

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## QUALITY AND OUTCOMES FRAMEWORK (QOF) INDICATOR DEVELOPMENT PROGRAMME

### Briefing paper

**QOF indicator area:** Peripheral arterial disease

**Potential output:** Recommendations for indicator development

**Date of Primary Care QOF Indicator Advisory Committee meeting:** 10  
December 2009

### Introduction

This briefing paper presents an assessment of the suitability of NICE clinical guideline recommendations relevant to primary care and proposed by stakeholders to progress for QOF indicator development.

The QOF indicator area is peripheral arterial disease and the recommendation(s) and underlying evidence review are taken from the following guidance:

- Hypertension: management of hypertension in adults in primary care. NICE clinical guideline 34 (2006). CG34 is a partial update (pharmacological update) of NICE clinical guideline 18. The recommendation presented in this paper is unchanged from the original clinical guideline 18.
- Diagnosis and management of peripheral arterial disease. SIGN clinical guideline 89 (2006).
- Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease. NICE clinical guideline 67 (2008)..

Searches to identify evidence for NICE clinical guidelines are re-run 6–8 weeks before consultation. This paper is based on the evidence presented in NICE clinical guideline 67, NICE clinical guideline 34 and SIGN clinical guideline 89 and no update searches have been performed. Recent literature

searches and analysis of practice data have been performed to provide information for the Advisory Committee on the current management of practice, impact on primary care and the timeliness of potential incentivisation.

The briefing paper is split into the following three sections:

- An overview of peripheral arterial disease, including an epidemiological summary and its current management in primary care.
- Specific recommendations highly relevant to primary care from NICE clinical guideline 67, NICE clinical guideline 34 and SIGN clinical guideline 89 identified for indicator development, a summary of the evidence that informs the recommendations, and an initial assessment of their feasibility.
- A summary of the key considerations against NICE's prioritisation criteria.

## **Overview of peripheral arterial disease**

### ***Epidemiological summary***

#### **Definition**

Peripheral arterial disease (PAD) in the legs, sometimes known as peripheral vascular disease, is caused by atheroma (fatty deposits) in the walls of the arteries leading to insufficient blood flow to the muscles and other tissues. Patients with PAD may have symptoms, but can also be asymptomatic. The most common symptom, intermittent claudication, is characterised by leg pain and weakness brought on by walking, with disappearance of the symptoms following rest.

PAD is one of the three main categories of cardiovascular disease (CVD), the other two being coronary heart disease (CHD) and cerebrovascular disease (stroke).

#### **Incidence, prevalence and evidence of variation by age, sex and ethnicity**

Approximately 20% of people aged from 55 to 75 years have evidence of lower extremity PAD. Five percent of this population appear to have symptoms, with the most common being intermittent claudication. Since the

UK population over 55 years is approximately 17 million, this equates to a prevalence of around 850,000 with intermittent claudication. In England and Wales, 110,000 new cases of stroke, 30,000 TIAs and 102,000 people with PAD are diagnosed every year (this equates to an annual population incidence of 0.20%). PAD is associated with older age and with smoking (which is more common in areas of social deprivation).

### **Morbidity and mortality**

Patients diagnosed with PAD, including those who are asymptomatic, have an increased risk of mortality from CVD (due to fatal myocardial infarction [MI] and fatal stroke). The relative risks of all cause mortality are two to three times that of age and sex matched to groups without PAD. Patients with claudication can have a significantly reduced quality of life due to their restricted mobility.

### ***Impact on health services***

#### **Primary care**

A practice with a list size of 10,000 registered patients would expect to see 20 people newly diagnosed with PAD each year.

#### **Secondary care**

People with PAD are at high risk of occlusive vascular events, including MI, stroke or TIA. The estimated annual number of MIs is approximately 237,000, and approximately 76,500 hospital admissions for MI were recorded in England and Wales for the financial year 2002/03.

