# Developing primary care review criteria from evidence-based guidelines: coronary heart disease as a model

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*SUMMARY*

***Background:*** *National Health Service (NHS) initiatives such as Clinical Governance, National Service Frameworks and the National Institute of Clinical Excellence (NICE) clinical guidelines programme create demand for tools to enable performance review by healthcare professionals. Ideally such tools should enable clinical teams to assess quality of care and highlight areas of good practice or where improvement is needed. They should also be able to be used to demonstrate progress towards goals and promote quality, while not unnecessarily increasing demand on limited resources or weakening professional control.*

***Aim:*** *To formulate and evaluate a method for developing, from clinical guidelines, evidence-based review criteria that are prioritised, useful and relevant to general practices assessing quality of care for the primary care management of coronary heart disease (CHD).*

***Design of study:*** *A two-stage study comprising, first, a review of available evidence-based guidelines for CHD and, second, the definition and prioritisation of associated review criteria from the most highly rated guidelines.*

***Setting:*** *Primary healthcare teams in England.*

***Methods:*** *Using structured methods, evidence-based clinical guidelines for CHD were identified and appraised to ensure their suitability as the basis for developing review criteria. Recommendations common to a number of guidelines were prioritised by a panel of general practitioners to develop review criteria suitable for use in primary care.*

***Results:*** *A standardised method has been developed for constructing evidence-based review criteria from clinical guidelines. A limited, prioritised set of review criteria was developed for the primary care management of CHD. This was distributed around the NHS through the Royal College of General Practitioners for use by primary care teams across the United Kingdom.*

***Conclusion:*** *Developing useful, evidence-based review criteria is not a straightforward process, partly because of a lack of consistency and clarity in guidelines currently available. A method was developed which accommodated these limitations and which can be applied to the development and evaluation of review criteria from guidelines for other conditions.*

***Keywords:*** *Audit; guidelines; review criteria; primary care; coronary heart disease (CHD); evidence-based practice.*

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## Introduction

RECENT United Kingdom (UK) government initiatives, such as Clinical Governance, National Service Frameworks[1] and the proposed new contract for general practitioners, are promoting a culture of effective practice and greater accountability within the National Health Service (NHS). For clinicians and managers alike there is an increased demand to demonstrate good practice, or at least progress towards achieving good practice.[2]

Clinical practice guidelines are viewed by the NHS as useful tools for promoting evidence-based practice,[3,4] and the National Institute for Clinical Excellence (NICE) is commissioning an array of disease-specific, evidence-based clinical guidelines on behalf of the Department for Health for England and the National Assembly for Wales.[1] Each NICE guideline will be accompanied by an audit tool, which includes review criteria, to support attempts to evaluate the quality of care being provided in conformance with the guideline recommendations.

Although low rates of uptake of clinical guidelines have so far been reported,[5,6] research has suggested that, among other implementation strategies, audit and feedback can be successful ways of increasing uptake of guidelines and, by implication, supporting evidence-based practice.[7,8] Recently, however, Baker and colleagues found no difference in usage rate between guidelines and review criteria when the criteria were prioritised on the grading of the evidence in the guideline recommendations.[9] Nevertheless, if guideline-based review criteria could be developed in a standardised manner by taking both the evidence and the views of users into account, the resultant product may be relevant and practical enough to guide care management and as the basis for a quality improvement programme.

A number of methods have been proposed for developing the measurement tools to support clinical audit and evaluation. The use of routinely collected data to support monitoring systems[10] has been proposed, with some success in field testing.[11] Campbell and colleagues[12] worked face-to-face with clinical panels, providing them with evidence of clinical effectiveness and then using the RAND appropriateness method to develop record-review criteria based on the requirements of necessity and appropriateness. This method was replicated in New Zealand[13] and was found to be valid and reliable, as were the criteria developed in the UK.[14] A review of the range of methods available for developing quality improvement assessment tools for primary care has recently been completed[15] and review criteria have also been characterised by Hearnshaw and colleagues.[16]

For the NHS clinical guideline programme in England and

**HOW THIS FITS IN**

*What do we know?*

There is an increasing requirement to monitor quality of care. There is an over-abundance of information defining what is quality care. This identified a need for a practical and relevant review tool based on clinically important areas.

