider whether treatment with a statin* is appropriate. (The doctor should consider offering treatment with medicines at higher levels of cholesterol or triglyceride.) <p>If it's decided to start treatment, the doctor should:</p> <ul style="list-style-type: none"> • offer treatment with a statin* • check the effect of the treatment within 3 months and if necessary change the amount of statin the person is taking • then check the effects of treatment once a year. <p>If it's decided not to start treatment, the doctor should check the blood lipid profile and cardiovascular risk once a year.</p>
<p>2 If someone: has a level of total cholesterol of 5.0 mmol/litre or more (or a level of LDL-C of 3.0 mmol/litre or more) or a triglyceride level of 2.3 mmol/litre or more but less than 10 mmol/litre</p>	<p>and has a coronary event risk of more than 15% but does not have obvious symptoms of cardiovascular disease</p>	<p>NICE recommends that the doctor should:</p> <ul style="list-style-type: none"> • offer treatment with a statin* • check the effect of the treatment within 3 months and if necessary change the amount of statin the person is taking • then check the effects of treatment once a year.
<p>3 If someone: has a level of total cholesterol of 5.0 mmol/litre or more (or a level of LDL-C of 3.0 mmol/litre or more) or a triglyceride level of 2.3 mmol/litre or more but less than 10 mmol/litre</p>	<p>and has obvious symptoms of cardiovascular disease</p>	<p>NICE recommends that the doctor should:</p> <ul style="list-style-type: none"> • offer treatment with a statin* • check the effect of the treatment within 3 months and if necessary change the amount of statin the person is taking • offer treatment with a fibrate* as well, if blood triglyceride level is still 2.3 mmol/litre or higher after 6 months' treatment with a statin • then check the effects of treatment once a year.

continued on page 29

continued from page 28

Table 2 NICE recommendations about when to use medicines to help lower lipid levels

4	If someone: has a level of total cholesterol of less than 5.0 mmol/litre (or a level of LDL-C of less than 3.0 mmol/litre and a triglyceride level of 2.3 mmol/litre or more but less than 10 mmol/litre	and has obvious symptoms of cardiovascular disease	NICE recommends that the doctor should: <ul style="list-style-type: none">• offer treatment with a statin* or a fibrate*• check the effect of the treatment within 3 months and if necessary change the amount of statin the person is taking• then check the effects of treatment once a year.
5	If someone: has a triglyceride level of 10 mmol/litre or more (in fasting blood samples)	–	NICE recommends that the doctor should: <ul style="list-style-type: none">• offer treatment with a fibrate• consider referring the person to a diabetes or lipid clinic at a hospital.

*There is more information about these medicines in the next section of this leaflet

Treatment with aspirin

Platelets are particles in the blood that are involved in blood clotting. Aspirin reduces the stickiness of the platelets. Taking low doses of aspirin regularly can reduce the risk of a clot forming inside your body and blocking a blood vessel. Using aspirin in this way is called 'anti-platelet therapy'.

NICE has made the following recommendations about aspirin treatment for people with type 2 diabetes.

- For people who have obvious signs of or a history of cardiovascular disease: 75 mg aspirin each day.
- For people with a more than 15% risk of heart problems in the next 10 years: 75 mg aspirin each day, with treatment starting **after** systolic blood pressure has been reduced to 145 mmHg or lower; blood pressure should be kept at 145 mmHg or lower while aspirin is being taken as anti-platelet therapy.

There may be medical reasons why you shouldn't take aspirin. Your doctor should discuss aspirin treatment with you and the side effects it may have.

Further information

You have the right to be fully informed and to share in decision-making about your healthcare. If you need further information about any aspects of your diabetes or treatment, please ask your GP or a relevant member of your healthcare team. You can discuss this guideline with them if you wish.

For further information about the National Institute for Clinical Excellence (NICE), the Clinical Guidelines Programme or other versions of this guideline (including the sources of evidence used to inform the recommendations for treatment and care), you can visit the NICE website at www.nice.org.uk.

NICE has also issued other guidance that may be of particular interest to people with type 2 diabetes. This guidance can be found on the NICE website, and paper copies can be ordered from the NHS Response Line – phone 08701 555 455 and quote the reference number.