### ***Current management in primary care***

The majority of people with PAD are managed in primary care. The focus of treatment is on the cardiovascular complications of atherosclerosis, i.e. cardiovascular risk factor management. Smoking is a very important risk factor for PAD, and management of PAD includes smoking cessation. Other established risk factors are high blood pressure and diabetes. This would mean that people with PAD and high blood pressure would be currently included in the hypertension indicator domain for QOF and people with

diabetes and PAD would be included in the diabetes indicator domain for QOF.

### **Current baseline practice**

Indicators relating to PAD and blood pressure would be expected to lead to a minor–moderate change in practice. The point at which statin therapy is initiated for people with PAD is not known. It is noted that the total cholesterol ‘target’ for diabetes (DM17) and CHD (CHD8) is 5 mmol/litre.

Two small UK studies assessing clinical risk management based on the medical records of patients with peripheral vascular disease (Bradley and Kirker 2006; Khan et al. 2007) identified poor hypertension control, low levels of statin and antiplatelet therapy and low levels of smoking cessation advice.

Additional information on baseline practice derived from primary care data will be provided at the QOF Advisory Committee on 10 December 2009 if available.

### ***NHS priorities and timeliness for guidance***

- Department of Health (2000) National service framework for coronary heart disease.
- Department of Health (2007) National stroke strategy.
- NICE (2005) Clopidogrel and dipyridamole for the prevention of atherosclerotic events. NICE technology appraisal 90
- SIGN (2006) Diagnosis and management of peripheral arterial disease. (SIGN clinical guideline 89)
- NICE (2006) Hypertension: management of hypertension in adults in primary care. NICE clinical guideline 34.
- NICE (2008) Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease. NICE clinical guideline 67
- SIGN (2007) Risk estimation and the prevention of cardiovascular disease. SIGN clinical guideline 97

## **Review of recommendations**

### ***Summary of guideline recommendations***

The recommendations presented in this briefing paper were identified as being potentially suitable for QOF indicator development and relate to a topic suggestion received through NICE's online suggestion facility in September 2009. The topic was submitted by a society and a patient organisation.

Six recommendations from NICE clinical guideline 67, NICE clinical guideline 34 and SIGN clinical guideline 89 have been identified by the QOF indicator programme team as being relevant to this topic suggestion.

#### **NICE clinical guideline 34 (hypertension)**

##### ***NICE recommendation 1.4.3***

Offer drug therapy, adding different drugs if necessary, to achieve a target of 140/90 mmHg, or until further treatment is inappropriate or declined. Titrate drug doses as described in the 'British national formulary' noting any cautions and contraindications.

#### **SIGN clinical guideline 89 (peripheral arterial disease)**

##### ***Sign recommendation 2.3***

Lipid lowering therapy with a statin is recommended for patients with peripheral arterial disease and total cholesterol level > 3.5 mmol/l.

##### ***SIGN recommendation 2.6***

Hypertensive patients with peripheral arterial disease should be treated to reduce their blood pressure.

##### ***SIGN recommendation 2.8***

- Antiplatelet therapy is recommended for patients with symptomatic peripheral arterial disease

### **NICE clinical guideline 67 (lipid modification)**

This guideline is for adults (aged 18 and older) who have established CVD (including CHD [angina only], stroke or *peripheral arterial disease*) or who are at high risk of developing CVD because of a combination of CVD risk factors, including raised blood pressure and hypertension, overweight and obesity.

The guideline does not cover people with diabetes, people with familial monogenic lipid disorders or people at high risk of CVD as a result of secondary disease processes or drug treatment.

#### ***NICE recommendation 1.4.19***

Statin therapy is recommended for adults with clinical evidence of CVD.

#### ***NICE recommendation 1.4.25***

An 'audit' level of total cholesterol of 5 mmol/litre should be used to assess progress in populations or groups of people with CVD, in recognition that more than a half of patients will not achieve a total cholesterol of less than 4 mmol/litre or an LDL cholesterol of less than 2 mmol/litre.