*What does this paper add?*

A method has been developed for constructing evidence-based review criteria from clinical guidelines that would be useful to general practice in meeting its clinical governance requirements.

Wales, NICE will publish review criteria based directly on the recommendations of each guideline.[4] However, just as guidelines must meet standards of validity and reliability,[17] review criteria must themselves meet a number of standards. They should:

- Be an accurate reflection of the guideline
- Be based on research evidence
- Be based on measurable data and address areas that are appropriate to, and important in, the clinical setting.[9,18,19]

Questions of importance, relevance and appropriateness are likely to be particularly problematic for primary care, which is the subject of many national guidelines, where overload is a real difficulty and where evidence of clinical effectiveness is often not available.

The US Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research)[18] noted that evaluation tools can be developed from any guideline, provided that:

1. The recommendations are rigorously developed
2. The recommendations are evidence based and relate to health outcomes
3. There is clarity about the source(s) from which the review criteria are derived.[20]

However, there are many recommendations within a guideline, and care needs to be taken to avoid an overload of performance measures — a problem that previously led to what Davies[21] termed 'paralysis of analysis'.

Furthermore, however well-developed the measures, concerns have been expressed over the actual use of review criteria and other performance measures. Such measures have been seen by a number of authors to have significant potential for misuse; for example, by diminishing physician 'control', leading to a lack of flexibility in care decisions and creating a substantial increase in workload and demand on time.[21–25]

There have been some attempts to design a uniform approach to developing guideline-based review criteria. Bradley *et al*[26] developed the process for selecting guideline recommendations from which to develop review criteria by identifying areas of consensus in guidelines and consulting experts in quality indicators, to derive a prioritised list of indicators. The process of incorporating expert opinion was also used by Hadorn *et al*[22] to select guideline-based review criteria founded on physician ratings of importance applied to quality of care and feasibility of monitoring.

In the context of a national policy to use guidelines as a basis for care in the NHS, this paper explores the development of a standardised approach for constructing clinical guideline-based review criteria for use in assessing the quality of primary care. Review criteria can have a number uses in clinical practice (Box 1).

The aim of the study was to formulate and evaluate a method for developing a prioritised, limited set of guideline-derived review criteria that are practical, useful and relevant in everyday practice. Practical means, in this case, a limited set of criteria, which also allows some choice to be made in relation to the level of information required and the aspect of care under study. Primary care management of coronary heart disease (CHD) is the model reported here but the methods are applicable to other conditions. The project was undertaken as part of the Royal College of General Practitioners Clinical Practice Evaluation Programme (CPEP).

## Method

The process of developing review criteria involved eight stages (see Figure 1), described below under two headings: 1) The derivation of aspects of care (stages 1–6) and 2) The prioritisation and development of review criteria (stages 7 and 8).

### *Derivation of aspects of care*

Existing evidence-based guidelines on the management of CHD in primary care were identified through a structured literature search of guideline databases and major journals, and known guideline producers, between December 1998 and November 1999.

Additionally, UK and worldwide Internet sources of guidelines published in English were identified and searched. Initially, a broadly inclusive search was undertaken which also identified some sets of review criteria which had a good-quality evidence base included with the criteria. The three important aspects of CHD covered by the guidelines were identified as primary care management of heart failure, stable angina and post-myocardial infarction care. Guidelines identified by the search were critically appraised to determine those suitable for use in primary care and those that also reached minimum quality criteria (Box 2). All guidelines meeting the initial quality screen were then subjected to a more detailed second stage of the appraisal process,

- Facilitating clinical audit (single- or multi-practice, primary care–secondary care interface)
- Undertaking a baseline assessment of the quality of care for CHD (and the quality of practice data)
- Acting as the basis for setting local standards of care for CHD (with or instead of the relevant guideline)
- Acting as a prompt for clinicians during consultations
- Material for local continuing professional development

