Effective audit in general practice: a method for systematically developing audit protocols containing evidence-based review criteria

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SUMMARY

Though many general practitioners (GPs) now take part in audit, there is still concern about the extent to which participation in audit leads to improvements in practice. Improved methods are needed for the incorporation of research evidence into criteria for use in audit. In this paper, a six-stage systematic method is described for developing audit protocols containing prioritized evidence-based criteria. The stages are: selection of a topic, identification of key elements of care, focused literature reviews, prioritization of the criteria on the strength of the evidence and impact on outcome, preparation of full documentation, and peer review.

Keywords: audit; criteria; protocols; guidelines.

Introduction

RECENTLY, both clinicians and health service managers have increasingly focused on methods for the implementation of research findings, an essential feature of which is review of care against explicit criteria based on research evidence.[1,2] This paper describes a systematic method for identifying such criteria (Box 1).

Audit with feedback to participants about the extent of their compliance with review criteria can not only promote beneficial change, but can also indicate whether alternative, or additional, strategies are needed to improve performance. Since no strategy for implementing change is invariably effective,[3] the impact of any strategy should be monitored. If anticipated improvements fail to occur, this would suggest that different implementation strategies are required.

Although much literature exists on methods for developing and using clinical guidelines,[4,5] less attention has been given to methods for developing evidence-based review criteria. One suggested method in the United States[6] is unlikely to be directly transferable to professionally-led clinical audit in the United Kingdom. Accordingly, we have developed an approach for deriving review criteria from research evidence and making them available to audit groups and health authorities, the underlying principles of which have been reported.[1] Here, we describe the detailed methodology and provide particular examples from our suggested criteria for the management of hypertension in primary care.[7]

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Method outline

Our method has six stages (Box 2). This systematic approach ensures critical appraisal of the evidence and its conversion into prioritized review criteria. Furthermore, by linking explicit criteria to the evidence by the inclusion of a descriptive test, it makes clear why each criterion has been included, highlights the most important, and allows potential users to reflect on the steps taken in their development.

Choosing a clinical topic

Efforts to improve quality should be concentrated on those topics for which compliance with research evidence would lead to the greatest improvement in health. Specific factors to take into account are:

- The importance of the condition in terms of prevalence and impact on morbidity and mortality
- Evidence that clinical practice is inadequate and could be improved
- The availability of convincing research evidence about appropriate practice.

Key elements of care

If a clinical topic is chosen, all the elements of care relevant to its diagnosis and management must be identified. In order to create an audit protocol containing all the appropriate criteria, use should be made of available research-based guidelines and systematic reviews; methods are already available for assessing their respective quality.[8,9]

However, it is difficult to derive criteria directly from guidelines for two principal reasons. First, guidelines generally include recommendations about every element of care of the condition concerned, without prioritizing their impact on outcomes; in making judgements about the quality of care, as in audit, it is fundamental to place greatest weight on those elements of care that are most influential. Secondly, guideline recommendations are usually based on research evidence *and* on the values and opinions of the guideline panel.[10] Frequently, these values are not made explicit, and without directly consulting primary sources of research evidence it is not usually possible to assess the relative importance of particular recommendations in terms of strength of evidence and impact on outcome.

If research evidence is lacking, we believe it is preferable not to proceed with the development of review criteria. Although some authoritative reviews and guidelines were available during the development of the Eli Lilly Centre hypertension protocol,[7,11-14] the guidelines alone were not sufficient for the full identification of evidence-based review criteria. The key elements of care that we identified in the diagnosis and management of patients with hypertension[7] are shown in Box 3.

Clinical practice guidelines
Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances[a]

Review criteria
Systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services, and outcomes[a]

Protocol
A comprehensive set of criteria for a single clinical condition or aspect of organization[b]

Standard
The precentage of events that should comply with the criterion.[b]

Box 1. Definitions of guidelines, criteria, and protocols for clinical practice. [a] From Institute of Medicine;[2] [b]from Baker and Fraser.[1]

- Selection of topic
- Identification of key elements of care
- Focused systematic literature reviews to develop, when justified by evidence, one or more criteria for each element of care
- Prioritization of the criteria on the strength of research evidence and impact on outcome
- Presentation of the criteria in a protocol
- Submission of the protocol to external peer review.

Box 2. Six-stage method for developing review criteria.