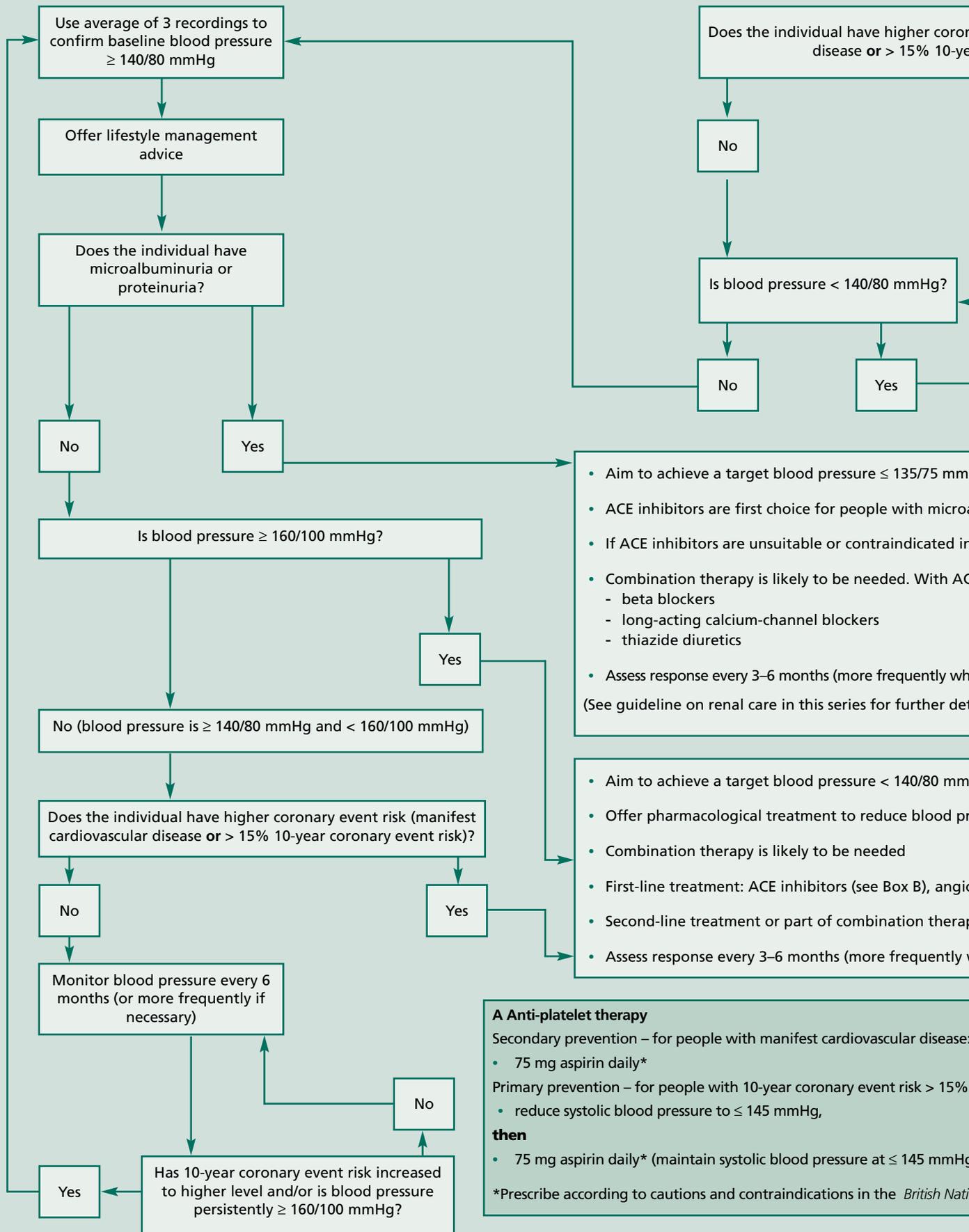
The guidance available covers the following.