*Box 1. Uses for primary care review criteria.*

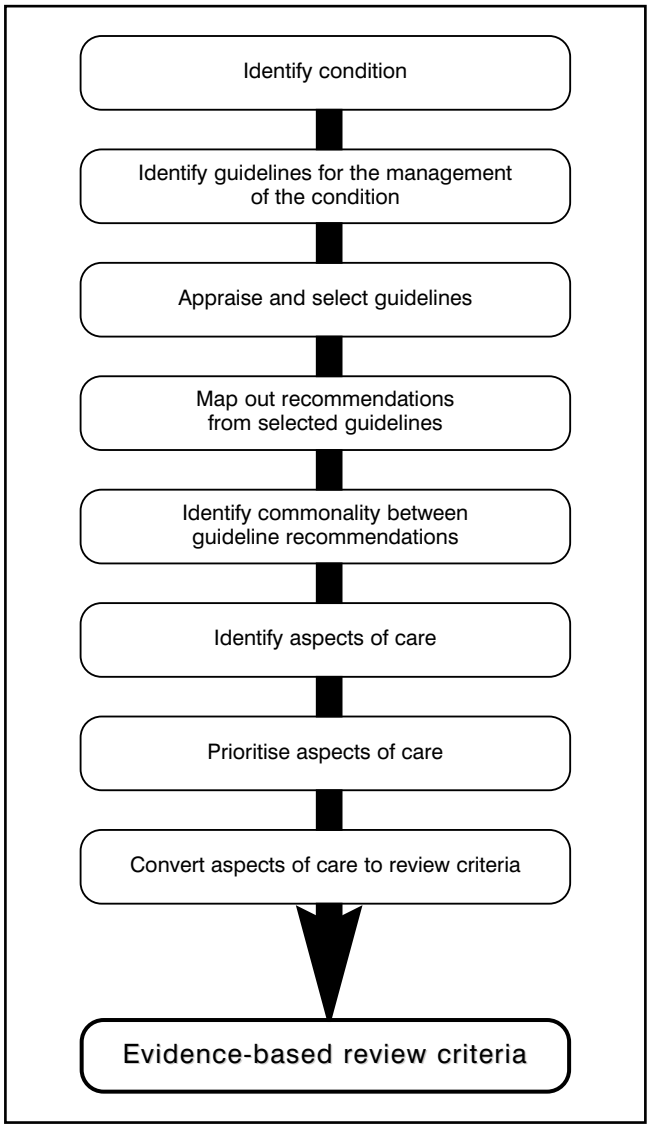


*Figure 1. Overview of the CPEP method for developing review criteria.*

based on an early version of the AGREE instrument,[27] to differentiate the quality of the guidelines. These were then ranked according to their rating.

The guideline that ranked highest in each clinical area was termed the 'principal' guideline and this had the greatest influence on the choice of recommendations from which the review criteria were constructed. None of the guidelines that ranked highest were accompanied by review criteria in the source documents.

In an attempt to ensure that a usable number of criteria addressing the most important areas of care could be produced, the project objectives required, where possible, some consensus between the recommendations on the most important clinical areas for each condition. Clinical practice recommendations were selected from all the guidelines that passed the appraisal process. These were then compared to identify recommendations common to more than one guideline. The recommendations were also mapped against the areas of care identified in the CHD

**Development**
1. Is the agency responsible for the development of the guidelines clearly identifiable?
2. Are the objectives of the guideline clearly defined?
3. Was the guideline independently reviewed before its publication/release?

**Evidence**
4. Are the sources of information used to select the evidence adequate and explicit?
5. Is there an explicit link between the major recommendations and the level of supporting evidence?

*Box 2. Initial CPEP guideline appraisal questions.*

National Service Framework.[28] If the National Service Framework identified an area of care only covered by one guideline, the recommendations relating to this area of care from this single guideline were used, because of the relevance to clinical practice.

Finally, a list of 'aspects of care' was produced from which to derive the review criteria, using the wording of recommendations from the principal guideline, supported by recommendations from the other (supplementary) guidelines. A statement of evidence was prepared for each key aspect of care, based on evidence reported in the principal guideline. Evidence that was cited in the principal and supplementary guidelines, but not given an evidence rating by the original authors, was sought out and then rated according to the method used in the North of England guideline on heart failure.[29]

### *Prioritisation and development of review criteria*

To ensure that the review criteria were meaningful (practical and useful) to everyday practice, the aspects of care were prioritised according to perceived clinical importance by three panels of over 60 UK general practitioners, selected from 120 who had registered an interest in the project. Because of the size and geographical distribution of the panel, a postal questionnaire method was used to gather clinical opinion, rather than using a face-to-face approach. The aspects of care were presented to panel members who were asked to rate each one according to clinical importance, using a simple weighting scale. Respondents were asked to allocate 20 points in total between all of the aspects of care (of uneven number), with more points allocated to indicate perceived greater clinical importance of the aspect of care.

