



**A guide to the
development, implementation
and evaluation of
clinical practice guidelines**

NHMRC

National Health and Medical Research Council

**A guide to the
development, implementation
and evaluation of
clinical practice guidelines**

Endorsed 16 November 1998

NHMRC

National Health and Medical Research Council

© Commonwealth of Australia 1999

ISBN 1864960485

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without permission from AusInfo. Requests and enquiries concerning reproduction and rights should be addressed to the Manager, Legislative Services, AusInfo, GPO Box 1920, Canberra ACT 2601.

The strategic intent of the National Health and Medical Research Council (NHMRC) is to work with others for the health of all Australians, by promoting informed debate on ethics and policy, providing knowledge-based advice, fostering a high quality and internationally recognised research base, and applying research rigour to health issues.

NHMRC documents are prepared by panels of experts drawn from appropriate Australian academic, professional, community and government organisations. NHMRC is grateful to these people for the excellent work they do on its behalf. This work is usually performed on an honorary basis and in addition to their usual work commitments.

This document is sold through AusInfo Government Info Bookshops at a price which covers the price which covers the cost of printing and distribution only. For publication purchases please contact AusInfo on their toll-free number 132 447, or through their internet address:

http://www.ausinfo.gov.au/general/gen_hottobuy.htm

CONTENTS

SUMMARY	1
Chapter 1 INTRODUCTION	9
1.1 Clinical practice guidelines	9
1.2 The evolution of guidelines in Australia	11
1.3 Endorsing externally developed guidelines	12
Chapter 2 THE GUIDING PRINCIPLES	13
2.1 Guideline development and evaluation	13
2.2 Using the best available evidence	14
2.2.1 The level and quality of evidence	15
2.2.2 The relevance of the evidence	16
2.2.3 The strength of the evidence	17
2.3 Using evidence in making recommendations for treatment	17
2.4 A multidisciplinary approach that includes consumers	18
2.5 Flexibility and adaptability	19
2.6 Economic implications	19
2.7 Guideline dissemination and implementation	20
2.8 Evaluation	20
2.9 Revision	20
Chapter 3 GUIDELINE DEVELOPMENT	21
3.1 Determining the need for and scope of guidelines	21
3.2 Convene a multidisciplinary panel to oversee the development of the guidelines	22
3.3 Define the purpose of and target audience for the guidelines	23
3.4 Identify health outcomes	23
3.5 Review the scientific evidence	24
3.6 Formulate the guidelines	24
3.7 Formulate a dissemination and implementation strategy	25

CONTENTS

3.8	Formulate an evaluation and revision strategy	25
3.9	The guidelines themselves	25
3.10	Reporting on the guideline-development process	27
3.11	Assessing the guideline document	28
3.12	Consultation	28
Chapter 4	GUIDELINE DISSEMINATION AND IMPLEMENTATION	31
4.1	Dissemination	33
4.1.1	Making the guidelines accessible	33
4.1.2	Publishing the guidelines	33
4.1.3	Informing the target audience of the guidelines' availability	34
4.2	Implementation	35
4.2.1	The use of opinion leaders and 'champions'	36
4.2.2	Endorsement by clinical groups	37
4.2.3	Practice visits from influential experts	37
4.2.4	Education of patients and patient-mediated intervention	37
4.2.5	Educational materials	38
4.2.6	Seminars and conferences	38
4.2.7	Reminder systems incorporated in clinicians' daily work	38
4.2.8	Quality assurance and quality improvement	39
4.2.9	Local adaptation and incorporation	40
4.2.10	Incentives	41
4.2.11	The use of information technology	41
4.3	A systems approach	43

CONTENTS

Chapter 5	GUIDELINE EVALUATION AND REVISION	45
	5.1 Evaluation	45
	5.1.1 Evaluation of dissemination	46
	5.1.2 Evaluation of changes in clinical practice and health outcomes	46
	5.1.3 Evaluation of the guidelines' contribution to changes in clinical practice and health outcomes	48
	5.1.4 Evaluation of consumer guidelines	48
	5.1.5 Economic evaluation	49
	5.1.6 Reporting on the evaluation	49
	5.2 Revision	50
Chapter 6	LEGAL CONSIDERATIONS	51
	6.1 Liability of practitioners	51
	6.2 Legal liability of guideline developers and bodies supporting guideline development	52
	6.3 Minimum legal requirements for guideline developers	52
Chapter 7	CONCLUSION	53

CONTENTS

Appendix A	Definitions	55
Appendix B	Designation of levels of evidence	56
Appendix C	Clinical practice guidelines flow chart	57
Appendix D	Generic outcome measures	58
Appendix E	Checklist for guideline development	59
Appendix F	Process report	60
Appendix G	Submissions received	62
Appendix H	Economic appraisal information	64
Appendix I	Implementation strategies that work	65
Appendix J	National Health and Medical Research Council standards for externally developed guidelines	66
	Glossary	72
	Bibliography	74

SUMMARY

Why these guidelines are needed

There has been a widespread move towards developing clinical practice guidelines, which are designed to improve the quality of health care, to reduce the use of unnecessary, ineffective or harmful interventions, and to facilitate the treatment of patients with maximum chance of benefit, with minimum risk of harm, and at an acceptable cost. Recent research has shown that clinical practice guidelines can be effective in bringing about change and improving health outcomes. But they are just one element of good medical decision making, which also takes account of patients' preferences and values, clinicians' values and experience, and the availability of resources.

There have been few widely accessible guides for groups seeking to develop clinical practice guidelines. This document puts forward a method for developing such guidelines in Australia.

Traditionally, guidelines have been based on the development of consensus among experts, although this process has limitations and can lead to flawed conclusions. There is now growing recognition that guidelines should be based, where possible, on the systematic identification and synthesis of the best available scientific evidence.

Clinical practice guidelines will be effective only if they are perceived to be helpful and are actually used in clinical decision making. Many individuals and groups found the earlier version of this document, published by the National Health and Medical Research Council in 1995, very helpful. This revised edition reflects concern that greater emphasis should be placed on guideline implementation and evaluation.

Key principles for developing guidelines

There are nine basic principles for developing guidelines.

1. Processes for developing and evaluating clinical practice guidelines should focus on outcomes. Outcome measures can range from survival rates to quality-of-life attributes.
2. Clinical practice guidelines should be based on the best available evidence and should include a statement about the strength of their recommendations. Evidence can be graded according to its level, quality, relevance and strength. The 'level' of evidence refers to the study design used to minimise bias: the highest level involves a systematic review of randomised controlled clinical trials. 'Quality' refers to the methods used to minimise bias in the design and conduct of a study. 'Relevance' refers to the extent to which research findings can be applied in other settings. The 'strength' of evidence relates to the

magnitude and reliability of the treatment effect seen in clinical studies: strong effects are more likely to be real and more likely to be clinically important. Ideally, recommendations would be based on the highest level of evidence, but this may be difficult to achieve in public health and social science interventions.

3. The method used to synthesise the available evidence should be the strongest applicable. Taking the evidence—of whatever level, quality, relevance or strength—and turning it into a clinically useful recommendation depends on the judgment, experience and good sense of the group developing the guidelines. The fact of having evidence from a high-level study does not automatically result in a good clinical recommendation.
4. The process of guideline development should be multidisciplinary and should include consumers. If guidelines are to be relevant, those who are expected to use them or to benefit from their use should play a part in their conception and development. Involving a range of generalist and specialist clinicians, allied health professionals, experts in methodology, and consumers will improve the quality and continuity of care and will make it more likely that the guidelines will be adopted.
5. Guidelines should be flexible and adaptable to varying local conditions. They should include evidence relevant to different target populations and geographic and clinical settings, take into account costs and constraints, and make provision for accommodating the different values and preferences of patients.
6. Guidelines should be developed with resource constraints in mind. They should incorporate an economic appraisal, which may be helpful for choosing between treatment options.
7. Guidelines are developed to be disseminated and implemented taking into account their target audiences. They should also be disseminated in such a way that practitioners and consumers become aware of them and use them.
8. The implementation and impact of guidelines should be evaluated.
9. Guidelines should be revised regularly.

Guideline development

When selecting guideline topics, there must be a clear problem or concern that would be redressed if guidelines were developed. A multidisciplinary panel consisting of representatives of all relevant groups should be convened. It should clarify the purpose of the guidelines—such as specifying what conditions and clinical problems they will cover—and identify the desired health outcomes. Rigorous and systematic review of the scientific evidence is essential.

