Complete Summary

GUIDELINE TITLE

Statins for the prevention of cardiovascular events.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Statins for the prevention of cardiovascular events. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan. 45 p. (Technology appraisal guidance; no. 94).

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

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

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

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Cardiovascular disease

- Coronary heart disease (CHD) (also known as coronary artery disease or ischaemic heart disease)
- Transient ischaemic attack (TIA) and stroke
- Peripheral arterial disease (PAD)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Prevention

CLINICAL SPECIALTY

Cardiology
Family Practice
Geriatrics
Internal Medicine
Neurology
Pharmacology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical and cost effectiveness of statins for the primary and secondary prevention of cardiovascular events

TARGET POPULATION

- Adults with clinical evidence of cardiovascular disease (CVD)
- Adults considered to be at risk of CVD

Note: Adults with genetic dyslipidaemias (for example, familial hypercholesterolaemia) are not included.

INTERVENTIONS AND PRACTICES CONSIDERED

Statin therapy (i.e., atorvastatin, fluvastatin, pravastatin, rosuvastatin and simvastatin)

MAJOR OUTCOMES CONSIDERED

- Cost effectiveness
- Clinical effectiveness
    - All-cause mortality
    - Cardiovascular mortality
    - Coronary heart disease (CHD) mortality
    - Stroke mortality
    - Other cardiovascular events (e.g. nonfatal myocardial infarction [MI], angina, surgical revascularisation, non-fatal stroke)
    - Adverse events
    - Health-related quality of life
    - Data relating to surrogate end-points (such as total, low-density lipoprotein [LDL] and high-density lipoprotein [HDL] cholesterol)

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
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by The University of Sheffield, School of Health and Related Research [ScHARR]. (See the "Availability of Companion Documents" field.)

Clinical Effectiveness

Search Strategy

The search aimed to identify all literature relating to the clinical effectiveness of statins for the prevention of coronary events. The main searches were conducted between November 2003 and April 2004.

Sources Searched

Nine electronic bibliographic databases were searched (Medline, EMBASE, Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CCTR), Database of Abstracts of Reviews of Effects (DARE), Science Citation Index, NHS Economic Evaluation Database (NHS EED), Health Technology Assessment Database (NHS HTA) and CINAHL). In addition, the reference lists of relevant articles and sponsor submissions were handsearched.

Search Terms

A copy of the Medline search strategy is included in Appendix 1 of the Assessment Report (see "Availability of Companion Documents" field). Search strategies for the other databases are available on request.

Search Restrictions

No language, study/publication, or date restrictions were applied to the main searches.

Inclusion and Exclusion Criteria

Inclusion Criteria

Participants: adults (defined as age ≥18 years) with, or at risk of, coronary heart disease

Interventions:

- Atorvastatin
- Fluvastatin
- Pravastatin
- Rosuvastatin
- Simvastatin

Comparators:

- Placebo
- Other statins
- 'Usual care'
- 'No statin treatment'

Outcome Measures: see "Major Outcomes Considered" field in this summary.

Methodology:

- Randomised controlled trials of at least 6 months' (defined as 26 weeks) duration. Trials were accepted as randomized controlled trials (RCTs) if the allocation of subjects to treatment groups was described by the authors as either randomised or double-blind.

Exclusion Criteria

- Studies considered methodologically unsound
- Studies of multi-interventional therapies where the effect of the statin could not be separated out.

Refer to the Assessment Report (see "Availability of Companion Documents" field in this summary) for discussion related to *interventions, comparators, outcome measures*, *adverse effects*, *continuance and compliance, and methodology*.

Sifting

The references identified by the literature searches were sifted in three stages. All studies were first screened for relevance by title, and the abstracts of those which were not excluded at this stage were read. Finally, all studies which seemed from their abstracts to be potentially relevant were obtained for a full reading (for studies which did not provide abstracts, the full studies were screened).

Economic Analysis

The primary objective of this review is to identify and evaluate studies exploring the cost effectiveness of statins in primary and secondary prevention of coronary heart disease (CHD) and cardiovascular disease (CVD) in the United Kingdom (UK). The secondary objective is to evaluate methodologies used to inform our own economic evaluation.

Search Strategy

Studies were identified through searches of MEDLINE (1996-present), EMBASE (from 1996), Cochrane Database of Systematic Reviews (CDSR), and the NHS Centre for Reviews and Dissemination databases (Database of Abstracts of Reviews of Effectiveness [DARE], National Health Service Economic Evaluation Database [NHS EED], HTA).