The stable angina aspects of care were ranked by 65 general practitioners, heart failure by 60 general practitioners and post-myocardial infarction by 63 general practitioners. The aspects of care were collated, ranked and grouped into three clinically meaningful categories — prevention/clinical assessment, advice, and therapy.

Finally, the aspects of care were adapted to form review criteria with wording that was suitable for clinical record review. This involved converting each individual-based aspect of care to a population level measure, that is, the proportion of the relevant population who had received (or been offered) a particular element of care. Three independent general practitioners, who were not panel members, were

then asked to identify whether any of the prioritised criteria were unsuitable for use in clinical practice, in terms of the practicality of data collection.

## Findings

### *Derivation of aspects of care*

The literature search identified existing guidelines relating to the three major elements of CHD — eight for stable angina, 12 for heart failure, and eight for post-myocardial infarction care (28 guidelines in all). There was considerable variation in quality as judged by the appraisal instruments. In particular, it was often difficult to identify a link between quoted evidence and the guideline recommendations. On the basis of initial appraisal, 12 guidelines were identified as suitable for use within the project — stable angina,[12,30,31,32] heart failure,[29,32,33,34] and post-myocardial infarction care.[32,35,36,37] Following more detailed appraisal it was possible to rank the selected guidelines as judged by the two-stage appraisal process, identifying three 'principal' guidelines.[29,30,35] Aspects of care reflecting recommendations common to at least two guidelines for each condition comprised 11 aspects of care for stable angina, 7 for heart failure and 8 for post-myocardial infarction.

### *Prioritisation and derivation of review criteria*

Figures 2, 3 and 4 show the mean rating score (number of points allocated out of 20) given to each aspect of care by general practitioners in the prioritisation task for stable angina, heart failure and post-myocardial infarction.

Box 3 displays the process by which several recommendations were collated to form one aspect of care and how a review criterion was derived.

The final set of review criteria for CHD is presented in Box 4. Some of the aspects of care that were rated very low by the panels were excluded from the final list of review criteria; for example, the use of verapamil, Figure 2.

Subsequently, in order to retain currency, some minor amendments were made to the review criteria following the publication of updated versions of some of the guidelines, available after the prioritisation process was completed. The CHD review criteria were published in a booklet explaining the development methodology and distributed throughout the NHS. They were well received by healthcare professionals and others working in the field of health care. Narrative feedback indicated that the criteria offered a practical and relevant tool for quality improvement.

## Discussion

This project adopted an approach to developing practical evidence-based review criteria from existing guideline recommendations because guidelines are becoming common currency as a means of synthesising evidence of effective care.

Whereas the outcome of the project was successful in creating a standardised process for review criteria development, there were a number of challenges to be overcome in the process. Reducing down the many components of the guidelines to a limited set of criteria required the construction of a complex analytical framework and therefore considerable investment. From among the guidelines available to the project, it was sometimes a significant challenge to specify the linkage between the evidence based on a particular guideline recommendation. There was no universal evidence grading system employed (as there will be with NICE guidelines) and, at times, there was a lack of clarity in the information reported, such as a lack of clear distinction between evidence and expert opinion. Taken together this meant that direct and accurate comparisons could not be drawn across the guidelines without the effort of going back to the original source evidence. This problem should be lessened in England and Wales through the adoption of a common standard of evidence presentation in the NICE guidelines and the provision of a single, high-quality guideline from which to derive review criteria.

It is probably best if the derivation of criteria is mainly undertaken at a national level. Though there have been some suggestions from the literature that involvement in the development process may aid with implementation,[38] it must be acknowledged that developing evidence-based review criteria is an intensive and time-consuming process; it is not one likely to be possible within practices or primary care trusts. Developing and promoting four sets of review criteria (of which CHD was one) took the research team 2 years.