### ***Evidence summary***

This is a summary of the evidence supporting the proposed NICE recommendations presented above in 'Summary of NICE guideline recommendations'. This section relates to the evidence summary table in appendix A of this briefing paper.

The stakeholder submissions for this topic identified four areas for QOF indicator development in relation to the management of PAD. These are:

- antiplatelet therapy
- blood pressure
- total cholesterol
- smoking.

Note: Smoking, which is the strongest risk factor for peripheral arterial disease, is not included in the scope of this briefing paper because the

smoking indicators will be reviewed separately at the December 2009 Advisory Committee.

## **Clinical effectiveness**

### ***Antiplatelet therapy***

There is evidence from meta-analyses and/or randomised controlled trials (level 1) for relevant health outcomes (serious vascular event, non-fatal MI, non-fatal stroke, vascular mortality) to support the use of antiplatelet therapy for symptomatic PAD, as recommended in recommendation 2.8 (SIGN clinical guideline 89).

### ***Blood pressure***

There is evidence from meta-analyses and/or randomised controlled trials (level 1) demonstrating that a sustained reduction in blood pressure by drugs reduces the incidence of stroke, coronary heart disease and overall mortality.

### ***Total cholesterol***

There is evidence from meta-analyses and/or randomised controlled trials (level 1) for relevant health outcomes (risk of fatal and non-fatal cardiovascular events) to support the use of statins in patients with PAD, as recommended in recommendation 2.3 (SIGN clinical guideline 89) and recommendation 1.4.19 (NICE clinical guideline 67).

## **Cost effectiveness**

No evidence on presented for recommendation 2.8 (antiplatelet therapy - SIGN clinical guideline 89). Health economic modelling suggests that the recommendations related to treatment of blood pressure are a cost effective use of NHS resources. There is strong economic evidence that therapy to achieve reductions in cholesterol is cost effective for people with clinical evidence of CVD.

## ***Discussion on the use of blood pressure and cholesterol targets***

### **Blood pressure 'targets'**

Recommendation 2.6 in SIGN clinical guideline 89 (PAD) does not specify a target blood pressure in patients with PAD. However, the guideline developers considered that 140/90 mmHg is a desirable upper limit and that around one third to one half of patients with PAD would be considered hypertensive above this level.

Recommendation 1.4.3 in NICE clinical guideline 34 (hypertension) recommends that drug therapy should be offered in people at raised cardiovascular risk to achieve a target of 140/90 mmHg.

None of the identified NICE guidance comments on the use of 'audit targets' for blood pressure.

A rationale to support the use of an 'audit standard' of 150/90 mmHg for QOF indicators **BP5** and **CHD6** is given in the QOF guidance (NHS Employers, 2008). The QOF guidance rationale references the British Hypertension Society (BHS) guidelines for hypertension management 2004 (BHS-IV) (Williams et al. 2004).

The BHS guideline developers considered that definitive evidence on optimal targets for blood pressure lowering was lacking. It was considered that the Hypertension optimal treatment (HOT) trial, although underpowered, provided the best evidence to date on optimal targets. The HOT trial reported that the optimal blood pressure for reduction of major cardiovascular events was 139/83 mmHg and that reduction of blood pressure below this value caused no harm. However, patients whose blood pressure was between 139/83 mmHg and 150/90 mmHg were also not disadvantaged. On the basis of these observations, the BHS guideline developers agreed that a blood pressure target of less than 150/90 mmHg was an appropriate 'audit standard', i.e. the minimal target that all treated patients should attain.



## **Cholesterol ‘targets’**

Recommendation 2.3 in SIGN clinical guideline 89 (PAD) recommends statin therapy for patients with PAD and total cholesterol level >3.5 mmol/litre.

Recommendation 1.4.3 in NICE clinical guideline 67 (lipid modification) recommends statin therapy for adults who have established CVD or who are at high risk of developing CVD. The guideline does not offer a specific treatment target, but recommends that an “‘audit’ level of total cholesterol of 5 mmol/litre should be used to assess progress in populations or groups of people with CVD”. This is in recognition that more than a half of patients will not achieve total cholesterol of less than 4 mmol/litre or an LDL cholesterol of less than 2 mmol/litre.

