The briefing paper is structured as follows:

1. Outline of the stakeholder topic suggestion
2. An overview of cardiovascular disease, including an epidemiological summary and its current management in primary care
3. Recommendations highly relevant to primary care from NICE clinical guideline 67 identified for indicator development and a summary of the evidence that informs the recommendations therein
4. An assessment of current practice
5. An initial assessment of feasibility
6. A summary of the key considerations
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 cardiovascular disease (CVD) and the recommendations and underlying evidence are taken from the following NICE guidance:

‘Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease’ (NICE clinical guideline 67).

1 Stakeholder topic suggestion

NICE has received suggestions for indicator development from the Care Quality Commission (see briefing note ‘CVD risk and health inequalities’). One area has been identified as suitable for QOF indicator development and has been prioritised by the NICE team for consideration by the Advisory Committee:

Statin therapy for people newly diagnosed with hypertension who are at increased risk or high risk of developing CVD (high risk is defined as having a 10 year CVD risk of over 20%)

2 Overview

Epidemiological summary

CVD is defined within the scope of NICE clinical guideline 67 as comprising coronary heart disease (CHD), stroke and peripheral arterial disease. It was determined that CVD includes ischaemic stroke and transient ischaemic attack, but does not include haemorrhagic stroke.
Incidence, prevalence and evidence of variation in CVD by age, sex and ethnicity

Age is the main determinant of CVD risk, with people over 50 years predominantly affected. Apart from age and sex, three modifiable risk factors – smoking, raised blood pressure and raised cholesterol – make a major contribution to CVD risk, particularly in combination. These factors account for 80% of all cases of premature CHD. The risk of a future CVD event can be calculated from these risk factors, and people at highest risk can be identified.

There are major identifiable population groups at particular risk of CVD. CVD is strongly associated with low income and social deprivation. The lifetime burden of CVD is greater in women because of their increased longevity and their increased risk of stroke over the age of 75. Women are more likely to be under-diagnosed and less likely to be optimally treated. South Asian men are more likely to develop CVD at a younger age. People with hypertension are one of the major groups of people at risk of CVD. The costing report for NICE clinical guideline 34 on hypertension estimates that the national treated prevalence of hypertension is 11.34%

Morbidity and mortality

Cardiovascular disease is the main cause of death in England and Wales. In 2005, CVD was the cause of one in three deaths, accounting for 124,000 deaths; 39,000 of those who died were younger than 75 years. For every one fatality, there are at least two people who have a major non-fatal cardiovascular event. There are over 3 million people living with CHD or stroke. Men under 75 years are three times more likely than women to die from CVD.

Despite evidence that mortality from CVD is falling, morbidity appears to be rising. CVD remains a leading cause of death (particularly premature death), and a major and increasing cause of disability and ill health.
Impact on health services

Primary care
Patients with CVD or hypertension form a significant part of general practice workload but NICE clinical guideline 67 does not present data on this.

Secondary care
Patients with CVD or hypertension form a significant part of acute activity in secondary care but the NICE guideline does not present data on this.
Vascular disease is responsible for one-fifth of all hospital admissions.

Current management in primary care
Primary care plays a significant role in delivering interventions for individual people at high risk of developing CVD. These include smoking cessation, with appropriate advice on diet, physical activity and treatment for high blood pressure and lipid modification.

Historically, the approach towards the identification of CVD risk in primary care has been opportunistic, for example, through the checking of blood pressure. However, in the last few years there has been a shift towards systematic identification. NICE clinical guideline 67 recommends a systematic approach to the identification of people aged 40–74 years who are likely to be at high risk of CVD, prior to a formal risk assessment.

For primary prevention, the practice is to address all other modifiable CVD risk factors before lipid modification therapy. NICE recommends statin therapy as part of the management strategy for the primary prevention of CVD for adults who have a 20% or greater 10-year risk of developing CVD. Risk is estimated using an appropriate risk calculator, or by clinical assessment in people for whom an appropriate risk calculator is not available or appropriate.