There do seem to be some advantages in attempting to use information from more than one guideline as the evidence base for the review criteria. Though covering the same topic, rarely do guidelines from different sources exactly map onto each other, since they usually reflect both the culture and the needs of the health system for which they are developed. Using more than one guideline can broaden the scope of the criteria and reinforce the recommendations where they match. The project demonstrated the importance of introducing the views of practitioners into the development of review criteria, through the prioritisation process.

**A – Identifying common recommendations.**
Patients who have stable angina should be treated with aspirin 75 mg daily for 4 years (A grade recommendation, level 1 evidence).[30]
After 4 years, aspirin should be continued long term at a dose of 75 mg daily (A grade recommendation, level 1 evidence).[30]
The records show that the patient is on daily aspirin unless there are contraindications (level 1a evidence).[31]
Give low-dose aspirin (eg 75 mg per day) indefinitely (level 1a evidence).[32]
The records show that the patient has been offered treatment with aspirin, in the absence of contraindications.[12]

**B – Aspect of care, reference to principal guideline or evidence-based criteria, level of evidence.**
Patients who have stable angina should be treated with aspirin 75 mg daily, unless contraindicated (level 1 evidence).[27]

**C – Review criterion derived for the Clinical Practice Evaluation Programme.**
The percentage of patients who have been treated with aspirin 75 mg daily, unless contraindicated.

*Box 3. Example of the derivation of review criteria from multiple recommendations.*

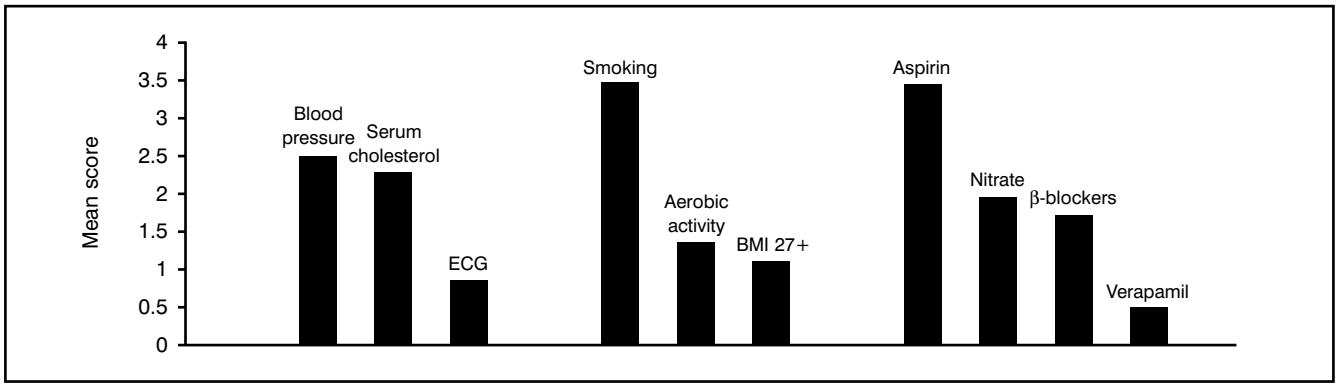


*Figure 2. Prioritised components of care for stable angina: screening, advice and therapy clusters.*

