Complete Summary

GUIDELINE TITLE

Risk estimation and the prevention of cardiovascular disease. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Risk estimation and the prevention of cardiovascular disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2007 Feb. 71 p. (SIGN publication; no. 97). [315 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates previous versions:

- Scottish Intercollegiate Guidelines Network. Secondary prevention of coronary heart disease following myocardial infarction. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2000 Jan. 26 p. (SIGN publication; no. 41).
- Lipids and the primary prevention of coronary heart disease. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 1999. 60 p. (SIGN publication; no. 40).

This guideline was issued in 2007 and will be considered for review in three years. Any updates to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

**** REGULATORY ALERT ****

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 2, 2007, Antidepressant drugs: Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

- March 2, 2005, Crestor (rosuvastatin calcium): Revisions to the WARNINGS, DOSAGE AND ADMINISTRATION, CLINICAL PHARMACOLOGY, and PRECAUTIONS sections of the labeling.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cardiovascular disease

GUIDELINE CATEGORY

Counseling
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present evidence-based interventions for risk estimation and prevention of primary and secondary cardiovascular disease

TARGET POPULATION

Patients at high risk for or with primary or secondary cardiovascular disease and the general population of Scotland

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment

1. Determination of cardiovascular risk in patients with and without symptoms of cardiovascular disease
2. Consideration of depression and social isolation or lack of quality social support when assessing individual risk

Prevention

1. Dietary changes, including recommendation of diets low in total and saturated fats, reduced salt intake, increased fruit and vegetable consumption, and weight reduction and maintenance interventions
2. Antioxidant vitamin supplementation (considered, but not recommended)
3. Recommendation of at least moderate levels of physical activity
4. Advise and support to stop smoking, including use of nicotine replacement or bupropion therapy and treatment of depression
5. Minimisation of exposure to passive smoking
6. Advise that moderate alcohol consumption may be protective against coronary heart disease or further coronary events
7. Interventions to reduce alcohol consumption if intake levels are hazardous to the patient's health
8. Antiplatelet therapy with aspirin, dipyridamole, or clopidogrel
9. Lipid lowering statin, fibrate, or nicotinic acid therapy
10. Blood pressure lowering with drug therapy and lifestyle advice
11. Psychological interventions, including cognitive behavioral therapy and motivational interviewing
12. Psychological interventions, including stress management training and use of the stages of change model alone (considered, but not recommended)

MAJOR OUTCOMES CONSIDERED

- Precision of estimate of cardiovascular disease (CVD) risk
- Risk of coronary heart disease (CHD)
- CVD mortality and morbidity
- Risk of in-hospital death and overall death or dependency
- Blood pressure
- Lipid profile
- Glucose handling
- Cardiovascular events, including CHD, stroke, peripheral arterial disease (PAD), myocardial infarction (MI)
- Smoking abstinence rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base for this guideline was synthesised in accordance with the Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Information Officer. Searches were focused on existing guidelines, systematic reviews, randomised controlled trials, and (where appropriate) observational and/or diagnostic studies. Databases searched include Medline, Embase, Cinahl, PsychINFO, and the Cochrane Library. The year range covered was 1999-2005. Internet searches were carried out on various websites including those for the Australian Centre for Clinical Effectiveness, National Institute for Health and Clinical Excellence, the National Library for Health, Swedish Council on Technology Assessment in Healthcare, US Agency for Healthcare Research and Quality, and the US National Guidelines Clearinghouse. The Medline version of the main search strategies can be found on the SIGN website, in the section covering supplementary guideline material. The main searches were supplemented by material identified by individual members of the development group. Each of the selected papers was evaluated by two members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g. case reports, case series)

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgment. The extent to which a study meets a particular criterion - e.g., an acceptable level of loss to follow up - and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN executive staff based on the quality assessments of individual studies provided by guideline development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook" (see "Availability of Companion Documents" field in this summary).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgment

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, SIGN has introduced the concept of considered judgment.

Under the heading of considered judgment, guideline development groups summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Directness of application to the target population for the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them)
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgment. Once they have considered these issues, the group is asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 6 of the companion document titled "SIGN 50: A Guideline Developers' Handbook" (see "Availability of Companion Documents" field).

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

COST ANALYSIS

Cost Effectiveness of Hypertension Therapy

In June 2006 the National Institute for Clinical Health and Excellence (NICE) and the British Hypertension Society (BHS) jointly released a revised evidence base to include recent meta-analyses and randomised clinical trials (RCTs) and included a cost effectiveness analysis comparing the various blood pressure lowering drug classes. The results showed that:

- Beta blockers were the least clinically and cost effective drug at preventing major cardiovascular events
- Calcium channel blockers and thiazide-type diuretics were the most clinically and cost effective choice for the majority of cases
- For people under the age of 55, drugs affecting the renin-angiotensin system are likely to be most effective

The recommendations based on this evidence are summarised in the A/CD algorithm shown in Figure 1 (see original guideline document).