The current QOF indicator **CHD8** uses an ‘audit level’ of total cholesterol 5 mmol/litre below which to aim for all eligible CHD patients.

The rationale to support the use of an ‘audit target’ of 5 mmol/litre for QOF indicator **CHD8** is given and is referenced in the QOF guidance (NHS Employers, 2008) and states that 5 mmol/litre should be treated as an audit target below which to aim for all eligible CHD patients.

### **An ‘audit target’ of 5 mmol/litre is consistent with NICE recommendation 1.4.3 (NICE clinical guideline 67 – lipid modification).**

Note: the NICE clinical guideline for lipid modification includes peripheral arterial disease.

See Appendix B for details of the NICE clinical guideline 67 (lipid modification) Guideline Development Group (GDG) considerations on the use of cholesterol targets.

## ***Assessment of recommendations against current practice***

### **Reduction of health inequalities**

The guideline recommendations presented in this briefing paper are unlikely to have an adverse or negative impact on any group or community. Rather,

the incentivisation of PAD through the QOF has the potential to have a positive impact by promoting management of PAD in people who may have previously been considered to be under-diagnosed. Relevance to inequalities: medium.

### **Will implementation of these recommendations lead to improvements in the delivery of primary care?**

PAD is not included in the current QOF. Patients with PAD commonly have comorbidities such as diabetes and hypertension. People with PAD and these conditions would be included in these registers. The recommendations presented in this paper are likely to lead to a moderate change in practice.

### ***Feasibility assessment***

Indicators relating to the use of antiplatelet therapy, blood pressure and total cholesterol already form part of QOF in several domains. Therefore, indicators related to these areas and the management of PAD are considered feasible.

A decision would be required as to whether the implementation of PAD within QOF would involve the following:

- Implementation as part of an existing disease register (for example, CHD or stroke).
- A disease register for PAD.
- A new composite register for CVD (defined as CHD, stroke and PAD).

## **1 Topic and recommendation status**

This section provides the overall topic and recommendation status that has been produced by the QOF programme team. This takes into account information presented in this briefing paper against the revised prioritisation checklist as agreed at the July 2009 Advisory Committee.

### ***Topic status***

Overall the topic has been given a status of **GREEN**. This overall topic status is based on an assessment the prevalence, primary care management and disease severity as outlined in 1A, 1B and 1C below.

<b>1A Population</b>		
The condition is considered to have population prevalence that is high		GREEN
<b>1B Management</b>		
The condition is commonly diagnosed in primary care*		GREEN
The condition is commonly treated in primary care*		GREEN
The condition is commonly monitored in primary care*		GREEN
* by GPs or directly employed practice staff		
<b>1C Disease severity</b>		
Score	Scoring criteria	
1	Minor quality-of-life impact, no disability, limited morbidity impact	<input type="checkbox"/>
2	Definite quality-of-life impact, no disability, limited morbidity impact	<input type="checkbox"/>
3	<b>Definite quality-of-life impact, some disability and/or intermediate morbidity impact</b>	<input checked="" type="checkbox"/>
4	Definite quality-of-life impact, significant disability and/or significant morbidity impact	<input type="checkbox"/>

### ***Recommendation status***

The status of each recommendation is given in the below table.

<b>Overall status of each recommendation</b>	
<b><i>Blood pressure</i></b>	
SIGN guideline 89 (PAD) rec 2.6	GREEN
NICE guideline 34 (hypertension) rec 1.4.3	GREEN
<b><i>Antiplatelet therapy</i></b>	
SIGN guideline 89 (PAD) rec 2.8	GREEN
<b><i>Total cholesterol</i></b>	
SIGN guideline 89 (PAD) rec 2.3	GREEN
NICE guideline 67 (lipid modification) rec 1.4.19	GREEN
NICE guideline 67 (lipid modification) rec 1.4.25	GREEN

The individual recommendation status provided in the table above is based on an assessment of feasibility, strength of clinical and cost-effectiveness evidence and expected change in practice.