- Screening for and the early management of retinopathy (eye problems). Available from www.nice.org.uk/cat.asp?c=27915. Reference numbers: NICE guidance, N0058; patient information, N0059. (Guideline published in February 2002.)
- The prevention and early management of renal (kidney) disease. Available from www.nice.org.uk/cat.asp?c=27915. Reference numbers: NICE guidance, N0061; patient information, N0062. (Guideline published in February 2002.)
- Managing blood glucose levels. Available from www.nice.org.uk/cat.asp?c=36733. Reference numbers: NICE guidance, N0128; patient information, N0129. (Guideline published in September 2002.)
- The use of rosiglitazone for type 2 diabetes mellitus. Available from www.nice.org.uk/cat.asp?c=8079. Reference numbers: NICE guidance, 22181; patient information, 22182. (Technology appraisal issued in August 2000.)
- The use of pioglitazone for type 2 diabetes mellitus. Available from www.nice.org.uk/cat.asp?c=15711. Reference numbers: NICE guidance, 23357; patient information, 23361. (Technology appraisal issued in March 2001.)
- The use of orlistat for the treatment of obesity in adults. Available from www.nice.org.uk/cat.asp?c=15712. Reference numbers: NICE guidance, 23358; patient information, 23364. (Technology appraisal issued in March 2001.)
- The use of sibutramine for the treatment of obesity in adults. Available from www.nice.org.uk/cat.asp?c=23003. Reference numbers: NICE guidance, N0033; patient information, N0035. (Technology appraisal published October 2001.)
- The use of nicotine replacement therapy (NRT) and bupropion for smoking cessation. Available from www.nice.org.uk/cat.asp?c=30590. Reference numbers: NICE guidance, N0082; patient information, N0084. (Technology appraisal published March 2002.)
- The use of surgery to aid weight reduction in people with morbid obesity. Available from www.nice.org.uk/cat.asp?c=34789. Reference numbers: NICE guidance, N0119; patient information, N0121. (Technology appraisal published July 2002.)

NICE is also in the process of preparing guidance on:

- long-acting insulin analogues for diabetes, due to be issued December 2002
- insulin pump therapy, due to be issued February 2003
- patient education for diabetes, due to be issued March 2003
- glitazones in the treatment of type 2 diabetes (review of current technology appraisal guidance no. 9 and no. 21), due to be issued March 2003.

Blood pressure management



- Aim to achieve a target blood pressure $\leq 135/75$ mmHg
 - ACE inhibitors are first choice for people with microalbuminuria
 - If ACE inhibitors are unsuitable or contraindicated in people with microalbuminuria, consider:
 - beta blockers
 - long-acting calcium-channel blockers
 - thiazide diuretics
 - Assess response every 3–6 months (more frequently when necessary)
- (See guideline on renal care in this series for further details)

- Aim to achieve a target blood pressure $< 140/80$ mmHg
- Offer pharmacological treatment to reduce blood pressure
- Combination therapy is likely to be needed
- First-line treatment: ACE inhibitors (see Box B), angiotensin receptor blockers
- Second-line treatment or part of combination therapy: beta blockers, long-acting calcium-channel blockers, thiazide diuretics
- Assess response every 3–6 months (more frequently when necessary)

A Anti-platelet therapy

Secondary prevention – for people with manifest cardiovascular disease:

- 75 mg aspirin daily*

Primary prevention – for people with 10-year coronary event risk $> 15\%$:

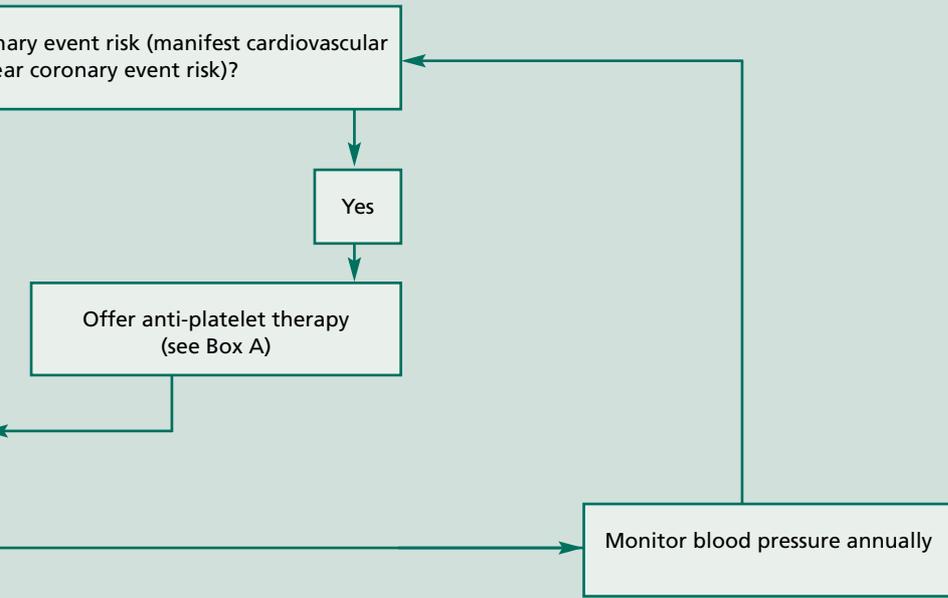
- reduce systolic blood pressure to ≤ 145 mmHg,