In formulating the guidelines, the panel should do the following:

- document the purpose for which the guidelines were developed;
- describe the natural history of the disease or condition in question and the various treatments that are possible;
- identify situations where any recommendations might not apply;
- detail the probable outcomes;
- ensure that the guidelines are comprehensive and flexible;
- describe the support services that may be required for each potential treatment;
- include information, for consumers and clinicians, on any special clinical training or equipment that is needed;
- compare the costs associated with the various options;
- provide a statement of the scientific basis on which the guidelines were developed and clearly specify the level, quality, relevance and strength of the evidence on which the recommendations are based;
- document the uncertainty associated with any conclusions; and
- document the economic appraisals used in formulating the guidelines.

If consensus-based recommendations are to be issued, they should acknowledge the desirability of developing evidence-based recommendations. Where non-consensus based statements are issued, there should be clear reference to each of the schools of thought and consumers should be made aware of the lack of consensus.

Different versions of the guidelines should be developed for different audiences—consumers, general practitioners, specialist nurses, and so on.

During the guideline development phase the panel should also develop a plan for disseminating and implementing the guidelines and a plan to ensure that the guidelines are evaluated properly and revised as necessary.

Once drafted, the guidelines document should be assessed to determine whether it conforms to the principles outlined in this guide. The draft should be referred for consultation to a wide range of interested parties—practising clinicians, clinical colleges, allied health and professional organisations, consumer groups, Commonwealth, State and Territory and local health authorities, industry groups, and so on.

Disseminating and implementing the guidelines

The multidisciplinary panel should identify any barriers to acceptance and implementation of the guidelines and work with members of target groups to develop ways of overcoming these barriers.

Guidelines should be presented in a format and style suitable for their target audience. Their cost should not constitute a barrier to access.

Strategies for dissemination and implementation will probably depend on the nature of the guidelines and the target audience. There are a number of possible strategies:

- compiling short summaries for use in professional or general publications or brochures, as posters, on the Internet, as audio or video tapes, or on disk;
- involving potential users in developing the guidelines;
- using the media, professional journals and the publications of other groups, such as consumer organisations, divisions of general practice, hospitals, area health services and universities;
- using the communication links developed by clinical colleges and other groups;
- asking respected clinical leaders to promote the guidelines;
- providing economic incentives;
- using the education processes of appropriate colleges and other groups;
- incorporating the guidelines in routine procedures, such as quality assurance, within relevant organisations;
- using information technology;
- arranging for a credible health provider to visit practitioners in the clinical setting;
- piloting the draft guidelines in order to facilitate their assessment;
- offering feedback on compliance with the guidelines;
- discussing the guidelines at conferences, seminars and other professional meetings; and
- using the services of a communications professional.

Dissemination of the guidelines alone will not change practitioners' behaviour. Doctors and other clinicians are most likely to change their behaviour if they themselves are involved in the change process and if that process involves interventions that directly affect consultation between patient and practitioner.

A variety of approaches have been shown to change clinicians' behaviour or health outcomes, or both:

- using opinion leaders and clinical 'champions' in the media and for marketing;
- endorsement by key clinical groups;
- practice visits from influential experts;
- educating patients;
- provision of educational materials;
- seminars and conferences;
- reminder systems incorporated in clinicians' daily work;
- continuing quality assurance and data feedback;
- local adaptation and incorporation;
- local involvement in evaluation; and
- incentives.

There is emerging evidence that the new information technologies can help in disseminating and implementing guidelines through improving databases, Internet publication, computerised medical records, more interactive styles of learning, and computerised prompting and decision-support systems. It is also easier to update electronic guidelines.

Evaluation and revision

Evaluation of the guidelines should consider the following:

- how well were they disseminated? For example, how many copies were mailed out?;
- is the general trend in clinical practice moving towards the guideline recommendations?;
- have the guidelines contributed to any specific changes in clinical practice? For example, compare clinical practice in areas where the guidelines have been heavily promoted with practice in areas where they have not been promoted;
- how have the guidelines affected consumers' knowledge and understanding?; and
- have health outcomes changed?

The guideline process should also be subjected to an economic evaluation. A cost-effectiveness analysis would assess all costs incurred in providing the guidelines and their impact.

In addition, the various sets of guidelines that are produced (for general practitioners, consumers, and so on) should be evaluated for their relevance, ease of access, clarity, how much information they contain, and general user satisfaction.

A date should be set for revision of the guidelines. The National Health and Medical Research Council recommends that this occur every three to five years and more often where the subject matter or circumstances are prone to rapid change.

Legal considerations

Liability of practitioners

Many practitioners are concerned about their potential legal liability if a patient does not receive treatment as specified in clinical practice guidelines. It is certainly possible that guidelines could be produced as evidence of what constitutes reasonable conduct by a medical practitioner. The National Health and Medical Research Council's Health Advisory Committee considers that practitioners who use guidelines will be afforded a measure of protection.

The case of *Rogers v Whitaker* (1992) 175 CLR 479 makes it clear that doctors should give information about the risks of any treatment, especially risks that may influence the patient's decision. Patients should be provided with as much information as they seek, and in a form that is appropriate to their culture and level of education. They should be encouraged to make their own decisions.

Liability of guideline developers and bodies supporting guideline development

If guidelines purport to be a definitive statement of the correct procedure, there would be a greater risk of liability than if they were clearly stated to be a general guide subject to the practitioner's expert judgment in each case.

Minimum legal requirements for guideline developers

The potential for guidelines to be used as evidence in court depends on the process used to develop them, the extent to which they are evidence-based, the degree of consensus about them, and whether they are up to date.

Guideline developers are unlikely to be held liable for any negative consequences of the implementation of guidelines. In general, guidelines should be summaries of the evidence, should have an expiry date, should not be unduly prescriptive, and should acknowledge areas where there is disagreement. An independent review of the guideline development process is recommended.

Conclusions

The development, dissemination, implementation, evaluation and revision processes described in this document are applicable to a wide range of clinical interventions and disciplines and could also be applied to protocols relating to the use of technology and pharmaceuticals.

Where possible, it is preferable, to use existing networks, facilities and publications to disseminate, implement and evaluate guidelines, rather than developing new processes. A systems approach is needed, which builds guideline development, dissemination, implementation and evaluation into the routine processes of care. Organisations such as hospitals, health care regions, and divisions of general practice should establish an approach that integrates guidelines into their local health care delivery processes. Such an approach would involve sensible use of resources, developing sustainable infrastructure, integrating available resources and strategies, and adapting to local needs.

The best approach to making sure guidelines work would appear to be a mix of strategies that are suitable for local conditions and are developed in concert with local clinicians, consumers and managers.

This document will be revised. For those seeking further information, a series of specialised 'tool kits', currently being developed, will be available in mid-1999. Users and reviewers of these guidelines are encouraged to contact the National Health and Medical Research Council if they have comments—negative or positive—to make. These comments will inform the revision process.

Users can contact the National Health and Medical Research Council by writing to:

Health Advisory Unit
Office of the National Health and Medical Research Council
Department of Health and Aged Care
GPO Box 9848 (MDP 50)
CANBERRA ACT 2601

Blank facing page to Chapter 1

CHAPTER 1

INTRODUCTION

The past decade has been marked by unprecedented interest in clinical practice guidelines and the processes by which they can best be developed and implemented. This worldwide interest has been prompted by concern about unjustifiable variations in clinical practice for the same condition, the increasing availability of new treatments and technologies, uncertainty about the effectiveness of many interventions in improving people's health, and a desire to make the best use of available health resources.

Guidelines are being designed to improve the quality of health care and decrease the use of unnecessary, ineffective or harmful interventions. In an era of evidence-based medicine (Sackett et al. 1996), guidelines are becoming one of the critical links between the best available evidence and good clinical practice. Guidelines constitute one element of a systems approach to quality health care.

Despite the acknowledged need, there are few widely accessible, comprehensive guides for groups seeking to develop clinical practice guidelines. This document puts forward a method for developing clinical practice guidelines in Australia, based on the best available models worldwide. The method has been trialed in Australia in recent years and modified in the light of that experience; it is applicable to a variety of conditions and procedures. In this document the term 'clinical' takes in all health care providers.

1.1 Clinical practice guidelines

Clinical practice guidelines are 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances' (Field & Lohr 1990). There is a move towards developing such statements to assist clinicians in the management of specific conditions. The procedures used to develop the statements are increasingly based on a thorough evaluation of the evidence, including, when appropriate, meta-analysis of published research studies on the outcomes of various treatment options, rather than the consensus of expert panels. The statements are intended to be 'a distillation of current evidence and opinion on best practice' (Clover et al. 1995; Grimshaw & Russell 1993).

Clinical practice guidelines are often referred to as algorithms, clinical pathways, protocols and practice policies, although these differ from clinical practice guidelines in that they are often much more prescriptive and not always based on evidence.