The cost effectiveness of different targets for the reduction in blood pressure (BP) was analysed using clinical data from the Hypertension Optimal Treatment (HOT) trial. The trial randomised patients to three target groups for diastolic BP, with the hypothesis that the lower the target, the better the outcome but the higher the drug costs. The clinical trial showed no statistical difference in the number of events avoided for the three target groups. Significant reductions in event rates were found in a subset analysis of people with diabetes, which limited the cost effectiveness analysis to this group. The study concluded that in patients with diabetes, compared to maintenance doses of calcium channel blockers, intensive treatment to a lower blood pressure target ($\leq$80 mm Hg), was cost effective.

Also, please refer to Annex 2 in the original guideline document for a discussion on the cost effectiveness of statin therapy and cardiovascular disease (CVD) prevention programmes.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development.

Peer Review

All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of general practitioners (GPs) and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and

their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to a lay reviewer in order to obtain comments from the patient's perspective. The comments received from peer reviewers and others are carefully tabulated and discussed with the chairman and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. Each member of the guideline development group is then asked formally to approve the final guideline for publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC)*: In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the full-text guideline document.*

The grades of recommendations (A–D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Estimating Cardiovascular Risk

D - Individuals with symptoms of cardiovascular disease or who are over the age of 40 years and have diabetes (type 1 or 2) or familial hypercholesterolaemia should be considered at high risk (≥20% risk over ten years) of cardiovascular events.

D - Cardiovascular risk should be estimated at least once every five years in adults over the age of 40 years with no history of cardiovascular disease, familial hypercholesterolaemia or diabetes and who are not being treated for blood pressure or lipid reduction.

D - Asymptomatic individuals should be considered at high risk if they are assessed as having ≥20% risk of a first cardiovascular event over ten years.

D - Individuals at high cardiovascular risk warrant intervention with lifestyle changes and consideration for drug therapy, to reduce their absolute risk.

Diet

A - Diets low in total and saturated fats should be recommended to all for the reduction of cardiovascular risk.

A - People with hypertension should be advised to reduce their salt intake as much as possible to lower blood pressure.

C - Increased fruit and vegetable consumption is recommended to reduce cardiovascular risk for the entire population.

A - Antioxidant vitamin supplementation is not recommended for the prevention or treatment of coronary heart disease.

B - Patients, and individuals at risk of cardiovascular disease, who are overweight, should be targeted with interventions designed to reduce weight, and to maintain this reduction.

Physical Activity

B - Physical activity of at least moderate intensity (e.g., makes person slightly out of breath) is recommended for the whole population (unless contraindicated by condition).

B - Physical activity should include occupational and/or leisure time activity and incorporate accumulated bouts of moderate intensity activities such as brisk walking.

B - Those who are moderately active and are able to increase their activity should be encouraged to do so. Activity can be increased through a combination of changes to intensity, duration or frequency.

Smoking

B - All people who smoke should be advised to stop and offered support to help facilitate this in order to minimise cardiovascular and general health risks.

B - Exposure to passive smoking increases cardiovascular risk and should be minimised.

A - Nicotine replacement therapies or bupropion should be used as part of a smoking cessation programme to augment professional advice and increase long term abstinence rates.

B - Smokers with coronary heart disease and comorbid clinical depression should have their depression treated both for alleviation of depressive symptoms and to increase the likelihood of stopping smoking.

Alcohol

B - Patients with no evidence of coronary heart disease may be advised that light to moderate alcohol consumption may be protective against the development of coronary heart disease.

C - Patients with established coronary heart disease may be advised that light to moderate alcohol consumption may be protective against further coronary events.

A - Brief multi-contact interventions should be used to encourage patients to reduce their levels of drinking if their current intake is hazardous to their health.

Antiplatelet Therapy

A - Individuals with established atherosclerotic disease should be treated with 75 mg aspirin daily.

A - Individuals with a history of stroke or transient ischaemic attack and who are in sinus rhythm should be considered for low dose aspirin (75 to 300 mg daily) and dipyridamole (200 mg twice daily) to prevent stroke recurrence and other vascular events. If aspirin is contraindicated, or there are side effects, clopidogrel 75 mg daily is an alternative.

A - Asymptomatic individuals without established atherosclerotic disease but with a calculated cardiovascular risk of $\geq$20% over ten years should be considered for treatment with aspirin 75 mg daily.

Lipid Lowering

A - All adults over the age of 40 years who are assessed as having a ten year risk of having a first cardiovascular event $\geq$20% should be considered for treatment with simvastatin 40 mg/day following an informed discussion of risks and benefits between the individual and responsible clinician.