then

- 75 mg aspirin daily* (maintain systolic blood pressure at ≤ 145 mmHg)

*Prescribe according to cautions and contraindications in the *British National Formulary*

Management for type 2 diabetes



Hg

albuminuria or proteinuria (see Box B)

In people with microalbuminuria or proteinuria, consider angiotensin II receptor antagonists as first-line therapy

ACE inhibitors or angiotensin II receptor antagonists use:

(when titrating treatment)

(tails)

Hg

pressure

angiotensin II receptor antagonists, beta blockers, thiazide diuretics

by: long-acting calcium-channel blockers (**not** short-acting calcium-channel blockers)

(when titrating treatment)

:

:

(during treatment)

ional Formulary

B Starting ACE inhibitor therapy

Caution in patients with peripheral vascular disease/renovascular disease

Caution in patients with raised serum creatinine

Some ACE inhibitors are not licensed for use at the blood pressure levels recommended in this guideline

In all patients, measure serum creatinine and electrolytes 1 week after:

- initiating ACE inhibitor therapy
- each increase in dose

Management of type 2 diabetes

*Management of blood pressure
and blood lipids: algorithm on the
management of blood pressure*

INHERITED *Clinical Guideline* H

Management of type 2 diabetes

Management of blood pressure and blood lipids

Issue date: October 2002

Review date: October 2005

The algorithm overlaid forms part of the guideline referenced above. The algorithm draws directly on the evidence presented in the guideline and should where necessary be interpreted with reference to the full guideline.

Copies of the guideline can be obtained free of charge from the Institute's website (www.nice.org.uk), and from the NHS Response Line by telephoning 0870 1555 455 and quoting ref. N0167. A patient version of this document, Managing Blood Pressure and Blood Lipid Levels, can also be obtained by quoting ref. N0168 for an English only version or ref. N0169 for an English/Welsh version.

This guideline is a part of the Inherited Clinical Guidelines work programme. It was commissioned by the Department of Health before the Institute was formed in April 1999. It has followed closely the development brief that was agreed at the time of commissioning. The developers have worked with the Institute to ensure, in the time available, that the guideline has been subjected to validation and to consultation with stakeholders. However, it has not been possible to subject it to the full guideline development process that the Institute has now adopted.

The Institute's guideline is derived from the full guideline entitled *Clinical Guidelines for Type 2 Diabetes: Blood Pressure Management and Clinical Guidelines for Type 2 Diabetes: Lipids Management* commissioned from a collaboration between the Royal College of General Practitioners, the Royal College of Physicians, the Royal College of Nursing and Diabetes UK. This guideline is one of a series of guidelines on type 2 diabetes. Other guidelines in the series cover the management of retinopathy, the prevention and early management of renal disease, and the management of blood glucose.

A guideline on foot care was published by the Royal College of General Practitioners in April 2000; this will be updated by NICE in 2003/04.

The full guideline is available on the NICE website, www.nice.org.uk, and on the National Electronic Library for Health's website, www.nelh.nhs.uk. The guideline developers are listed in Appendix A.

This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient in consultation with the patient and/or guardian or carer.