Clinical practice guidelines are one component of good medical decision-making, which takes into account patients' preferences and values, clinicians' values and experience, and the available resources. The guidelines' main purpose is to achieve better health outcomes by improving the practice of health professionals and providing consumers with better information about treatment options. Guidelines can inform consumers about risk factors and how to avert them; they can be used to broaden the education of practitioners and the community, thus contributing to quality assurance processes; and they can assist in the resolution of legal disputes and ethical dilemmas.

Research has shown that clinical practice guidelines can be an effective means of changing the process of health care and improving health outcomes (Grimshaw & Russell 1993, EHCB 1994). A systematic review of many studies of guidelines' effectiveness revealed strong evidence that they can change clinical practice. Moreover, of those studies that assessed changes in consumer health, a majority reported an improvement in health outcomes (EHCB 1994).

Guidelines vary, however, in the extent to which they produce improved health outcomes. There are two main reasons for this. First, acceptance of a guideline is likely to depend on the quality of the evidence on which it is based. Second, the extent to which the potential health gain is realised from adherence to a guideline will depend on how effectively the guideline is implemented.

Traditionally, guidelines have been based on consensus among experts. But this method has its limitations. Expert opinion does not always reflect the state of current medical knowledge (Antman et al. 1992). And, even where guidelines are supported by literature surveys, if the medical literature has been analysed in an unsystematic way biased conclusions can result (Woolf 1992 Vol 152; Mulrow 1994; EHCB 1994). In the past this has led to unnecessary delays in the recommendation of effective interventions and delays in the withdrawal of ineffective or harmful treatments (Antman et al. 1992; Advisory Group on Health Technology Assessment 1992).

It is now acknowledged that guideline recommendations should be based on systematic identification and synthesis of the best available scientific evidence. Given the extensive research activity in some health care areas, identifying and synthesising the available evidence can be a major undertaking.

The formulation and drafting of guidelines is only one part of the guideline development process. Guidelines will be effective only if they are perceived to be useful and are actually used in clinical decision making. It is therefore important to ensure that clinicians are aware of the guidelines and that the guidelines are incorporated in clinical practice. At present little is known about the relative effectiveness of different dissemination and implementation strategies (Grimshaw

& Russell 1994), but the available evidence does suggest that implementation strategies are most likely to succeed if they are relevant to the people the guidelines are targeting and if they are integrated into the health care delivery process (EHCB 1994).

Clinical practice guidelines should be linked to effective evaluation plans. This involves documenting the beneficial and adverse consequences of different interventions when applied in normal clinical practice and how their application is viewed by the consumer.

Rather than being treated as a stand-alone item, clinical practice guidelines will be most effective when incorporated fully in the health care system and used alongside existing quality assurance activities such as continuing medical education, accreditation, audit and certification.

Guidelines will also be most effective when they are part of a system in which good data collection on outcomes is the norm and where the data collected are used to inform the continuing development of the guidelines and their dissemination and implementation. The challenge is to develop a systems approach that can support guideline development, implementation and evaluation as part of mainstream health care delivery.

Finally, it must be remembered that there are no 'magic bullets' or simple answers when it comes to developing and implementing guidelines (Oxman et al. 1995). The cycle of development, implementation, evaluation, and revision in the light of new scientific evidence and consumer feedback will be central to the success of future clinical guidelines.

1.2 The evolution of guidelines in Australia

The National Health and Medical Research Council has been piloting and funding the process of clinical guideline development in areas such as early breast cancer, coronary heart disease, unstable angina, stroke prevention, preterm birth, depression in young people, uncomplicated lower urinary tract symptoms in men, and diabetic retinopathy.

Many individuals and groups found the earlier version of this document, produced in 1995, very helpful in developing guidelines. Feedback collected by the National Health and Medical Research Council, from guideline developers, shows overwhelming support for the idea of evidence-based guidelines. It also shows general agreement about the inclusion of 'decision trees' in guidelines, as well as the need for some kind of systems approach to make the guidelines work effectively.

There is, however, a strong feeling that much more attention should be given to implementation and evaluation once guidelines have been developed. Many of those involved in producing guidelines have become frustrated by the lack of implementation.

Further, health care professionals' acceptance of clinical practice guidelines has to some degree been marred by lingering concern that the guidelines represent 'cookbook' medicine.

1.3 Endorsing externally developed guidelines

Many of the newly developed evidence-based guidelines have been produced under the auspices of the National Health and Medical Research Council. It is anticipated, however, that in the future many outside bodies will seek to produce their own guidelines. Regulating the quality of such critically important processes and endorsing externally developed guidelines pose challenges that are now being tackled.

CHAPTER 2

THE GUIDING PRINCIPLES

This chapter describes the nine guiding principles underlying the guideline development process. They are as follows:

- processes for guideline development and evaluation should be outcome focused;
- guidelines should be based on the best available evidence and should include a statement about the strength of recommendations;
- the method used to synthesise the available evidence should be the strongest applicable;
- the process of guideline development should be multidisciplinary and should include consumers;
- guidelines should be flexible and capable of adapting to varying local conditions;
- guidelines should be developed with resource constraints in mind;
- guidelines should be developed, disseminated and implemented taking into account their target audiences;
- the validity and usefulness of the guidelines should be evaluated; and
- guidelines should be revised regularly.

2.1 Guideline development and evaluation

The process for guideline development should be aimed at identifying interventions that will ensure the best possible health outcomes.

A health outcome has been defined as ‘a change in the health of an individual, a group of people or population which is attributable to an intervention or a series of interventions’ (AHMAC 1993). Donabedian describes outcomes as ‘what is accomplished for patients’ and points out that they reflect the ‘contribution of all those who provide care’ as well as the ‘appropriateness of the choice of a strategy of care’ (1992b).

Outcome measures can range from survival rates to quality-of-life attributes. Outcomes can be positive or negative and may differ according to population group—for example, socio-economic group, gender, or current health or risk factor status.

To date much of the evaluation of health care has centred around the process of health care (whether clinicians conform to recommended practices), rather than the outcomes (whether the recommended practices produce a change in health). Whilst the ultimate goal of the guideline-evaluation process should be to establish the degree to which the guidelines are effective in producing the health outcomes

sought, this may not be practical because of the difficulty of attributing outcomes to the guidelines.

2.2 Using the best available evidence

The purpose of clinical practice guidelines is to encourage treatment that offers individual patients maximum likelihood of benefit and minimum harm and is acceptable in terms of cost. Recommendations contained in guidelines should be based on the best possible evidence of the link between the intervention and the clinical outcomes of interest.

The evidence on which a recommendation is based can be graded according to level, quality, relevance and strength. Appendix A provides definitions of these criteria, as used by the Health Advisory Committee of the National Health and Medical Research Council.

Ideally, recommendations should be based on the highest level of evidence, preferably a systematic review of high-quality randomised controlled clinical trials that measure relevant outcomes and demonstrate a strong, clinically important, beneficial effect of the intervention. It is important, though, to recognise that this ideal may be difficult to attain in the case of public health and social science interventions: these important areas of health care should not be disadvantaged by the rigid application of a 'hierarchy' of evidence.

In many cases it may not be possible, or feasible, to evaluate a large-scale public health intervention using a randomised controlled trial. Other forms of evidence—such as well-designed controlled studies and time series analyses—may be the most appropriate and feasible method. Although there is currently no agreed separate grading for assessing the level of evidence in relation to public health interventions, the primary objective is to strive for evidence derived from a study design that is the most practical and feasible available in order to maximally control for potential bias. In addition, evidence derived from a systematic review of all the available studies that meet this criterion is obviously preferable to evidence from a single study.

Until an agreed rating scale is developed to assess levels of evidence associated with public health interventions, guideline developers are advised to use the levels of evidence referred to in this document but to recognise that much of the evidence currently available in relation to public health interventions will be level III—see Appendix B. In this context it is important to note that the evidence from public health interventions is often supported by strong biological data.

Where appropriate, guideline developers should include in the text a statement on the level, quality, relevance and strength of the evidence and recommendations made should reflect this statement.

2.2.1 The level and quality of evidence

The level of evidence and the quality of evidence need to be considered together.

‘Level of evidence’ refers to the study design used by investigators to minimise bias (see Appendix B). Level I, the highest level, is generally accorded to randomised clinical trials. A methodologically poor randomised trial (level II) may, however, provide a weaker basis for a recommendation than a high-quality observational study without randomisation, which can provide level III-2 evidence.