Current practice
The current QOF indicator PP1 incentivises cardiovascular risk assessment in those with a new diagnosis of hypertension, who constitute one of the major groups of people at risk of CVD.
The current QOF indicator PP2 incentivises lifestyle advice on increasing physical activity, smoking cessation, safe alcohol consumption and a healthy diet for those newly diagnosed with hypertension.

Statin therapy for people newly diagnosed with hypertension who are at increased risk of developing CVD is not currently incentivised through the QOF. The prescription of statins increases more noticeably with increasing socioeconomic deprivation than with increasing CVD prevalence.

The QOF already incentivises statin therapy through indicators CHD 8, DM17 and Stroke 8. For these indicators, statin therapy is incentivised by aiming to achieve or maintain a target of total cholesterol of 5 mmol/litre or less.

**NHS priorities and timeliness for guidance**

The NICE QOF team examined national clinical guidelines, policy documents and national strategies across the UK to assess timeliness of indicators in this topic area. The following were found to be of relevance:

- **The NHS in England: The operating framework for 2009/10** (Department of Health 2008)
- **Coronary heart disease: National service framework for coronary heart disease – modern standards and service models** (Department of Health 2000)
- **Risk estimation and the prevention of cardiovascular disease**. A national clinical guideline (Scottish Intercollegiate Guidelines Network 2007)
- Closing the gap: Tackling cardiovascular disease and health inequalities by prescribing statins and stop smoking services (Care Quality Commission 2009)
3 Review of recommendations

Summary of NICE guideline recommendations

One recommendation from NICE clinical guideline 67 (CG67) has been identified as being potentially suitable for QOF indicator development.

Drug therapy for primary prevention – statins

NICE recommendation 1.4.3 (NICE CG67)

Statin therapy is recommended as part of the management strategy for the primary prevention of CVD for adults who have a 20% or greater 10-year risk of developing CVD. This level of risk should be estimated using an appropriate risk calculator, or by clinical assessment for people for whom an appropriate risk calculator is not available or appropriate (for example, older people, people with diabetes or people in high-risk ethnic groups).

Clinical effectiveness

Statin therapy is effective in reducing fatal and nonfatal myocardial infarction (MI) and the composite outcome CHD death or nonfatal MI; fatal and nonfatal stroke; and revascularisation. In trials predominantly comprising primary prevention but including a minority of people with established CVD, meta-analysis found that statin therapy was associated with a reduction in the risk of all cause mortality, fatal and nonfatal MI and the composite outcomes of CHD death, nonfatal MI, fatal or nonfatal stroke and coronary revascularisation.

NICE clinical guideline 67 recommends that all other modifiable CVD risk factors (for example, alcohol, smoking status and blood pressure) should be considered and their management optimised if possible, before treatment with statin therapy is optimised.

The Guideline Development Group (GDG) for lipid modification found no clinical trials in primary prevention that had evaluated the relative and absolute benefits of cholesterol-lowering to different total and LDL cholesterol targets in relation to clinical events. Therefore the GDG decided that due to
the lack of evidence, it would not recommend the use of target levels of cholesterol for people at high risk of CVD.

Cost effectiveness
Cost-effectiveness analysis indicates that simvastatin 40 mg and pravastatin 40 mg are both cost effective options for the primary prevention of CVD and the GDG considered that they were the most effective preparations at the lowest acquisition cost.

4 Assessment of recommendations against current practice

Health inequalities
The guideline recommendations have considerable potential to reduce health inequalities through promoting the use of statin therapy to often under-treated people who are at increased risk of CVD (for example, women, people of South Asian origin, and those in lower socioeconomic groups). [Relevance to health inequalities: high]

Will implementation of these recommendations lead to cost-effective improvements in the delivery of primary care?

There is strong clinical and health economic evidence to support recommendation 1.4.3. The selection of an appropriate statin at an appropriate dose, in line with NICE guidance would represent cost-effective care. Additionally, the initiation of statin therapy for primary prevention of CVD with preparations at lowest acquisition cost represents good clinical practice and efficient use of resources.