B - All patients with established symptomatic atherosclerotic cardiovascular disease should be considered for more intensive statin therapy following an informed discussion of risks and benefits between the individual and responsible clinician.

A - Individuals with hypertriglyceridaemia *(>1.7 mmol/l)* and/or low high density lipoprotein cholesterol level *(<1 mmol/l in men, or <1.2 mmol/l in women)* should be considered for treatment with a fibrate or niconitic acid.

A - Statins are the drugs of choice in the management of diabetic subjects with mixed dyslipidaemia and elevated low density lipoprotein cholesterol.

Blood Pressure Lowering

A - Individuals with sustained systolic blood pressures >140 mm Hg systolic and/or diastolic blood pressures >90 mm Hg and clinical evidence of cardiovascular disease should be considered for blood pressure lowering drug therapy.

A - Individuals with established cardiovascular disease, who also have chronic renal disease or diabetes with complications, or target organ damage may be considered for treatment at the lower threshold of systolic >130 mm Hg and/or diastolic >80 mm Hg.

B - Individuals with blood pressure greater than 160/100 mm Hg should have drug treatment and specific lifestyle advice to lower their blood pressure and risk of cardiovascular disease.

Psychological Issues

B - Depression and social isolation or lack of quality social support are risk factors for the development of and prognosis with coronary heart disease and should be taken into account when assessing individual risk.

A - Stress management training is not recommended as a technique to reduce coronary heart disease mortality or morbidity or conventional risk factors. It may have a role in improving patients' mood, including depressed mood.

A - Cognitive behaviour therapy should be considered for increasing physical function and improving mood in patients with coronary heart disease.

A - Use of the stages of change model alone is not recommended as a method for changing the health behaviour of individuals with coronary heart disease.

B - Motivational interviewing should be considered in patients with cardiovascular disease who require to change health behaviours including diet, exercise, alcohol and compliance with treatment.

Definitions:

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; *or*

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g. case reports, case series)

4: Expert opinion

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document titled, "The British Hypertension Society A/CD algorithm for blood pressure."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate risk estimation and prevention of cardiovascular disease

POTENTIAL HARMS

- Although it is generally accepted that the benefits of activity greatly outweigh the risks, there is some evidence of increased risk with activity, particularly in those who are currently sedentary. It has been suggested that those with low levels of habitual vigorous activity are twice as likely to suffer sudden cardiac death during or after exercise compared to those with high levels of habitual activity.
- Serious adverse effects using bupropion at the doses indicated for smoking cessation are rare (less than one per 1,000 treated).
- Aspirin increases the risk for haemorrhagic strokes by about 40% and of major gastrointestinal bleeding by 70%. Enteric coated products do not prevent the major gastrointestinal complications of aspirin therapy and are significantly more expensive than the standard dispersible formulation.
- Raised levels of liver enzymes (aspartate and alanine aminotransferase) to more than three times their upper normal limit occur in fewer than 1% of subjects treated across the dose range of the marketed statins, with the exception of atorvastatin administered at maximal (80 mg) dose and combination statin and ezetimibe therapy. This effect is completely reversible upon withdrawal of treatment. Minor muscle discomfort is common with statin therapy, though its incidence varies. Myopathy, with raised levels of creatine kinase to more than ten times the upper normal limit, though more serious, is rare, occurring in less than one in 1,000 subjects. Rhabdomyolysis, in which myopathy is associated with end organ (renal) damage is even rarer, with a frequency of less than 1 in 10,000 per year of exposure to statins. Withdrawal of therapy leads to recovery in the majority of cases, although deaths have been reported in some subjects suffering from pathology of several systems and receiving multiple concomitant drug therapies.

  Statins interact with a number of other medications. The risk of myopathy increases when statins are used in combination with fibrates (e.g., gemfibrozil) or nicotinic acid (niacin) and they should only be used concomitantly under specialist supervision.

  Some statins (particularly atorvastatin and simvastatin) are metabolised by cytochrome P450 and concomitant use of other potent inhibitors of this enzyme (e.g., 'azole' anti-fungal agent and human immunodeficiency virus [HIV] protease inhibitors) may increase plasma levels of these statins and increase the risk of adverse effects, such as rhabdomyolysis. The risk of serious myopathy is also increased when high doses of simvastatin are combined with less potent cytochrome P450 inhibitors, including amiodarone, verapamil, and diltiazem. The consumption of even modest quantities of grapefruit juice can significantly increase exposure to simvastatin, increasing the risk of serious myopathy. Patients taking atorvastatin should also avoid drinking large quantities of grapefruit juice. These concerns do not apply to fluvastatin, which is metabolised by a different cytochrome P450 enzyme, or to pravastatin and rosuvastatin, which are not substantially metabolised by cytochrome P450.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Statins are contraindicated in patients with active liver disease (or persistently abnormal liver function tests), in pregnancy (adequate contraception is required during treatment and for one month afterwards), in and patients who are breast-feeding.
- Simvastin is contraindicated with concomitant use of medications that influence cytochrome P450 metabolism.
- Angiotensin-converting enzyme (ACE) inhibitors or angiotensin-II receptor antagonists (ARBs) are contraindicated in women of childbearing potential.
- Nortriptyline is not licensed for use in smoking cessation and is contraindicated in patients with recent myocardial infarction or arrhythmias (particularly heart block).