‘Quality of evidence’ refers to the methods used by investigators to minimise bias in study design and in the conduct of a study. The types of bias and their possible effects depend on the study type. There are now fairly well established criteria for assessing the quality of randomised trials; they concern the degree to which allocation to treatment groups is concealed from investigator and subject, whether the study is double blind, and the completeness of follow-up of subjects.

Methods of assessing the quality of non-randomised studies (levels III-2 and III-3) are less well established and the factors will probably vary depending on the study type. In general, factors that are likely to influence the estimate of the effect size are the methods used to select subjects for the trial, the comparability of the treatment and control (if there is one) groups, the methods of measuring outcomes, and the completeness of the follow-up.

The quality of systematic reviews also needs to be considered if they are being used as the basis of guideline development. Standard methods for conducting and reporting systematic reviews have been published (see Greenhalgh 1997).

Lack of empirical evidence

No formal level of evidence is attached to expert opinion, the findings of expert working parties, or anecdotal information. In the absence of empirical evidence, however, or where there is only poor-quality evidence, guidelines may in some instances contain recommendations based on findings outside the levels-of-evidence hierarchy. Such recommendations should be derived using a consensus approach.

If a consensus approach is not possible non-consensus practice statements can be issued, but there should be clear reference to all schools of thought and consumers should be made aware of the lack of consensus (see Appendix C).

2.2.2 The relevance of the evidence

'Relevance of the evidence' refers to the study question's similarity to the clinical question and the extent to which the findings from the study can be applied in other clinical settings to different patients. The types of outcomes that are measured and reported in a clinical trial determine whether all of the possible benefits and harms associated with a treatment can be assessed properly—among the factors that are important are the nature of the outcomes that have been measured in the trial and the period over which the measurements have been made.

It may be useful to consider outcomes as being of one type or a combination of two or three types: 'surrogate' outcomes, 'clinical' outcomes, and 'patient-relevant' outcomes. In general, the types of outcomes that clinical trials measure and report are either surrogate or clinical outcomes; these may or may not be of importance to the patient.

A surrogate outcome is commonly a physiological variable; for example, serum cholesterol concentration or blood pressure. There is a statistical association between the surrogate outcome and the clinical outcome of interest; for example, bone mineral density and fracture or measures of HIV viral load and progression of AIDS. There is a biological and pathophysiological basis for believing that the surrogate outcome is a primary determinant of the clinical outcome in the disease being studied; for example, glycosylated haemoglobin measurements and diabetic complications.

If the trials that form the basis of the recommendations are restricted to surrogate outcomes it is important to determine that there is a relationship between these surrogate outcomes and the clinical outcome of interest.

Clinical outcomes tend to be defined on the basis of the disease being studied. In many cases the outcome that appears to the clinician to be of primary concern, and that can be measured, is chosen; for example, survival in cancer, vertebral fracture in osteoporosis, peptic ulcer healing and relapse, walking distance in angina or claudication, or microbiological 'cure' of infection. But such an approach does not necessarily capture all of the relevant outcomes from the patient's perspective: other factors that are often more difficult to measure may be more relevant, in particular factors relating to improved quality of life.

One of the difficulties in measuring patient-relevant outcomes is that they may be ‘composite’ outcomes and include items that are not readily amenable to objective measurement. They are likely to include a measure of a clinical effect, adverse effects, and change in quality of life and may need to be individualised for each treatment. In this situation the following types of outcomes should be considered:

- all-cause mortality;
- cause-specific mortality;
- changes in morbidity, subdivided according to type—for example, hospital admission or nursing home requirements;
- side-effects of treatment—including adverse reactions to drug therapies—and co-interventions that may be necessitated by the primary treatment; and
- disease-specific outcomes—including disease-specific quality-of-life measures.

Emphasis should be given to studies that measure clinical or patient-relevant outcomes. Guideline developers should seek the advice of experts and patient-support groups in determining what the most appropriate outcomes are. Many clinical trials and studies do not consider all the outcomes, beneficial and harmful, that are relevant to patients with a particular condition and to those who care for them. Clinical endpoints—such as a small change in blood cholesterol in a ‘low-risk’ patient—may not be as relevant as the side-effects of a particular treatment. Equally, a condition that impairs the social functioning of a person might be very effectively alleviated by a new intervention. Formal quality-of-life measures such as the SF-36 often do not capture the information that is of real importance in assessing the potential impact or value of a new technology.

2.2.3 The strength of the evidence

The strength of the evidence depends on the magnitude of the treatment effect seen in the clinical studies. It also depends on how confident we are of the observed effect—in other words, the size of the confidence interval—and the extent to which the findings have been reproduced across a series of studies.

Strength of evidence is important for two main reasons. Strong effects are less likely than weak effects to be the result of bias in the studies: they are more likely to be real. And strong effects are more likely to be clinically important.

2.3 Using evidence in making recommendations for treatment

Evidence is necessary, but not sufficient, when making recommendations for treatment. Taking the evidence—of whatever level, quality, relevance or strength—and turning it into a clinically useful recommendation depends on the judgment, experience and good sense of the guideline developers.

Having evidence from a high-level study such as a randomised controlled trial does not immediately mean that a good clinical recommendation will result. Suppose we had one well-conducted randomised controlled trial on which to base our recommendations: if the effects of the intervention were small and the outcome measures were surrogates, rather than clinical outcomes, the evidence would be relatively unhelpful.

In assessing the likely ratio of benefit to harm it is often helpful to produce a simple 'balance sheet' in an attempt to estimate, for a 'typical' group of patients, the number of subjects who will experience benefit or harm. All of the known beneficial and harmful effects of the treatment should be included in the balance sheet. In order to assess the applicability of the guideline advice to other groups of patients, an attempt should be made to create a new balance sheet with revised estimates of the number of beneficial and harmful effects.

For instance, if an effective preventive treatment (such as treatment to lower cholesterol or the use of warfarin for non-rheumatic atrial fibrillation) is being applied to a population at low risk of the outcome of interest, the estimated number of benefits may not exceed the estimated number of harms by a satisfactory margin. The guideline development group must make a judgment about how wide this margin should be in order to justify a recommendation for treatment.

Other factors warranting consideration when making recommendations are the cost-effectiveness of the interventions, the financial implications for the health budget of full implementation of the recommendations, and any inequity that may arise if only certain sections of the community can afford to pay for the interventions recommended.

2.4 A multidisciplinary approach that includes consumers

If guidelines are to be relevant, those who are expected to use them or to benefit from their use should play a part in their conception and development.

The involvement of a range of specialist and generalist clinicians, allied health professionals, experts in methodology (such as epidemiologists and health economists), and consumers will improve the quality and continuity of care and increase the likelihood of the guidelines' adoption. These groups can make significant contributions to the identification of relevant outcomes, values, target audiences and guideline formats for different users. They can also play a critical role in identifying potential obstacles to guideline implementation and in the formulation of implementation strategies.

2.5 Flexibility and adaptability

Guidelines should provide a clear statement of the evidence but allow for flexibility and adaptability in implementation. Thus, they should:

- provide evidence relevant to different target populations, which may vary in terms of age, gender, ethnicity, diagnosis, disease severity, co-morbidity and social support;
- provide evidence relevant to different geographic and clinical settings;
- take into account resource benefits, costs and constraints; and
- offer a means of accommodating different consumer values and preferences.

2.6 Economic implications

Guideline developers should be mindful of the resources required for development and implementation of guidelines. Further, in adapting guidelines to accommodate local conditions account should be taken of the following:

- limited treatment options;
- variations in the available equipment;
- variations in the training, experience and skills of existing and incoming clinicians; and
- variations in the availability of staff—in terms of numbers and professions.

It is important that an economic appraisal be incorporated in guidelines. In many circumstances this may be useful in guiding clinical decisions about treatment options. There are three types of economic appraisal comparing two interventions, or one intervention against a placebo:

- a cost-minimisation analysis, in which the direct costs of the proposed intervention are compared, assuming equal efficacy but differences in side-effects, or on the basis of the use of different patterns of care that generate different costs;
- a cost-effectiveness analysis, in which the relative effectiveness (measured, for example, by a reduction in blood pressure or days of disability averted) and the relative direct costs of two interventions are compared using a ratio of marginal cost to marginal effectiveness (for example, cost per life-year gained or cost per day or disability averted); and
- a cost-utility analysis, in which the effectiveness measure derived in the cost-effectiveness analysis is weighted by the recipient's quality of life resulting from each intervention (thus producing a measure such as marginal cost per quality-adjusted year of life gained).

2.7 Guideline dissemination and implementation

Guidelines are developed to be disseminated and implemented in such a way that practitioners and consumers become aware of them and use them. This will involve identifying potential obstacles to implementation and tailoring implementation strategies to the particular contexts in which the guidelines are to be introduced.