- Definition of hypertension, treatment thresholds
- Measurement of blood pressure: equipment, technique, ambulatory blood pressure monitoring
- Clinical evaluation
- Target organ damage evaluation
- Assessment of risk factors
- Investigations in general practice
- Non-pharmacological treatment
- Drug treatment
- Quality of life on drugs
- Organization of care
- Follow-up intervals
- Target blood pressure.

Box 3. Key elements of care of patients with hypertension.

Identification of research evidence

The process of identifying the key elements is analogous to the first step of evidence-based medical practice, in which the problem or question is defined in precise terms, followed by a literature search and appraisal of research evidence.[15] However, this can be a major task; for example, some 18 000 papers have been published on hypertension since 1989.[7] Moreover, it is inappropriate to duplicate sound systematic reviews that are already available. Therefore, the detailed specification of each criterion is undertaken by means of a systematic literature search focused on the key elements.[16] A focused literature search involves analysis, evaluation, and synthesis of scientific evidence identified by the searches.

In undertaking a focused literature search, questions are constructed related to the key elements of care. An essential requirement is that the extent of a literature search, including any restrictions, is subsequently made explicit.[17] In our method, the focused searches are performed by a trained clinician, and a brief summary of the search parameters are documented in the final published protocol. At present, electronic searching is conducted using MEDLINE, and only English language literature is included. Cross-referencing from identified articles often reveals further studies for consideration.

Appraising the literature

Identified studies about an element of care are then appraised to identify those with the most reliable study designs.[18] In assessing research evidence about treatment interventions, the greatest weight is attached to a meta-analysis of randomized controlled trails, or individual high-quality randomized controlled trials.[19] Some trials cannot be used because they involve only small numbers of patients, have major methodological flaws, or relate to patients not typical of general practice. If acceptable randomized controlled trials are not available, controlled trials, quasi-experimental, or observational studies are sought, although less weight is placed on such studies.

Development of criteria from the evidence

Review criteria are then formulated for particular elements of care if justified by the research evidence. Such criteria have to be worded so that they are precise, unambiguous, and measurable. For example, there is compelling evidence that hypertensives with target organ damage have a higher morbidity and mortality rate, which can be reduced by appropriate treatment, than those without. Accordingly, patients with target organ damage should first be identified and then offered effective treatment. Converting the first step into a review criterion led to the following statement: 'The records show that, at diagnosis, the following symptoms and signs of target organ damage have been sought: retinopathy, left ventricular hypertrophy, angina, stroke, heart failure, peripheral vascular disease, and renal disease.'[7] The criterion therefore makes clear what information is required to make an assessment of target organ damage, and when that information should be obtained.

Prioritizing criteria

The development of criteria and their prioritization are closely linked steps, which, in practice, often take place simultaneously. Criteria are prioritized on the strength of the evidence and impact on outcome. Our approach is to prioritize audit criteria at two levels: 'must do' and 'should do'. The 'must do' criteria are supported by convincing evidence that they have a substantial impact on outcome, whereas the 'should do' criteria have less explicit impact on outcome.[1] By adopting this approach, participants in audits in practice can concentrate their efforts on meaningful activity.

Various elements of care have differential impacts on outcomes. Those associated with more severe outcomes are given greater weight, an approach similar to that of the Agency for Health Care Policy and Research (AHCPR).[20] In audit, judgements are made about performance, and the quality of those judgements depends on the validity of the criteria in relation to their influence on outcome; for example, in patients with hyperlipidaemia, an intervention that lowers serum lipids must also reduce morbidity and mortality if it is to be categorized as a 'must do' criterion. In some instances, there may be strong evidence that change in a measurable aspect of patient function can occur, but the overall impact on outcome may be minimal or absent; for example, salt restriction has been shown to lower blood pressure, an intermediate outcome, but at the time our hypertension protocol was being developed no evidence was available about its impact on mortality, heart attacks, and strokes.[21-23]