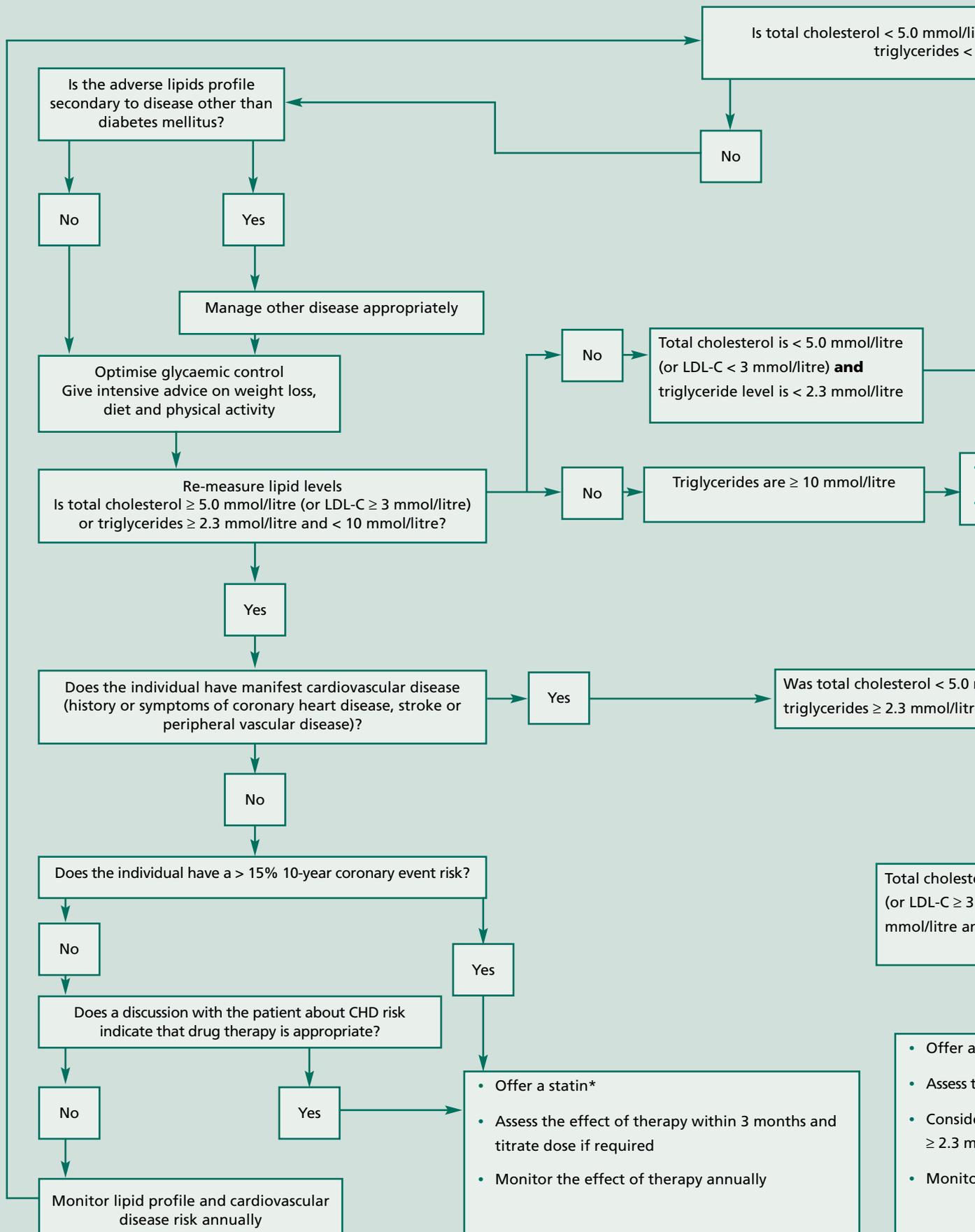
National Institute for Clinical Excellence