2.8 Evaluation

It is important to evaluate the implementation process to determine the extent to which the guidelines affected practitioners' knowledge and behaviour and what, if any, factors contributed to non-compliance with the guidelines. These results might inform the development of more effective implementation strategies.

It is also important to establish whether the introduction of the guidelines produced the anticipated health outcomes. Thus, once the guidelines are implemented, health outcomes should be routinely monitored wherever practical. Outcomes associated with the introduction of evidence-based guidelines must be evaluated since the efficacy of treatments delivered in strictly controlled trials may not always be realised in day-to-day practice.

2.9 Revision

Because guidelines need to be based on the best available evidence, they should be reviewed regularly and modified where necessary to take into account new research, new technologies, and the results of evaluation of guideline outcomes.

CHAPTER 3

GUIDELINE DEVELOPMENT

This chapter describes the general steps involved in developing guidelines. The steps are consistent with the principles discussed in Chapter 2. The process of developing guidelines should run in tandem with formulating a strategy for their dissemination and implementation and a plan for their evaluation and revision. Chapter 4 deals with dissemination and implementation and Chapter 5 deals with evaluation and revision.

It is important that guideline developers consider, at the beginning of the guideline development process, what data will be needed. Data collection, storage and retrieval must have due regard for principles of privacy and confidentiality and should take into account matters associated with data ownership.

It should be noted that the sequence of steps detailed in this chapter is intended as a guide rather than a prescription for developing guidelines. Context may require that the steps be taken in an order that differs from what is described here. In addition, some early steps may be revisited at later stages in the process. Appendix C illustrates the process of developing, disseminating, implementing, evaluating and revising clinical practice guidelines.

3.1 Determining the need for and scope of guidelines

The body responsible for developing the guidelines should specify the problem or objective and define what is involved in general terms. When selecting topics there must be a clear problem that may well be resolved by the establishment and dissemination of guidelines on what is the most appropriate practice. The problem could relate to the extent of the health burden, cost, variations in practice, or the availability of evidence.

Clinical practice guidelines are appropriate only if the problem or objective is related to clinical decision making or decisions about the organisation of health services. Guidelines may be developed, for instance, in response to an identified variation in treatment among practitioners for the same condition. If this variation is caused by lack of knowledge or information, the development of evidence-based guidelines is an appropriate response. But variations in clinical practice may be based on patients' needs and sound evidence: such 'legitimate variation' can result from variations in morbidity rates and variations in consumer preferences for different outcomes (Anderson & Mooney 1990, McPherson 1990). Guidelines may not be necessary in such situations. Nor are they an appropriate response to variations caused by unreliable data sources and random variations in data. Furthermore, guidelines may not be needed if practice variations are a consequence solely of resources or supply constraints (beds, technology, facilities, specialists, and so on) or if clinical decisions are based on sound evidence.

Previously developed guidelines for redressing the same problem or a related one should be assessed. If those guidelines are applicable to the current circumstance or can be adapted, new guidelines may not be required. It is important, however, to assess the previously developed guidelines according to the principles discussed in this document, particularly in terms of the quality of the evidence on which they are based. If the old guidelines have been implemented, establish whether they were effective. Although they may be considered acceptable, it may still be necessary to take steps to evaluate their effectiveness in clinical practice.

3.2 Convene a multidisciplinary panel to oversee the development of the guidelines

The overseeing panel should consist of representatives of all relevant groups. The panel's precise composition will depend on the nature of the guidelines but should be designed to encourage the expression of diverse interests. In general, consideration should be given to involving the following groups, as appropriate:

- clinicians from all disciplines with relevant specialist expertise;
- clinicians with general expertise;
- other relevant health professionals;
- representatives of consumer groups;
- experts in research methods relevant to guideline development;
- health economists;
- public policy analysts;
- other relevant experts;
- industry representatives;
- bioethicists; and
- representatives of regulatory agencies.

To ensure that decision making takes full account of the consumer perspective, the panel may need to establish a separate consumer focus group to identify all the relevant consumer concerns.

Workshops for members of guideline development working parties may be beneficial in bringing together multidisciplinary groups as well as consumers to consider the need for clinical practice guidelines and the methods to be used in their preparation, dissemination, implementation, evaluation and revision.

All members of guideline development groups should make declarations of their interests available to the National Health and Medical Research Council or other appropriate bodies. Both personal and non-personal interests should be declared; for example, personal shares in companies, consultancies to companies, corporate support for specific research, or general departmental activity (SIGN 1995).

3.3 Define the purpose of and target audience for the guidelines

Before proceeding, the panel should clarify the purpose of and target audience for the guidelines. This will involve a careful specification of the following:

- the conditions and clinical problems that are at issue;
- the type of care providers for whom the guidelines are intended;
- the type of consumers for whom the guidelines are intended;
- a description of consumers not covered by the guidelines (where it might otherwise be assumed that the guidelines are relevant to these consumers);
- the types of settings in which the guidelines will be employed; and
- the interventions to be evaluated.

The panel should also determine how many versions of the guidelines are required. As a minimum requirement, separate consumer and practitioner documents should be produced, but the panel will also need to determine whether different documents are required for different care providers in different clinical settings and for different consumers.

3.4 Identify health outcomes

The purpose of clinical practice guidelines is to improve health outcomes and to encourage the appropriate use of resources. The appropriate outcome measures will differ depending on what is under consideration. There is, however, a clear difference between the following categories of measures:

- immediate or short-term measures such as mortality, morbidity, and treatment complications;
- rates of relapse, complication, late morbidity and re-admission;
- return to work and physical and social functioning; and
- other measures such as quality of life, general health status and patient satisfaction.

Each of these measures should be taken into account. Some measures will be clinically defined and some will be socially defined and, again, both types should be included. Appendix D outlines generic outcome measures that can be applied to specific conditions and interventions.

3.5 Review the scientific evidence

If possible, a systematic literature review should be undertaken to establish the benefits and harms of the possible interventions.

Methods for reviewing and evaluating the literature range from highly formal, quantitative information syntheses (such as meta-analysis of randomised controlled trials) to subjective synopses of observational data. The more formal the review, the more credible and valid the resulting guidelines. The panel should select the most rigorous and systematic review methods practicable according to the approach outlined in Chapter 2 and the methods described in *The Cochrane Collaboration Handbook* (Sackett 1994).

The guidelines should clearly state the methods used to review the literature. There should be rigorous discussion of and debate about the literature, and any gaps in it should be identified.

3.6 Formulate the guidelines

The guidelines should be constructed on the basis of the best available scientific evidence of the probable outcomes associated with different clinical interventions. The panel should consider the following:

- the natural history of the disease or condition in question, if appropriate;
- the probable outcomes of each intervention, taking into account the strength of evidence associated with each, with preference given to empirical evidence over expert judgment;
- the balance of benefits against risks;
- a comparison between the outcomes for alternative interventions, including conservative or expectant management where appropriate, for the disease or condition in question; and
- an economic appraisal of the best investment for the best health outcomes (see Appendix E).

3.7 Formulate a dissemination and implementation strategy

During the guideline development phase the panel should also develop a plan for disseminating and implementing the guidelines. Ideally, this plan will target all potential users and define and recommend processes that will encourage them to adopt and implement the guidelines. Such a plan may be developed in consultation with the wider group of interested parties. Chapter 4 provides detailed information about dissemination and implementation.

3.8 Formulate an evaluation and revision strategy

The panel should develop a strategy designed to ensure that the guidelines are evaluated properly and revised when necessary.

This will involve specifying both short-term and long-term frameworks for evaluation and identifying who will conduct the studies. The evaluation should assess how effectively information has been disseminated to patients consenting to the treatment in question as well as to practitioners providing the treatment. It may also include a consideration of alternative evaluation procedures.

Most importantly, the evaluation will assess whether implementation of the guidelines has led to improvements in health outcomes. Chapter 5 provides detailed information about evaluation and revision.

3.9 The guidelines themselves

Once the dissemination and implementation and evaluation and revision strategies have been developed, the panel should proceed to produce the guidelines.

The guidelines should be presented as clearly and concisely as possible, bearing in mind that different formats may be appropriate for different types of guidelines or different types of users. Guidelines may be presented as free text, as flow charts or in any other format that facilitates comprehension. Abbreviations and symbols should be consistent and easy to follow. Important terms and others that might be misinterpreted should be defined.

The guideline document's content will vary according to its specific purpose—for example, whether it relates to diagnosis, choosing treatment options, implementation of specific treatment, or managing an extended process of care. In some cases an additional document with more explanation or in a different format may be required for use by consumers. Consideration might also be given to producing different guideline documents for specialist and non-specialist health professionals and for different health care settings.