<b>Feasibility of each recommendation</b>			
<b><i>Blood pressure</i></b>			
SIGN guideline 89 (PAD) rec 2.6	GREEN		
NICE guideline 34 (hypertension) rec 1.4.3	GREEN		
<b><i>Antiplatelet therapy</i></b>			
SIGN guideline 89 (PAD) rec 2.8	GREEN		
<b><i>Total cholesterol</i></b>			
SIGN guideline 89 (PAD) rec 2.3	GREEN		
NICE guideline 67 (lipid modification) rec 1.4.19	GREEN		
NICE guideline 67 (lipid modification) rec 1.4.25	GREEN		
<b>Scores for each recommendation</b>			
	<b>Evidence of clinical effectiveness</b>	<b>Evidence of cost effectiveness</b>	<b>Expected change in practice</b>
<b><i>Blood pressure</i></b>			
SIGN guideline 89 (PAD) rec 2.6	High	None available	Minor–moderate
NICE guideline 34 (hypertension) rec 1.4.3	High	Likely to be cost effective	Minor–moderate
<b><i>Antiplatelet therapy</i></b>			
SIGN guideline 89 (PAD) rec 2.8	High	None available	Minor–moderate
<b><i>Total cholesterol</i></b>			
SIGN guideline 89 (PAD) rec 2.3	High	None available	Moderate
NICE guideline 67 (lipid modification) rec 1.4.19	High	Likely to be cost effective	Moderate
NICE guideline 67 (lipid modification) rec 1.4.25	Low	None available	Minor

## **Key considerations**

The following key considerations summarise the main points made in the briefing paper and should be used by the Committee in their deliberations.

- PAD is not included in the current QOF.

- Patients with PAD commonly have diabetes and hypertension as comorbidities. People with PAD and these conditions would be included in these registers.
- Indicators based on the recommendations presented in this briefing paper are considered feasible.
- There are several options for possible implementation of PAD into the QOF. These include an existing QOF domain as part of an existing disease register (for example, CHD or stroke), a disease register for PAD or a new composite register for CVD (defined as CHD, stroke and PAD).

## References

Bradley L, Kirker SGB (2006) Secondary prevention of arteriosclerosis in lower limb vascular amputees: a missed opportunity. *Eur J Vasc Endovasc Surg.* 32:491–3

Khan S, Flather M, Mister R et al. (2007) Characteristics and treatments of patients with peripheral arterial disease referred to UK vascular clinics: results of a prospective registry. *Eur J Vasc Endovasc Surg.* 33(4):442–50

Williams B, Poulter NR, Brown MJ et al. (2004) The BHS Guidelines Working Party Guidelines for Management of Hypertension: Report of the Fourth Working Party of the British Hypertension Society, 2004 - BHS IV. *Journal of Human Hypertension* 18: 139–85 Available from:

[http://www.bhsoc.org/Latest\\_BHS\\_management\\_Guidelines.stm](http://www.bhsoc.org/Latest_BHS_management_Guidelines.stm)

## Appendix A: Evidence summary

### Evidence summary of selected recommendations from NICE clinical guideline 34, NICE clinical guideline 67 and SIGN clinical guideline 89