11 Strand
London
WC2N 5HR

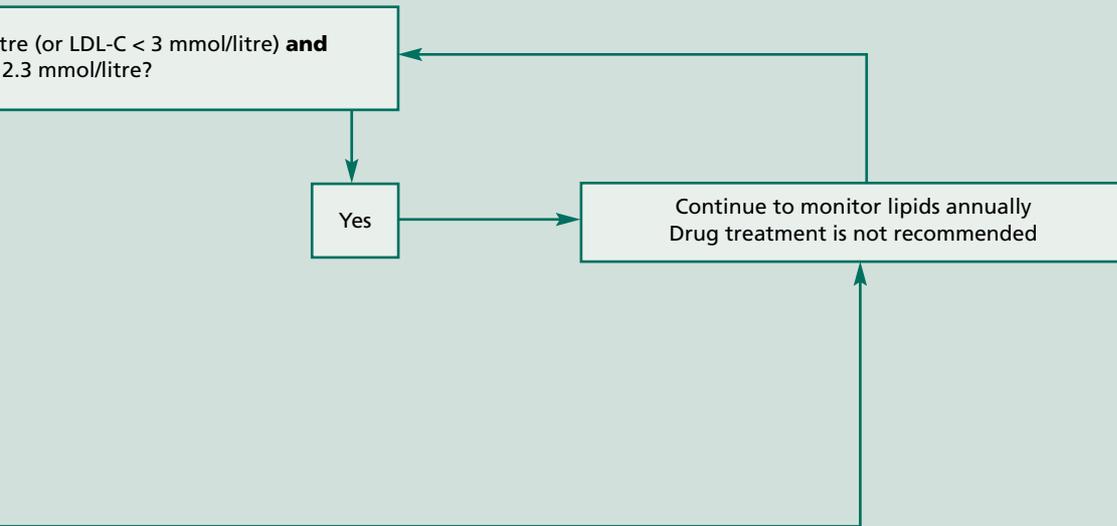
Web: www.nice.org.uk

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Lipids management



t for type 2 diabetes



- Offer a fibrate
- Consider referral to a diabetes or lipid clinic

Anti-platelet therapy
Regardless of blood lipid levels, for people with higher 10-year coronary event risk (manifest cardiovascular disease or >15% 10-year coronary event risk), offer anti-platelet therapy

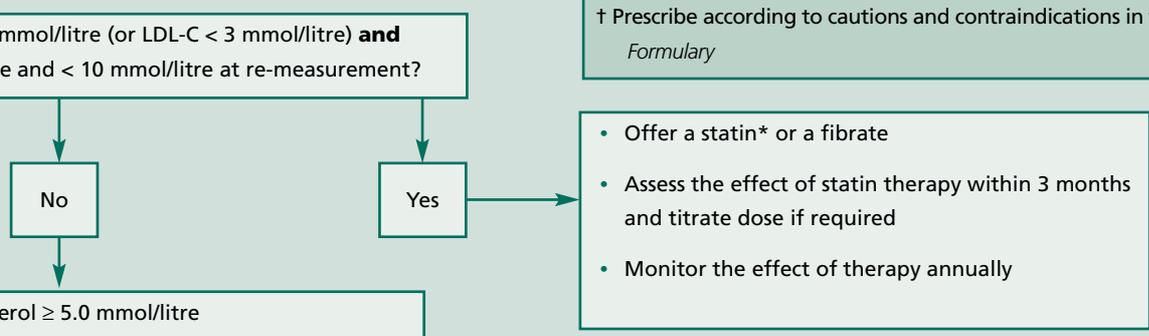
Secondary prevention – for people with manifest cardiovascular disease:

- 75 mg aspirin daily†

Primary prevention – for people with 10-year coronary event risk > 15%:

- reduce systolic blood pressure to ≤ 145 mmHg, then
- 75 mg aspirin daily† (maintain systolic blood pressure at ≤ 145 mmHg during treatment)

† Prescribe according to cautions and contraindications in the *British National Formulary*



...erol ≥ 5.0 mmol/litre
...mmol/litre) or triglycerides ≥ 2.3
...d < 10 mmol/litre

...statin*

...he effect of therapy within 3 months and titrate dose if required

...er adding a fibrate after 6 months if triglyceride remains
...mol/litre**

...or the effect of therapy annually

*Minimum target thresholds: cholesterol < 5.0 mmol/litre or reduced by 20–25% (whichever is lower) or LDL-C < 3.0 mmol/litre or reduced by 30% (whichever is lower)

**Ensure there is no evidence of drug interaction between proposed choices of fibrate and statin. Use of a statin and fibrate together increases the likelihood of adverse effects

Before starting drug treatment, consult the *British National Formulary* for precautions and contraindications

Management of type 2 diabetes

*Management of blood pressure
and blood lipids: algorithm on the
management of blood lipids*

INHERITED *Clinical Guideline H*

Management of type 2 diabetes

Management of blood pressure and blood lipids

Issue date: October 2002

Review date: October 2005

The algorithm overleaf forms part of the guideline referenced above. The algorithm draws directly on the evidence presented in the guideline and should where necessary be interpreted with reference to the full guideline.

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