In general, the guidelines should do the following:

- document the purpose for which they were developed;
- describe each treatment option, including conservative or expectant management, if appropriate;
- describe the natural history of the disease(s) or condition(s) under discussion, where appropriate;
- detail the probable outcomes—the benefits and harmful side-effects specified in terms of changes in physical, social or psychological function, changes in pain and expected additional morbidity or mortality—associated with each treatment option. The extent to which potentially harmful side-effects need to be detailed in consumer documents should be determined in consultation with consumers;
- be comprehensive and flexible enough to allow adaptation to the diverse settings and circumstances of day-to-day clinical practice;
- identify the specifically known or generally expected exceptions—circumstances in which the guidelines would not apply—or potential risks;
- indicate the probability (risk) of different outcomes occurring;
- identify the patient population to which they apply, bearing in mind possible differences in expected outcomes for different populations;
- contain a description of the support services that may be required for each treatment option, to allow consumers to assess the social consequences of the options;
- include information for consumers and clinicians on any special training needs for clinicians or equipment necessary for the safe delivery of the treatment;
- provide a comparison of the costs associated with treatment options;
- provide a statement detailing the scientific basis on which the guidelines were developed and explicitly note the strength of the evidence on which any conclusions are based;
- document the uncertainty associated with any conclusion—uncertainty exists where the evidence on outcomes is not strong and/or clinical opinion may differ as to what outcomes may be;
- in the case of consensus-based guidelines, acknowledge the desirability of developing evidence-based guidelines;
- in the case of non-consensus practice statements, make clear reference to each of the schools of thought and direct consumer attention to the lack of consensus. Note that the National Health and Medical Research Council has issued guidelines on human experimentation—these should apply to interventions for which non-consensus practice statements are issued; and
- document the economic appraisals used in formulating the guidelines.

3.10 Reporting on the guideline development process

The report should contain a description of the guideline development process, the dissemination and implementation and evaluation and revision strategies, and matters for future research.

The part of the report referring to guideline development should do the following:

- identify the organisation under whose aegis the guidelines were developed—who proposed, endorsed and funded the guidelines;
- define the purpose of the guidelines—for what audience(s) are the guidelines intended?
- indicate if different formats were required for different users;
- list the individuals and groups involved in developing the guidelines;
- document the processes and nature of the scientific evaluation of the evidence—for example, specify whether meta-analyses were used to analyse the literature or if consensus formed part of the guideline development process;
- provide a bibliography of materials used;
- contain a clear description of the scientific assumptions—whether relating to physiological assumptions, methods of actions of drugs or processes, expectations of deaths or morbidity following treatment, side-effects, and so on—that were incorporated in the evidence;
- record the public policy and cost questions considered and the method by which they were incorporated in the guidelines;
- identify the need for special training, equipment or facilities;
- describe the testing processes to which the guidelines were subjected;
- document the consultations undertaken; and
- record how consumer concerns were taken into account.

The part of the report dealing with dissemination, implementation, evaluation and revision should contain the following details:

- the target audience and other interested parties;
- methods of consultation and dissemination;
- specific plans for particular circumstances—such as remote or rural locations and links to institutional activities;
- the time frame for evaluation;

-
- the plan for assessing guideline implementation and barriers to implementation;
 - the plan for assessing the validity of the guidelines; and
 - revision plans.

The part of the report dealing with matters for future research should contain the following:

- suggestions for improving the guidelines and their capacity for enhancing future care and optimising resource use;
- gaps in scientific knowledge or other information gaps—for example, costing data—for future investigation; and
- organisational, funding or other ‘process’ factors that might enhance the quality of outcomes expected from the guidelines’ implementation.

3.11 Assessing the guideline document

The adequacy of the guideline document itself should be evaluated by examining whether it conforms to the principles outlined in this guide. Note that the Institute of Medicine has developed a provisional instrument for prospectively assessing the soundness of guidelines and the method by which they were developed (Field & Lohr 1992). The Institute’s provisional assessment instrument is a formal questionnaire that requires experts to rate the guidelines according to a range of characteristics, such as their clinical applicability and flexibility, reliability and reproducibility, validity and clarity.

The Scottish Intercollegiate Guidelines Network has also developed criteria for appraising the guideline development process; it may be of value in the Australian setting (SIGN 1995).

3.12 Consultation

The guidelines should be referred for examination to a wider group of interested parties that may not have already been involved:

- practising clinicians;
- clinical colleges and allied health and professional organisations;
- consumer groups;
- Commonwealth, State and Territory and local health authorities; and
- industry groups.

It may be useful to convene a conference of interested parties, provided this forms only one part of the overall approach to guideline development and provided the principles outlined in this document are incorporated in the decision-making process.

In some instances an agency or group such as a professional college may disagree with one or two of the recommendations in an otherwise acceptable document. These points of disagreement should be noted in the guidelines.

The final guidelines should take into account comments received during the consultations and in response to pilot testing.

Blank facing page to Chapter 4

CHAPTER 4

GUIDELINE DISSEMINATION AND IMPLEMENTATION

Field and Lohr make the important point that 'guidelines do not implement themselves' (1992). If guidelines are to be effective, their dissemination and implementation must be vigorously pursued. If not, the time, energy and cost devoted to the guidelines' development will be wasted and potential improvements in consumer health will be lost.

A multidisciplinary panel should oversee the various steps needed to disseminate and implement the guidelines. The panel, which may be the same as the panel responsible for developing the guidelines, should also identify any barriers to the guidelines' acceptance and implementation and work with members of target groups to develop ways of overcoming these barriers. Identifying barriers to change requires an understanding of sociological and psychological factors: it is essential that the guideline development panel has expertise in these areas; otherwise, inappropriate or ineffective methods of dissemination and implementation may be advocated.

Although the guideline document may support a specific strategy for adapting guidelines to local conditions, the guideline development panel may need to help local groups with the adaptation process.

There is evidence that a range of dissemination and implementation strategies can be effective (EHCB 1994). It is probable, however, that those strategies will depend on the nature of the guidelines and which group is being targeted. There are a number of possible strategies, such as the following:

- producing short summaries for use in a range of forums, including on the Internet and websites;
- involving potential users in the development of the guidelines, directly or through consultative mechanisms, or both, to promote ownership. The consultation process on the draft guidelines can form part of the dissemination strategy;
- using the media—local, regional or national, or a combination—to publicise both the development process and the availability of the guidelines;
- using professional journals and magazines to inform people about guideline development and promote the completed guidelines;
- using the communication links developed by clinical colleges, allied health organisations, specialty societies, State and regional medical societies, consumers, consumer groups, medical libraries and health education facilities;
- asking respected clinical leaders to promote the guidelines;
- providing economic incentives;
- using the educational processes of relevant colleges, professional organisations and consumer groups, including conferences, workshops, seminars and specialist journals;

-
- incorporating the guidelines in routine procedures—such as quality assurance and review processes—of institutions and organisations that provide care;
 - using information technology, particularly systems focusing on consultations with individual patients;
 - arranging for a credible health care provider to visit practitioners in the clinical setting;
 - piloting the draft guidelines in practices, clinics or hospitals, to facilitate assessment of their relevance, applicability, comprehensiveness and flexibility; and
 - offering feedback on compliance with the guidelines.

Some of these strategies may be more effective when used in combination. There is evidence that the more educational the dissemination strategy, the greater the probability that the guidelines will be incorporated in clinical practice, provided that dissemination is reinforced by an appropriate implementation strategy.

The initial dissemination strategy should define target audiences and design accessible formats for the guidelines. Different versions of the guidelines should be developed for different audiences—consumers, general practitioners, specialist nurses, and so on. For example, the primary target audience for the National Health and Medical Research Council's guidelines on the management of early breast cancer is consumers and specialists in breast surgery, medical oncology and radiation oncology; the secondary target audience is general practitioners, registered nurses involved in caring for women with breast cancer, funders, managers, accreditors and others.

Implementation strategies should take into account the ways in which privacy and confidentiality concerns might impede the implementation of guidelines. Questions raised by the need to manage patient care across several locations (hospitals, communities, nursing homes, and so on) or with the involvement of several clinicians need to be considered.

In summary, the group producing the guidelines should inform the target audience that the guidelines are being developed, let the audience know when they are available, ensure that they are distributed, and work with the audience on effective implementation.

4.1 Dissemination

4.1.1 Making the guidelines accessible

Guidelines should be presented in formats and styles suitable for their target audience. Where the target audience is varied—as with, for example, the breast cancer guidelines—the guidelines need to be presented in a range of formats and styles suitable for each segment of the target audience. The cost of guidelines should not present a barrier to access.