NICE / SIGN recommendation	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
<b>Antiplatelet therapy</b>					
SIGN clinical guideline 89 (rec 2.8)	Antiplatelet therapy is recommended for patients with symptomatic peripheral arterial disease.	Systematic review of randomised controlled trials (RCTs).	Serious vascular event, non-fatal MI, non-fatal stroke, vascular mortality	In a major systematic review (Antithrombotic Trialists Collaboration) of RCTs, antiplatelet drugs were found to reduce the risk of any serious vascular event by one quarter, non-fatal MI by one third, non fatal stroke by one quarter and vascular mortality by one sixth in a wide range of atherosclerotic cardiovascular diseases (including patients with PAD).	None presented.
<b>Blood pressure</b>					
SIGN clinical guideline 89 (rec 2.6)	Hypertensive patients with peripheral arterial disease should be treated to reduce their blood pressure.	Systematic review of RCTs.	Blood pressure control.	The guideline developers considered that blood pressure may be elevated above a desirable upper limit of 140/90 mmHg in around one third to one half of patients with PAD such that these patients would be considered hypertensive.  The guideline developers noted that treatment for PAD has often been considered difficult because of concerns that antihypertensives,	None presented.

NICE / SIGN recommendation	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
				especially beta blockers, may have adverse effects on PAD due to possible drug induced peripheral vasoconstriction leading to further ischaemia in the leg. The reviewers did not find any strong evidence to suggest that beta blockers should not be used in the presence of PAD, although no study was sufficiently large to demonstrate with certainty an absence of adverse events.	
NICE clinical guideline 34 (rec 1.4.3)	Offer drug therapy, adding different drugs if necessary, to achieve a target of 140/90 mmHg, or until further treatment is inappropriate or declined. Titrate drug doses as described in the 'British national formulary' noting any cautions and contraindications.	RCTs.	Blood pressure control.	In trials aiming to reduce blood pressure to below 140/90 mmHg using stepped medication regimes, between half and three quarters of patients achieve target blood pressure.	Health economic modelling of the disease and the costs and consequences of treatment over the lifetime of patients suggests that this is a cost effective use of NHS resources.
<b>Total cholesterol</b>					
SIGN clinical guideline 89 (rec 2.3)	Lipid lowering therapy with a statin is recommended for patients with peripheral arterial disease and total	Meta-analyses of 16 RCTs and 2 RCTs.	All cause mortality and/or total fatal and non-fatal cardiovascular	This recommendation is based on one meta-analyses and 2 RCTs assessing the impact of cholesterol lowering on cardiovascular events in people with PAD of the lower limb.	None presented.

NICE / SIGN recommendation	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
	cholesterol level > 3.5 mmol/l.		events.	<p>In the meta-analysis, three small trials of lipid lowering in patients with peripheral arterial disease produced a marked, but non-significant, reduction in mortality, but little change in non-fatal events.</p> <p>In one RCT (Heart Protection Study), high risk individuals with a total cholesterol level of at least 3.5 mmol/litre were randomised to either simvastatin 40 mg daily or placebo. Among a subgroup of individuals with PAD, there was a significant reduction in vascular events.</p> <p>In one RCT, men with peripheral arterial disease were randomised to either bezafibrate daily or placebo. Treatment with bezafibrate had a beneficial effect on the incidence of non-fatal coronary events but did not reduce the incidence of total fatal and non-fatal cardiovascular events.</p>	
NICE clinical guideline 89 (rec 1.4.19)	Statin therapy is recommended for adults with clinical evidence of CVD.	Meta analyses and/or RCTs.	Total mortality, cardiovascular mortality, cardiovascular events.	<p>This recommendation was based on level 1 evidence presented in NICE technology appraisal 94 'Cardiovascular disease – statins'</p> <p>The GDG considered that there is</p>	The Technology Appraisal Committee (TA94) concluded that statin therapy is cost effective for people with clinical