QUALIFYING STATEMENTS

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- This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.
- Alcohol is known to have both beneficial and harmful effects on the biochemical basis for coronary heart disease (CHD) and the psychological consequences of the disease. The adverse effects of alcohol on other clinical conditions (e.g., mental health, liver disease, cancer risk, and societal effects) have not been reviewed in this guideline and should be taken into account when advice is provided in the clinical setting. Long term alcohol related health consequences are now giving rise to serious concerns in Scotland. Consuming over 40 g/day alcohol increases a man's risk for liver disease, raised blood pressure, some cancers (for which smoking is a confounding factor) and violent death. For women, consuming over 24 g/day average alcohol increases their risk for developing liver disease and breast cancer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Services (NHS) Board and is an essential part of clinical governance. It is acknowledged that every Board cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is

reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Key points for audit are identified in the original guideline document.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Chart Documentation/Checklists/Forms
Clinical Algorithm
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Sep (revised 2007 Feb)

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr James Grant (*Chair*) General Practitioner, Auchterarder; Mrs Brenda Anderson, Cardiac Rehabilitation Co-ordinator, Aberdeen Royal Infirmary; Mrs Mandy Andrew Tayside, Managed Clinical Network Manager, CHD, Dundee; Professor Christine Bond, Consultant in Pharmaceutical Public Health, University of Aberdeen; Dr Adrian Brady, Consultant Cardiologist, Glasgow Royal Infirmary; Dr Neil Campbell, Reader in General Practice, Department of General Practice and Primary Care, University of Aberdeen; Ms Joyce Craig, Senior Health Economist, NHS Quality Improvement Scotland; Dr John Dick, Consultant Physician, Ninewells Hospital, Dundee; Dr Penelope Fraser, Consultant Clinical Psychologist, Ninewells Hospital, Dundee; Mr James Grant, Lay Representative, Balerno; Ms Marianne Hayward, Managed Clinical Network Manager for diabetes, Greater Glasgow Health Board; Dr Matthew Lowther, Heart Health Network Co-ordinator, NHS Health Scotland; Dr Jill Murie, General Practitioner Principal, Forth; Dr Moray Nairn, Programme Manager, SIGN Executive; Professor Rudolph Riemersma, Consultant Biochemist, University of Edinburgh; Ms Ann Ross, Physiotherapist, Western Infirmary, Glasgow; Mr Duncan Service, Senior Information Officer, SIGN Executive; Dr Indrani Sinnak-Aruppan, Consultant Clinical (Neuro and Health) Psychologist, Ayrshire Central Hospital; Mr Roger Stableford, Lay Representative, Falkirk; Ms Nicola Stuckey, Consultant Clinical Psychologist, Astley Ainslie Hospital, Edinburgh; Ms Joan Thain, Cardiac Rehabilitation Health Visitor, Westburn Centre, Aberdeen; Dr Deborah Tinson, Consultant Clinical Psychologist, Astley Ainslie Hospital, Edinburgh; Dr Iain C Todd, Consultant in Cardiovascular Rehabilitation, Astley Ainslie Hospital, Edinburgh

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates previous versions:

- Scottish Intercollegiate Guidelines Network. Secondary prevention of coronary heart disease following myocardial infarction. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2000 Jan. 26 p. (SIGN publication; no. 41).
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This guideline was issued in 2007 and will be considered for review in three years. Any updates to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Heart disease. Scottish Intercollegiate Guidelines Network, 2007 Feb. 31 p. Available in Portable Document Format (PDF) from the SIGN Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.
- Management of coronary heart disease: A national clinical and resource impact assessment. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2007 Feb. 120 p. Available in Portable Document Format (PDF) from the SIGN Web site.
- Excel spreadsheets to assist health boards to estimate their local costs (used in conjunction with the national clinical and resource impact assessment). Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2007 Feb. Available from the SIGN Web site.

PATIENT RESOURCES

The following is available:

- Prevention of cardiovascular disease for patients. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2007 Feb. 28 p.

Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site. Urdu translation is also available from the SIGN Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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Readers with questions regarding guideline content are directed to contact the guideline developer.

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