5 Initial feasibility assessment
The current QOF indicator PP1 incentivises cardiovascular risk assessment for people newly diagnosed with hypertension. This would form the basis of identifying those at increased risk of developing CVD and subsequent
initiation of statin therapy. This proposed suggestion for indicator development is considered technically feasible.

6 Key considerations

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

- The Care Quality Commission has asked NICE to consider indicators incentivising the use of statins as a means to reducing health inequalities.
- Statin therapy for those newly diagnosed with hypertension who are at increased risk of developing CVD is considered feasible, is supported by evidence that is judged to be high, is likely to be cost effective and lead to a moderate change in practice.
- The current QOF indicator PP1 incentivises cardiovascular risk assessment for those people newly diagnosed with hypertension, to form the basis of identifying those at increased risk.
- High risk of developing CVD is defined as having a 10-year CVD risk of over 20%.
- The proposed suggestion presented in this briefing is considered to have the potential to help reduce health inequalities through the cost-effective prescription of statins.

Assessment against NICE’s prioritisation criteria

Cardiovascular disease and hypertension are considered to have population prevalence that is high and fully meets the criteria for diagnosis, treatment and monitoring in primary care (by general practitioners or directly employed practice staff).

Statin therapy for those newly diagnosed with hypertension and are at increased risk of developing CVD is considered feasible, is supported by evidence that is judged to be high, is likely to be cost effective and lead to a moderate change in practice.
## Appendix A: Evidence Summary

### Evidence summary of NICE clinical guideline CG67 selected recommendations

<table>
<thead>
<tr>
<th>NICE recommendation</th>
<th>Recommendation</th>
<th>Level of evidence</th>
<th>Key outcomes considered (for interventions)</th>
<th>Specific considerations highlighted by guideline developers (GDG/National Collaborating Centre)</th>
<th>Cost-effectiveness evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statins for primary prevention of CVD</strong></td>
<td>1.4.3 Statin therapy is recommended as part of the management strategy for the primary prevention of CVD for adults who have a 20% or greater 10-year risk of developing CVD. This level of risk should be estimated using an appropriate risk calculator, or by clinical assessment for people for whom an appropriate risk calculator is not available or appropriate (for example, older people, people with diabetes or people in high-risk ethnic groups).</td>
<td>RCTs and meta-analysis</td>
<td>Fatal and nonfatal MI. The composite outcome CHD death or nonfatal MI, fatal and nonfatal stroke and revascularisation, all cause mortality.</td>
<td>The NICE technology appraisal also considered whether statins differ in their relative effectiveness in the following population subgroups: in women compared with men at a similar level of cardiovascular risk; in people with diabetes compared to people without diabetes; or in people aged over 65 years compared with people aged under 65 years. Evidence from placebo controlled trials showed that statins do not differ in their relative effectiveness in these subgroups. No placebo-controlled trials were identified that provided information relating to people from different ethnic groups.</td>
<td>Cost-effectiveness analysis indicates that simvastatin 40 mg and pravastatin 40 mg are both cost effective options for the primary prevention of CVD and the GDG considered that they were the most effective preparations at the lowest acquisition cost.</td>
</tr>
</tbody>
</table>
Appendix B: Assessment of topic and recommendations against prioritisation checklist criteria status

This appendix provides assessment of the overall topic and recommendation 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**

This topic meets the prioritisation criteria for prevalence, primary care management and disease severity as outlined in 1A, 1B and 1C below.