In order to decide which criteria are to be included in an audit protocol, the developers hold regular meetings at which each criterion is subjected to critical scrutiny to re-appraise the identified research evidence and its impact on outcome. This facilitates prioritization into 'must do' or 'should do' categories. When evidence is lacking about a particular element of care in an otherwise well-researched topic,[5] some reliance may need to be placed on professional concensus; for example, there is usually little or no evidence to support decisions about the frequency of review of patients with chronic diseases. Nevertheless, in our hypertension protocol,[7] the criterion about regular review is prioritized as 'must do'. This is because 'controlled' hypertensives have better outcomes than 'uncontrolled' hypertensives,[24] although research evidence about the optimum review interval is not available. In such instances, the recommendation is often made after peer review and discussion. Box 4 shows some of the criteria that were prioritized into the 'must do' and 'should do' categories in our hypertension protocol.[7]

Peer review

Each protocol is subjected to peer review, which also helps to identify any major omissions and to ensure that they are easy to understand and are acceptable. Nevertheless, as there is evidence that expert opinion may often be inconsistent with reported findings,[25] criteria are not modified unless supported by convincing research evidence. The reviewers are selected from relevant disciplines and may be academics, hospital specialists, GPs, or practice nurses with expertise in the particular topic in question. Only one round of peer review is carried out before modifying the protocol.

The hypertension protocol was sent to three hospital specialists and three GPs, all of whom were recognized authorities on the topic. Some reviewers felt that electrocardiographs should be a routine investigation for all hypertensives. Since no convincing research evidence could be identified to support this view, we decided not to include this criterion. Conversely, the reviewers pointed out that we had originally overlooked evidence about the effect of physical activity in reducing the risk of heart attacks and strokes, and one criterion was modified accordingly.

Documentation

The review criteria are then incorporated in an audit protocol, which includes fully referenced explanations justifying their inclusion and classification into either 'must do' or 'should do' categories. A short summary of the criteria is included along with information about the development methods used. The final document includes a date for a scheduled review of the protocol, instructions about organizing the audit, information on data collection, and advice about change. With some conditions, there may be the potential to include very large numbers of patients in any formal audit, even in relatively small practices; accordingly, instructions are also included about selecting appropriate samples.

Protocol for the management of hypertension in general practice

'Must do' criteria
- Patients diagnosed as hypertensive have been recorded in a practice hypertension register
- At diagnosis, symptoms and signs of target organ damage have been sought: retinopathy, left ventricular hypertrophy, angina, stroke, heart failure, peripheral vascular disease, and renal disease
- In patients without target organ damage, the blood pressure has been measured at least twice on each of at least three separate occasions prior to drug therapy.

'Should do' criteria
- The records show that at least annually: there is an assessment of side effects caused by antihypertensive drugs that the patient is taking; the patient has been given advice about dietary salt restriction.

Box 4. Some examples of 'must do' and 'should do' criteria.

Conclusion

In this paper, a detailed method for the systematic development of evidence-based and prioritized review criteria has been described. The method includes the selection of a topic, identification of key elements of care, focused literature reviews, prioritization of the criteria, and peer review. Although the development process is time-consuming and requires considerable expertise, it is practical and acceptable to audit groups and practitioners. Indeed, the first four protocols using this method have been used by more than 1000 general practices.[26] A range of protocols have been produced for a variety of clinical and community nursing topics in primary health care (Appendix 1). Further protocols are planned for community nursing topics and care across the interface with secondary care.

If audit is to lead to improvements in care, the criteria used must be supported by convincing research evidence which confirms that they do influence the outcome of care. Although the majority of GPs have taken part in audit in recent years, many audits have used criteria that are not chosen systematically, and the degree of improvement in care has been disappointing. We would recommend that those designing or undertaking audits should use evidence-based and prioritized criteria. Practitioners wishing to participate in audit should also be encouraged to use available protocols that are constructed in the same way. By doing so, practitioners will be able to concentrate their efforts on producing improvements in the quality of care delivered in their practices.

Appendix 1. Audit protocols already developed.

CT1	Gout
CT2	Monitoring diabetes
CT3	Monitoring asthma
CT4	Monitoring lithium
CT5	Benzodiazepines: long-term users
CT6	Benzodiazepines: new prescriptions
CT7	Management of angina in general practice
CT8	Management of hypertension in primary care
CT11	Management of depression in primary care
PC1–4	Patient's Charter set 1 (routine non-urgent appointments; urgent appointments; surgery waiting times; telephone calls)
PC5–8	Patient's Charter set 2 (comments, suggestions, and complaints; home visits; repeat prescription system; patients who do not attend their appointments)
PC9	Comments and complaints.

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