NICE / SIGN recommendation	Recommendation	Level of evidence	Key outcomes considered (for interventions)	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
				substantive trial evidence that statins reduce total mortality, cardiovascular mortality and morbidity and total mortality and that this evidence is strongest in people with CHD.	evidence of CVD.
NICE clinical guideline 89 (rec 1.4.25)	An 'audit' level of total cholesterol of 5 mmol/litre should be used to assess progress in populations or groups of people with CVD, in recognition that more than a half of patients will not achieve a total cholesterol of less than 4 mmol/litre or an LDL cholesterol of less than 2 mmol/litre.	GDG consensus.	-	<p>The GDG accepted by a majority that the use of a target figure for total cholesterol can be helpful in guiding increases of lipid lowering drugs as long as it is clear that this target is intended to guide treatment rather than be a level patients are expected to achieve.</p> <p>The GDG concluded that an 'audit' level of total cholesterol 5 mmol/litre may help to assess progress in populations and groups. This consensus is reflected in recommendation 1.4.25 which recommends that an "audit' level of total cholesterol of 5 mmol/litre should be used to assess progress in populations or groups of people with CVD".</p>	None presented.

## **Appendix B: NICE GDG for the clinical guideline on lipid modification – discussion of cholesterol ‘targets’**

The issue of cholesterol targets has been discussed by the NICE GDG for lipid modification and are documented in the full guideline.<sup>1</sup> The GDG noted that international and national guidelines on lipid lowering have defined goals or targets of therapy, and these targets have become progressively lower over time and differ between guidelines.

- In 1998, the Joint British Societies first recommended a total cholesterol target of less than 5.0 mmol/litre and an LDL cholesterol target of less than 3.0 mmol/litre, or a 25% total cholesterol reduction or a 30% LDL cholesterol reduction, whichever is greater.
- The National Service Framework for CHD in 2000 recommended levels of less than 5 mmol/litre total cholesterol or 3 mmol/litre LDL cholesterol (or a 25% total cholesterol reduction or 30% LDL cholesterol reduction whichever is greater) and these remain the current national advice.
- In 2003, the Joint European Societies Task Force on CVD Prevention recommended a total cholesterol level of less than 4.5 mmol/litre and LDL cholesterol levels below 2.5 mmol/litre.
- The most recent Joint British Societies 2005 guideline recommended target levels below 4 mmol/litre total cholesterol and 2 mmol/litre LDL cholesterol (or a 25% reduction in total cholesterol and a 30% reduction in cholesterol if that yields a lower value).
- In 2007, SIGN clinical guideline 97 considered that total cholesterol targets of 4 mmol/litre or 4.5 mmol/litre would have major resource implications for NHS Scotland (SIGN 2007), but this was not based on a formal cost-effectiveness analysis. SIGN recommended that pending further studies on mortality, safety, and cost-effectiveness, a total cholesterol target of less than 5 mmol/litre in individuals with CVD should be a minimum standard of care.

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<sup>1</sup> See pages 203-210 of the full clinical guideline on lipid modification including recommendations and methods used. Available from [www.nice.org.uk/nicemedia/pdf/CG67FullGuideline.pdf](http://www.nice.org.uk/nicemedia/pdf/CG67FullGuideline.pdf)

The GDG for NICE clinical guideline 67 recognised there were differing views on the use of cholesterol 'targets' i.e. levels of total and LDL cholesterol that patients on lipid lowering therapy should either aim to be below or should achieve.

Proponents of targets considered that the log linear hypothesis from the Cholesterol Trialists Collaboration supported the use of targets because it confirmed that for LDL cholesterol 'lower is better'.

Opponents of setting targets considered it misleading for both professionals and patients to set a target that is interpreted as 'should be achieved', knowing that many patients will not achieve this.

### ***Conclusion***

The GDG concluded by majority that the use of higher intensity statins or drug combinations should be driven by trial evidence of absolute benefit in clinical outcomes and cost effectiveness, and less by targets and relative risk. The GDG accepted again by a majority that the use of a target figure can be helpful in guiding increases of lipid lowering drugs as long as it is clear that this figure is intended to guide treatment rather than be a figure patients are expected to achieve.

The GDG concluded that an 'audit' level of total cholesterol 5 mmol/litre may help to assess progress in populations and groups. This consensus is reflected in recommendation 1.4.25 (NICE clinical guideline 67) which recommends that an "audit' level of total cholesterol of 5 mmol/litre should be used to assess progress in populations or groups of people with CVD".