<table>
<thead>
<tr>
<th>1A Population</th>
<th>The condition is considered to have population prevalence that is high</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>The condition is considered to have population prevalence that is medium</td>
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<tr>
<td></td>
<td>The condition is considered to have population prevalence that is low</td>
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</table>

<table>
<thead>
<tr>
<th>1B Management</th>
<th>Fully meets criteria</th>
<th>Partly meets criteria</th>
<th>Doesn't meet criteria</th>
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<tbody>
<tr>
<td>Score:</td>
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<td>[2]</td>
<td>[1]</td>
</tr>
<tr>
<td>The condition is diagnosed in primary care*</td>
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<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>The condition is treated in primary care*</td>
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<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>The condition is monitored in primary care*</td>
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<td>☐️</td>
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</table>

* by *general practitioners or directly employed practice staff*

<table>
<thead>
<tr>
<th>1C Disease severity</th>
<th>Scoring criteria</th>
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<tbody>
<tr>
<td>Score 1</td>
<td>Minor quality-of-life impact, no disability, limited morbidity impact</td>
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<tr>
<td>2</td>
<td>Definite quality-of-life impact, no disability, limited morbidity impact</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>3</td>
<td>Definite quality-of-life impact, some disability and/or intermediate morbidity impact</td>
</tr>
<tr>
<td>4</td>
<td>Definite quality-of-life impact, significant disability and/or significant morbidity impact</td>
</tr>
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</table>

**Recommendation Status**

The individual recommendations are assessed on feasibility, strength of clinical and cost-effectiveness evidence and expected change in practice.

<table>
<thead>
<tr>
<th>Feasibility of each recommendation</th>
</tr>
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<tbody>
<tr>
<td><strong>Dietary review</strong></td>
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<tr>
<td>NICE recommendation 1.4.3 (NICE CG67)</td>
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</table>

**Scores for each recommendation**

<table>
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<tr>
<th>Dietary Review</th>
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</thead>
<tbody>
<tr>
<td>NICE recommendation 1.4.3 (CG67)</td>
</tr>
</tbody>
</table>
Appendix D: Relevant recommendations from clinical guideline 67 Lipid modification

Drug therapy for primary prevention

1.4.2 Before offering lipid modification therapy for primary prevention, all other modifiable CVD risk factors should be considered and their management optimised if possible. Baseline blood tests and clinical assessment should be performed, and comorbidities and secondary causes of dyslipidaemia should be treated. Assessment should include:

• smoking status

• alcohol consumption

• blood pressure (see 'Hypertension', NICE clinical guideline 34)

• body mass index or other measure of obesity (see 'Obesity', NICE clinical guideline 43)

• fasting total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides (if fasting levels are not already available)

• fasting blood glucose

• renal function

• liver function (transaminases)

• thyroid-stimulating hormone (TSH) if dyslipidaemia is present.

Statins for primary prevention

1.4.3 Statin therapy is recommended as part of the management strategy for the primary prevention of CVD for adults who have a 20% or greater 10-year risk of developing CVD. This level of risk should be estimated using an appropriate risk calculator, or by clinical assessment for people for whom an
appropriate risk calculator is not available or appropriate (for example, older people, people with diabetes or people in high-risk ethnic groups).

1.4.4 The decision whether to initiate statin therapy should be made after an informed discussion between the responsible clinician and the person about the risks and benefits of statin treatment, taking into account additional factors such as comorbidities and life expectancy.

1.4.5 If statin treatment is appropriate, it should be offered as soon as practicable after a full risk factor assessment.

1.4.6 When the decision has been made to prescribe a statin, it is recommended that therapy should usually be initiated with a drug with a low acquisition cost (taking into account required daily dose and product price per dose).

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

1.4.8 Higher intensity statins should not routinely be offered to people for the primary prevention of CVD.

1.4.9 A target for total or LDL cholesterol is not recommended for people who are treated with a statin for primary prevention of CVD.

1.4.10 Once a person has been started on a statin for primary prevention, repeat lipid measurement is unnecessary. Clinical judgement and patient preference should guide the review of drug therapy and whether to review the lipid profile.

17 This recommendation has been taken from ‘Statins for the prevention of cardiovascular events’, NICE technology appraisal 94. See www.nice.org.uk/TA094

18 ‘Higher intensity statins’ are statins used in doses that produce greater cholesterol lowering than simvastatin 40 mg, for example simvastatin 80 mg.