In their initial format, most guidelines will be large documents providing detailed recommendations on diagnosis, investigation or treatment (or all of these things) and providing evidence to support the recommendations.

Health professionals manage an array of conditions in a variety of circumstances, so consideration should be given to the development of documents and formats that are suitable for general practitioners, clinicians working in emergency departments, ambulance officers, public health officials, quality assurance managers, discharge planners, consumers and others.

4.1.2 Publishing the guidelines

Guidelines can be published as booklets, containing comprehensive information and available from a central authority, or in summary form, providing information about the main findings and recommendations and also available from a central authority.

Summaries of the guidelines can also be published in other ways:

- in professional journals;
- in professional associations' newsletters and magazines;
- in trade publications and industry newspapers;
- in institutional newsletters, such as those of divisions of general practice, hospitals, consumer groups and area health services;
- in the popular media;
- as brochures—an example is the desk-top summary for General Practitioners on the management of early breast cancer;
- as posters;
- in summary form or as full guidelines published on the Internet and linked to websites appropriate for the target audience;
- as audio or video tapes; and
- on computer disks.

In each case the language and style should be appropriate for both a general audience and the target audience. Dissemination of guidelines will be improved if more than one guideline format is used since, generally, multiple strategies yield better results than individual strategies.

4.1.3 Informing the target audience of the guidelines' availability

Ensuring that the target audience is aware of guideline development is a process that should begin when consideration is being given to developing or revising existing guidelines. The process is facilitated by advertising and wide publicity. It is important to keep the target audience informed of progress, to alert them to impending publication, to notify them when the guidelines are available, and to distribute the guidelines to them.

A range of methods can be used to inform the target audience of the guidelines' availability. These methods rely on informing clinicians directly; informing consumers, who will request action based on the guidelines; and informing managers, funders, accreditors and governments, who will all have their own reasons for wanting the guidelines. Among strategies for informing the target audience are the following:

- using national, regional and local media;
- publicity in trade publications and possibly writing articles for them;
- publicity through professional associations and their publications and possibly writing articles for them;
- publicity in professional journals;
- publicity through consumer groups and their publications;
- contact with undergraduate and postgraduate educators;
- contact with undergraduate and postgraduate students;
- publicity through institutions such as colleges, hospitals, divisions of general practice, area health services and universities;
- discussion at conferences, seminars and professional meetings;
- using 'champions' or local authorities to promote the guidelines or to be interviewed about the guidelines in the media; and
- identifying 'human interest' stories for the media to highlight the need for and benefits to be gained from the guidelines.

Although dissemination is an essential feature of guideline development, it alone is not enough to change physicians' behaviour. Most evaluations of guidelines have shown that relying solely on printed material does not influence clinicians' behaviour or health outcomes (Oxman et al. 1995). There is also evidence that unsolicited mailing of guidelines does not influence clinicians' behaviour, although it can increase awareness of the guidelines (Grimshaw et al. 1995).

It may be appropriate to consult a professional communicator or seek expert help from government, professional or consumer bodies.

In summary, dissemination involves making guidelines accessible, advertising their availability, and distributing them widely. Strategies will vary according to the target audience, but multiple strategies will ensure greater coverage than a single strategy.

4.2 Implementation

Many studies have examined strategies for continuing medical education (see, for example, Davis et al. 1995) and there is a considerable body of evidence on which to draw. The most striking finding is that the simple dissemination of guidelines is likely to have no impact at all on implementation (Oxman et al. 1995; Wise & Billi 1995).

Change will occur only if specific interventions designed to encourage it are used. The interventions most likely to induce change are those that require the clinicians' participation in the change process (Wise & Billi 1995).

There is also evidence that the most effective implementation strategies are those that have a direct effect on consultation between patient and health care professional. Examples are restructuring medical records and patient-specific reminders to incorporate guideline recommendations in decision making. In this way, the guidelines become part of the process of care.

No single implementation strategy is effective in all circumstances for all people. Successful implementation of guidelines requires that they become embedded in many different aspects of the health care system and are informed by many different aspects of the system. For more information about what implementation strategies work, see Appendix I.

There is insufficient evidence to allow firm statements to be made about which strategies work in which circumstances, and it is difficult to differentiate which elements of strategies are the effective ones. Nevertheless, the following strategies have been shown to be effective in changing clinicians' behaviour or health outcomes, or both, at least some of the time:

-
- media marketing;
 - the use of opinion leaders and ‘champions’;
 - endorsement by clinical groups;
 - practice visits from influential experts;
 - education of patients;
 - educational materials;
 - seminars and conferences;
 - reminder systems incorporated in clinicians’ daily work;
 - continuing quality assurance and data feedback;
 - local adaptation and incorporation;
 - local involvement in evaluation; and
 - incentives (Lomas & Haynes 1988; Lomas 1993, 1994; Oxman et al. 1995).

Each of these strategies requires different levels of input because of variations in the degree of difficulty and in the cost of implementation. The implementation plan should be developed to ensure that the most expensive implementation strategies are used only when current practice differs from the recommendations.

Information technology, including the Internet and decision-support software, is playing an increasingly important role in the implementation of guidelines, in both summary and extended forms. A large body of work has already been generated in this area and more is emerging.

4.2.1 The use of opinion leaders and ‘champions’

Highly regarded individuals—whether local specialists, general practitioners or national figures—influence the practice of their peers (Lomas et al. 1991; Oxman et al. 1995). They can deal with misconceptions about guidelines and help clinicians observe the outcome of a particular innovation (Davis et al. 1995).

Consumer-support groups and well-recognised individual consumers can also champion guidelines and guideline processes. Opinion leaders can be enlisted to promote clinical practice guidelines at every opportunity, both formally and informally.

4.2.2 Endorsement by clinical groups

If guidelines are endorsed by professional groups such as colleges and the National Health and Medical Research Council they are more likely to be taken up by clinicians. Endorsement by local groups is also important because the process of endorsement means the guidelines will be examined closely by clinicians. This may lead to adaptation to suit local circumstances, thus contributing to a sense of ownership of the guidelines.

4.2.3 Practice visits from influential experts

The pharmaceutical industry employs a large number of marketing representatives who visit clinicians in the practice setting and provide advice. This has been shown to influence prescribing patterns (Todd 1995): meeting a sales representative from a pharmaceutical company increases the likelihood that a doctor will prescribe that company's product (Chren & Landefeld 1994).

This approach has been adapted as academic detailing—where influential but independent peers visit clinicians in their usual practice setting. Although expensive, it has been shown to be effective (Oxman et al. 1995). In a typical program, a clinical pharmacist armed with scientific data and simple memory aids visits a clinician in his or her own practice and provides advice about a particular matter, such as the appropriate use of non-steroidal anti-inflammatory drugs (May et al. 1993). As noted, such programs have been shown to affect prescribing (Todd 1995).

4.2.4 Education of patients and patient-mediated intervention

Providing patients with information and education—about guidelines or about the condition under discussion—has been shown to change clinicians' behaviour. Educating patients raises their expectations, which then increases the demand on clinicians, which improves performance. Information and education lead to improved health outcomes when combined with other interventions, such as academic detailing and clinician education (EHCB 1994; Oxman et al. 1995).

In developing education material for patients, and in considering the material's dissemination, it should be remembered that different groups of patients and consumers have different needs.

4.2.5 Educational materials

Educational materials include the guidelines themselves, adaptations or summaries of the guidelines, and articles about them in the general media, professional and trade publications. Most studies have found that educational materials used alone have little impact on professional behaviour and health outcomes (Oxman et al. 1995). Incorporation of educational materials in problem-based learning styles has, however, been shown to be effective (B. Booth, pers. comm., 1996).

4.2.6 Seminars and conferences

Seminars and conferences requiring only passive attendance have not shown benefit. Conferences requiring active participation through workshops, and with follow-up, have been shown to influence clinicians' behaviour (Oxman et al. 1995).

Based on the principles of adult learning and research evidence on the effectiveness of continuing medical education, seminars and conferences should be planned with the following principles in mind.

- the primary purpose of the activity is to improve the quality of patient care;
- the content of the activity demonstrates high clinical and ethical standards;
- clinicians participate in planning the activity;
- a learning needs assessment is conducted;
- the activity has clear learning objectives;
- the learning environment promotes fulfilment of the learning objectives; and
- the educational activity is evaluated (Royal Australian College of General Practitioners 1995).

4.2.7 Reminder systems incorporated in clinicians' daily work

Reminders—whether involving patient records or computerised prompting—may influence clinicians' behaviour (Grimshaw & Russell 1994; Oxman et al. 1995). These reminders provide a prompt that can be acted on immediately. Their effectiveness probably comes partly from their immediacy.