Inclusion and Exclusion Strategy

The titles and abstracts of papers identified through the searches outlined above were assessed for inclusion using the following criteria:

Inclusion Criteria

- Cost-effectiveness analyses – as opposed to cost-benefit or cost minimisation
- United Kingdom (UK) setting
- Statin therapy as one of the studied alternatives (possibly combined with other interventions such as lifestyle advice/diet)
- The benefits were estimated in terms of life-years saved (LYS) or quality adjusted lifeyears (QALYs)
- Adult populations
- The study was fully published in English

Exclusion Criteria

- Studies that adapted published evaluations for other settings
- Studies not considered methodologically sound
- Studies that did not report results in sufficient detail

Reviews discussing cost-effectiveness studies of statin treatment were not included in this review but were retained for use in discussion. Non UK cost-effectiveness studies were retained and used to inform on possible modelling methodologies.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

One hundred fifty seven articles were identified relating to 40 randomised controlled trials which met the inclusion criteria.

Cost Effectiveness

The Assessment Group identified five published economic evaluations that assessed the cost effectiveness of statin therapy in a United Kingdom (UK) setting and expressed outcomes in terms of life years gained (LYG) or quality-adjusted life years (QALYs). In addition, five manufacturers submitted economic evidence (four developed economic models), and the Assessment Group also developed its own economic model.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by The University of Sheffield, School of Health and Related Research [ScHARR]. (See the "Availability of Companion Documents" field in this summary.)

Clinical Effectiveness

Data Extraction Strategy

Data were extracted by one reviewer, using a customized data extraction form based on that proposed by the NHS Centre for Reviews and Dissemination. Extracted data were checked by another reviewer.

Where available, the following data were reviewed:

- All-cause mortality
- Cardiovascular disease (CVD) mortality
- Coronary heart disease (CHD) mortality
- Stroke mortality
- Fatal myocardial infarction (MI)
- Nonfatal MI
- Unstable angina
- Stable angina
- Transient ischaemic attack
- Peripheral arterial disease
- Coronary artery bypass graft (CABG)
- Percutaneous transluminal coronary angioplasty (PTCA)
- Quality of life
- Adverse effects
- Continuance and compliance

Quality Assessment Strategy

The quality of randomised controlled trials was assessed according to criteria based on those proposed by the NHS Centre for Reviews and Dissemination.

Meta-Analysis Strategy

Studies which met the review's entry criteria were eligible for inclusion in the meta-analyses provided that they reported outcomes in terms of the number of subjects suffering clinical outcomes, as only this would allow calculation of the relative risk of subjects in the intervention group developing each outcome, compared with subjects in the control group. Studies which reported only numbers of events, or event rates (i.e. numbers of events per hundred or thousand patient years), could not be included in the meta-analyses as this would have violated the basic statistical assumption that the occurrence of one event does not increase the likelihood of a subsequent event: once a subject has suffered one cardiovascular event, the risk of a subsequent event increases. It was obviously also impossible to include in the meta-analyses studies which only presented results in the form of relative risks, relative hazards or odds ratios, without the underlying numbers. Because of the number of relevant studies, and the tight timescale of the review, it was not considered feasible to contact the authors for missing data.

Meta-analysis was carried out using Review Manager. The random-effects model was used, to allow generalisation beyond the sample of patients represented by the studies included in the meta-analysis; this model also provides wider, more conservative, confidence intervals than the fixed-effects model. Unless stated otherwise, relative risks for individual studies have also been calculated using Review Manager.

Absolute risks and numbers needed to treat have also been calculated for some key outcomes, using GraphPad. Both of these statistics involve a time element: they indicate the absolute risk of an event, or the number needed to treat to avoid an event, over a specific period of time. Consequently, it is not possible to include studies of different lengths in these analyses, which have therefore been carried out only for key studies of primary and secondary coronary heart disease (CHD) prevention.

In the above series of meta-analyses the data on the trials on each outcome is analysed separately. The implication of this is that the impact of statins on each outcome is independent. In order to incorporate correlations between outcomes in the economic analyses a Bayesian meta-analysis has also been undertaken. This analysis has the advantage that the relative risks can be defined in a form suitable for inclusion in the economic modelling, that is in terms of the relative risks conditional on no death.

The Bayesian meta-analysis provides distributions of relative risks of various events for treatment versus control. The events considered were cardiovascular disease (CVD) death, CHD death, non-fatal stroke, non-fatal myocardial infarction (MI) and unstable angina.

The five events were considered separately and the same underlying probability model was used in each case. For more information related to the meta-analysis, refer to the Assessment Report (see "Availability of Companion Documents" in this summary).