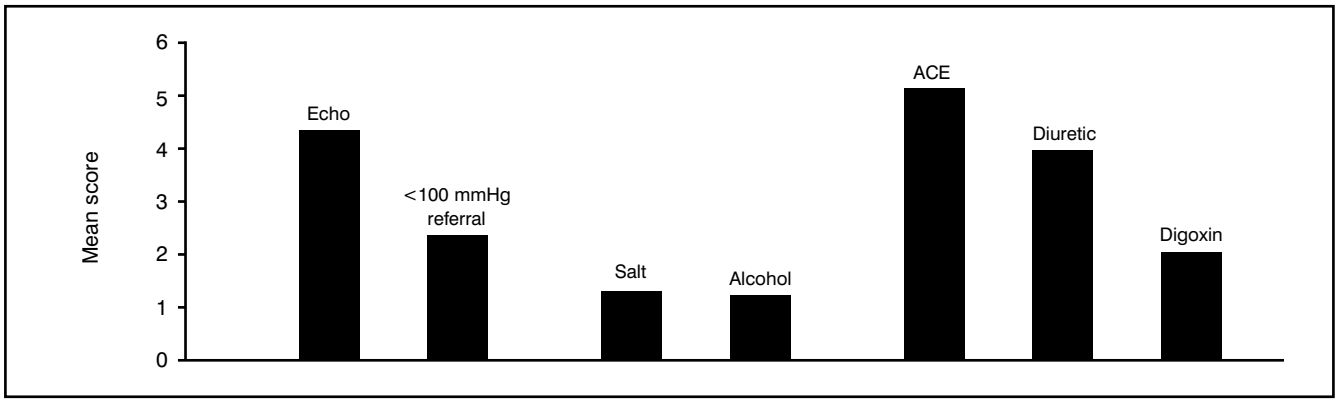


*Figure 3. Prioritised components of care for heart failure: screening, advice and therapy clusters.*

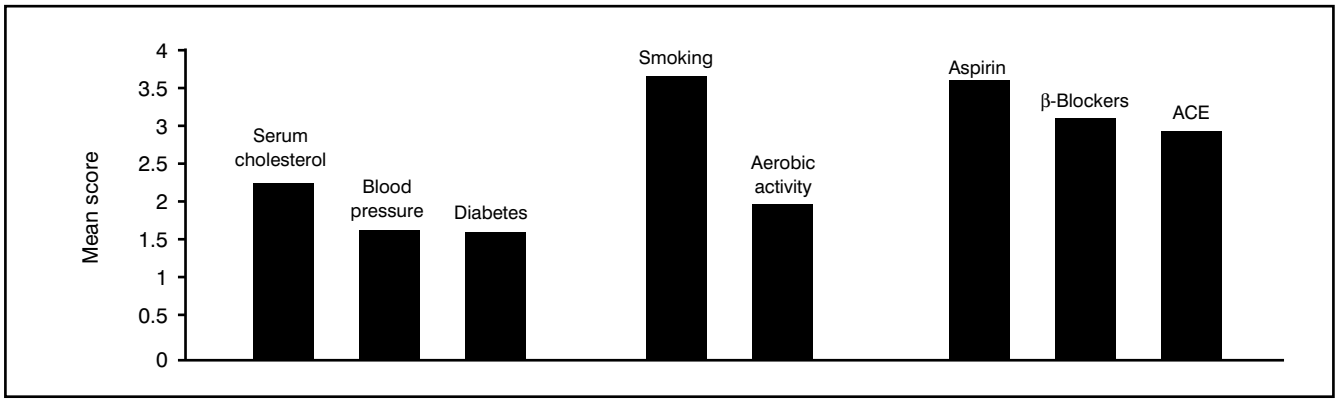


*Figure 4. Prioritised components of care for post-myocardial infarction: screening, advice and therapy clusters.*

A full clinical practice guideline might produce a substantial number of recommendations and these are rarely explicitly prioritised (although some element of prioritisation may be undertaken while establishing the scope of the guideline). It is unlikely that a quality improvement programme in a general practice or outpatient clinic could manage to capture, or wish to capture, the data for all the possible review criteria that could be developed from a guideline. A limited set should be the aim, taking account of the needs and preferences of the clinical teams.

On the other hand, general practices are at different stages of sophistication and efficiency in capturing clinical data. What might be a first difficult step or starting point for one practice or primary care trust may be no longer challenging for another. A process of prioritisation of the review criteria by some form of structured professional review, akin to the 'must, should, could'[19] approach, is a key step in developing a set of review criteria which can be of use across the NHS. NICE currently publishes short lists of review criteria for each guideline (about six). Although this has practical advantages, it may also limit the choice for those practices that have already addressed the 'basic' aspects of care proposed by a guideline.

Prioritisation can present its own challenges. It should be noted that clinicians, when expressing choices, might use criteria that appear to conflict with the evidence base. For example, in prioritising the use of nitrates over beta-blockers in stable angina management, clinicians have given priority to

**Stable angina**
**Clinical assessment**
1. The percentage of patients who have had their blood pressure measured.
2. The percentage of patients who have had their serum lipids measured.
3. The percentage of patients who have had a resting 12–lead ECG.