Cost Effectiveness

Quality Assessment Strategy

The quality of studies was assessed using a combination of key components of the British Medical Journal checklist for economic evaluations together with the Eddy checklist on mathematical models employed in technology assessments.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies

representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The Assessment Group identified five published economic evaluations that assessed the cost effectiveness of statin therapy in a United Kingdom (UK) setting and expressed outcomes in terms of life years gained (LYG) or quality-adjusted life years (QALYs). In addition, five manufacturers submitted economic evidence

(four developed economic models), and the Assessment Group also developed its own economic model.

For a detailed discussion of the cost effectiveness analysis, including published studies, manufacturers' analyses, and the Assessment Group's model, see Section 4.2 of the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This guidance relates only to the initiation of statin therapy in adults with clinical evidence of cardiovascular disease (CVD) and in adults considered to be at risk of CVD. It assumes that other strategies for managing CVD risk are being appropriately considered when initiating statin therapy. The guidance does not include specific advice for genetic dyslipidaemias (for example, familial hypercholesterolaemia). The guidance relates only to the use of statins within their licensed indications.

A clinical guideline on cardiovascular risk assessment is currently in development (expected date of publication: September 2007). This guidance should be read in the context of the clinical guideline when it is available.

1. Statin therapy is recommended for adults with clinical evidence of CVD.
2. 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 CVD risk should be estimated using an appropriate risk calculator, or by clinical assessment for people for whom an appropriate risk calculator is not available (for example, older people, people with diabetes or people in high-risk ethnic groups).
3. Within the recommendations outlined in Section 1 (above) and Section 2 (above), the decision whether to initiate statin therapy should be made after

an informed discussion between the responsible clinician and the individual about the risks and benefits of statin treatment, and taking into account additional factors such as comorbidities and life expectancy.

4. 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).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of statins for the prevention of cardiovascular events

POTENTIAL HARMS

Adverse events associated with statins include headache, altered liver function, paraesthesia and gastrointestinal effects (including abdominal pain, flatulence, diarrhoea, nausea and vomiting). Rash and hypersensitivity reactions have been reported but are rare. Muscle effects (myalgia, myositis and myopathy) have also been reported with the use of statins. Severe muscle damage (rhabdomyolysis) is a very rare but significant side effect.

Further adverse events are associated with individual statins. For full details of side effects and contraindications, see the Summaries of Product Characteristics available at http://emc.medicines.org.uk/.

CONTRAINDICATIONS

CONTRAINDICATIONS

Not specifically stated

For full details of adverse effects, contraindications and interactions, see the Summaries of Product Characteristics available at http://emc.medicines.org.uk/.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

1. National Health Service (NHS) organisations and all clinicians who care for people who have cardiovascular disease (CVD) or who are at risk of CVD should review their current practice and policies to take account of the guidance (see the "Major Recommendations" field).
2. Local guidelines or care pathways for people with CVD or people who are at risk of CVD should incorporate the guidance.
3. To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document. The criteria relate only to the initiation of statin therapy in adults.
    a. Statin therapy is prescribed for adults with clinical evidence of CVD.
    b. Statin therapy is prescribed as part of the management strategy for the primary prevention of CVD for adults who are at risk, defined as having a 20% or greater 10-year risk of developing CVD as estimated by an appropriate risk calculator or after a clinical assessment for people for whom an appropriate risk calculator is not available.
    c. The decision whether to initiate statin therapy for adults with clinical evidence of CVD or as part of the management strategy for the primary prevention of CVD for adults who are at risk (see Sections 3a and 3b [above]) is made on an individual basis after informed discussion between the responsible clinician and the individual about the risks and benefits of statin treatment, and taking into account other factors.
    d. When the decision has been made to prescribe a statin, therapy is usually initiated with a drug with a low acquisition cost.

4. Local clinical audits on the care of patients with CVD could also include criteria for the management of CVD based on the national standards, including standards in the National Service Framework (NSF).

IMPLEMENTATION TOOLS

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)

National Institute for Health and Clinical Excellence (NICE). Statins for the prevention of cardiovascular events. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan. 45 p. (Technology appraisal guidance; no. 94).

ADAPTATION

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

DATE RELEASED

2006 Jan

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Statins for the prevention of cardiovascular events. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan. 2 p. (Technology appraisal 94). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Costing template and costing report. Statins for the prevention of cardiovascular events. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan. Various p. (Technology appraisal 94). Available in Portable Document Format (PDF) from the NICE Web site.
- Statins for the Prevention of Coronary Events. Assessment report. The School of Health and Related Research (ScHARR), University of Sheffield. 2005 Jan 12. Electronic copies: Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0971. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Statins for the prevention of cardiovascular events. Understanding NICE guidance – information for people who have or are at increased risk of cardiovascular disease, their families and the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan. 7 p. (Technology appraisal 94).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N0972. 11 Strand, London, WC2N 5HR.

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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