**Therapy**
4. The percentage of patients who have been treated with aspirin 75 mg daily, unless contraindicated.
5. The percentage of patients who have been treated with short-acting nitrates as required in response to pain and before performing activities that are known to bring on pain, unless contraindicated.
6. The percentage of patients who require regular symptomatic treatment who have been treated with a beta-blocker, unless contraindicated.

**Advice**
7. The percentage of patients who smoke and have been advised to stop.
8. The percentage of patients who have been recommended moderate exercise within their capabilities to improve general fitness and well-being.
9. The percentage of patients who have a BMI over 27 who have had dietary advice.

**Heart failure**
**Clinical assessment**
1. The percentage of patients suspected of having heart failure who have had their left ventricular function evaluated.
2. The percentage of patients with heart failure who have systolic blood pressure 100mm Hg who have been considered for referral for assessment and supervised initiation of ACE inhibitors.

**Therapy**
3. The percentage of patients with symptomatic heart failure and evidence of impaired left ventricular function who have been treated with an ACE inhibitor, unless contraindicated.
4. The percentage of patients with heart failure and signs of significant volume overload who have been started immediately on a diuretic, unless contraindicated.
5. For those with mild or moderate heart failure who remain symptomatic after optimal management with ACE inhibitors and diuretics — the percentage of patients who have also been treated with digoxin, unless contraindicated.

**Advice**
6. The percentage of patients with heart failure who have been advised to restrict dietary sodium to as close to 2 g per day as possible.
7. The percentage of patients with heart failure who have been advised to restrict their consumption of alcohol to one drink per day.

**Post-myocardial infarction**
**Clinical assessment**
1. The percentage of patients post-myocardial infarction who have had their serum lipids measured.
2. The percentage of patients post-myocardial infarction whose blood pressure is maintained below 140/85 mmHg, where practical.
3. The percentage of patients post-myocardial infarction who have had their blood glucose measured.

**Therapy**
4. The percentage of patients post-myocardial infarction who have been treated with aspirin 75 mg daily, unless contraindicated.
5. The percentage of patients post-myocardial infarction who have been treated with a beta-blocker, unless contraindicated.
6. The percentage of patients post-myocardial infarction with symptomatic heart failure and evidence of impaired left ventricular function who have been treated with an ACE-inhibitor, unless contraindicated.
7. For those whose total cholesterol remains equal to or greater than 5mmol/l and/or LDL-cholesterol equal to or greater than 3 mmol/l, even after dietary advice for at least 6 weeks — the percentage of patients who have been considered for treatment with a statin, unless contraindicated.

**Advice**
8. The percentage of patients post-myocardial infarction who smoke and have been advised to stop.
9. The percentage of patients post-myocardial infarction who have been recommended moderate exercise within their capabilities to improve general fitness and well-being.

*Box 4. Review criteria for stable angina, CHD and post-myocardial infarction.*

symptom management rather than to (evidence-based) reduction in mortality. Although the differences in scores in Figure 2 are probably not clinically significant, the similar weighting may reflect the tension between enabling short-term (symptom) outcomes and longer-term mortality outcomes. This makes the need for the involvement of professional users in the prioritisation all the greater. There is no indication from this study of how people with CHD might make choices — they may also make symptom-based choices.

One important practical issue is the currency of the review criteria. There is a considerable lead time between the publication of new evidence, its assessment and possible assimilation into a guideline and then into review criteria. By the time the criteria are published, perhaps with a proposed 'shelf-life' of 2–3 years, clinical practice may have moved away from one or more aspects of care covered by the review criteria. In this study, the use of verapamil in the management of stable angina was proposed by a guideline but the therapy was no longer usual practice. It was given a low priority by the review panel and was omitted from the final set of criteria. Prioritisation of the criteria should therefore ideally be undertaken close to the publication date so as to identify areas of redundancy.

The use of uniform methods to produce review criteria by NICE and other bodies would enhance the usefulness of the criteria as tools for quality assessment. Indeed, criteria devel-

oped by a standardised method from a good-quality guideline may provide an efficient means by which a primary care team can focus on the main aspects of the guideline, creating clarity where complexity reigns. Professional (and patient) choice, either at the development stage or at the user stage, will be essential in order to arrive at prioritised and useful sets of criteria to reflect both the evidence and the needs of users.

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