Mailed reminder systems—such as those used for mammographic screening and Pap smears—have also been shown to be effective (Lomas & Haynes 1988).

4.2.8 Quality assurance and quality improvement

Quality assurance and quality improvement activities have a complementary and reciprocal relationship with clinical practice guidelines. Quality assurance activities encourage the implementation of guidelines, and guidelines are a crucial component of quality assurance activities.

Continuous clinical practice improvement claims to improve the quality of care by bringing together research on variation of cost, access, quality and standardised care. It requires a knowledge of processes and systems, human behaviour and an approach to continuous learning.

Continuous clinical practice improvement generates valid statistical inferences about the operational day-to-day elements in the process of clinical care. It applies the scientific method to the day-to-day practice of health care. It also analyses the content and timing of individual steps of the care process in order to determine how to achieve superior health outcomes, for the least necessary cost, over the continuum of a patient/client's care.

There is evidence that the inclusion of evidence-based guidelines will strengthen formal quality assurance activities such as clinical audit (Oxman et al. 1995). The information in guidelines may also be used for developing utilisation reviews, continuous quality improvement, total quality management and accreditation of institutions or services, as well as providing a reference for interpreting data feedback on clinical units' practices and the health outcomes of their patients.

In effect, guidelines can become incorporated in routine processes of care. Using guidelines as a basis, it is possible to develop hospital admission and discharge policies, care pathways and referral protocols. These systems will also facilitate evaluation of the uptake of guideline recommendations and their impact on health outcomes.

Data collection systems measuring the impact of guidelines also allow comparison between the evidence about outcomes gathered from clinical trials and the real 'outcomes' achieved in routine clinical practice. In this way both clinicians and patients can become better informed about the risks and benefits of medical interventions.

4.2.9 Local adaptation and incorporation

The effectiveness of nationally developed guidelines may be enhanced if local groups—such as clinicians at a particular hospital, a division of general practice or a State faculty of a specialist group—adapt the guidelines for local use, while taking into account geographic, demographic, resource and other factors (Oxman et al. 1995). In one case studied, this process improved the scientific integrity of the guidelines (Brown et al. 1995). The process of local adaptation exposes clinicians to the guidelines, makes the guidelines more relevant to local conditions, and encourages a feeling of ownership (Wise & Billi 1995).

Local adaptation could be assisted if the guideline publisher were to make the document available on disk or on the Internet.

In adapting guidelines for local use, the core content in most circumstances could include the following:

- identification of a specific patient population;
- details of the likely outcomes of care—benefits, adverse effects, changes in physical, social or psychological functioning, changes in pain, and expected changes to overall morbidity and mortality;
- indication of the probability of different outcomes occurring;
- a description of each treatment option available;
- identification of the specifically known or generally expected circumstances where guidelines do not apply;
- identification of relevant support services;
- information on any special clinical training needs or equipment necessary for safe treatment; and
- comparative costs associated with different treatments.

Care should be taken not to impair the scientific integrity of the primary guidelines while making local adaptations. If local groups alter the guidelines in the light of evidence not previously considered, they should inform the guideline developers of the availability of that evidence.

4.2.10 Incentives

Guidelines are more likely to be implemented if clinicians have incentives such as the following to implement them:

- financial incentives—for example, differential fees, prospective payment systems, clinical budgeting, the removal of items not recommended by guidelines from reimbursement schedules, and the provision of funds for retraining in specific techniques recommended by the guidelines (Stocking 1993);
- personal satisfaction, compounded by recognition from peers, experts or 'champions';
- professional incentives such as accreditation or continuing medical education points;
- invitations to attend professional conferences (Orlowski & Wateska 1992);
- the offer of increased protection against litigation (NHMRC 1995);
- government regulation; and
- the receipt of personalised, relevant data through the evaluation process.

It is important that there be no disincentives to implementing guidelines. For clinicians, disincentives could be associated with workload, time, remuneration and the need for resources and specialised skills and equipment. For consumers, disincentives could be associated with costs directly related to the treatment itself or costs associated with obtaining that treatment, such as the need to travel to cities or specialised centres for treatment.

No single implementation strategy is effective enough to be recommended for use on its own. Multiple implementation strategies are more likely to be effective (Wensing & Grol 1994).

4.2.11 The use of information technology

Recent feedback from Australian guideline developers highlights the important role of information technology in implementing clinical practice guidelines. Advances in technology such as the Internet and improved systems of data management and storage mean that information technology will occupy an increasingly important place in future implementation strategies.

This technology is yet to be widely applied and evaluated. Associated with this is the fact that information technology is not a 'quick fix'. The infrastructure necessary to make use of the technology takes time to establish and training and education need to occur concurrently. Nevertheless, this should not be seen as an insurmountable problem—rather, it should be seen a factor that warrants due consideration.

Data management is one aspect of information technology that should be examined when assessing technology's impact on the dissemination and implementation of guidelines. Secure, reliable data and data-management procedures are essential if the full potential of the opportunities offered by information technology is to be realised.

Internationally, the use of information technology in relation to clinical practice guidelines has advanced most rapidly in the United States. Guidelines have been developed as part of computerised decision-support systems, largely as an initiative of health insurance funds. Although guidelines incorporated in these systems seek to improve health outcomes, a disproportionate emphasis, in the health insurance fund context, is placed on the minimisation of costs.

The use of automated guidelines is receiving much attention. Few studies have been done, but there is evidence to suggest that such guidelines are effective in the implementation of clinical practice guidelines (Conroy & Shannon 1995). Through this technology, the entire process of patient consultation can be prompted step by step. It is also possible to progress through an appropriate guideline module that not only guides decision making but also records and saves the patient's medical history. There is strong evidence that computer-based clinical decision-support systems can enhance clinicians' performance and improve health outcomes (Johnston et al. 1994).

Clinicians are far more likely to make use of guidelines if the guidelines provide information at the point of patient contact, not just on a bookshelf. It may be that the immediacy is the attraction. Problems with revising guidelines are also more readily solved when the guidelines are in electronic form.

Future directions in information technology seem set to include the Internet as a major mechanism for the dissemination of clinical guidelines. People can gain access to worldwide information and resources; they can locate guidelines that pertain to their health and use this important source of information in joint decision making with their health care professional. At present there are no comprehensive guidelines spanning all the major areas of health, although some corporations in the United States (such as Medaccess) are already providing electronic copies of guidelines produced by the US Department of Health and Human Services and the US Agency for Health Care Policy and Research. The latter agency is planning to post all guidelines registered with it on the Internet.

Information technology is also very amenable to use as a tool for total quality management. Evaluation and audit are important factors in developing and maintaining quality guidelines, and information technology can provide 'tagging' of patients' records in order to remind health care staff to deliver treatment in

keeping with appropriate guidelines (Forrest et al. 1996). The use of audit, made more effective by computer records, also allows feedback to users such as General Practitioners. This has been demonstrated to be an effective way of inducing change in the clinical setting (Forrest et al. 1996).

In summary, developments in information technology make possible the following:

- better database access to store, retrieve and interpret data;
- use of the Internet as a tool for dissemination and implementation of professional and consumer guidelines;
- computerisation of medical records;
- computerised prompting, either as part of clinical practice or linked only to accounting records;
- computerised decision-support systems; and
- more interactive styles of learning.

Although it will be some time before the full potential of information technology for guideline dissemination and implementation is realised, the opportunities cannot be overlooked.

Whatever strategies are used to disseminate and implement guidelines, interventions most likely to induce change are those that require clinicians' participation in the change process.

4.3 A systems approach

If guidelines are to have maximum impact they need to form one element of an integrated quality-planning and improvement strategy, rather than being developed and implemented in isolation. Other elements of such a strategy are systematic review and revision, evidence-based policies and clinical pathways.

For maximum effectiveness, guidelines should be integrated with broader activities—such as peer review, continuing medical education and quality assurance, performance monitoring and accreditation—to promote and improve the quality of care at the local level.

Blank facing page to Chapter 5

CHAPTER 5

GUIDELINE EVALUATION AND REVISION

5.1 Evaluation

Evaluation of clinical practice guidelines is essential. How will we know if guidelines are worth developing, disseminating and implementing if we do not know whether they make a difference to clinical practice and health outcomes?

The evaluation process is intended to assess the validity of the guidelines and the effectiveness of their dissemination and implementation. Thus, it should yield information about the extent to which the guidelines produce the health outcomes identified in the guideline development stage. It should also produce data on actual costs compared with the projected costs of producing the required outcomes.

The dissemination and implementation strategies should be analysed in terms of their effectiveness in reaching clinicians and consumers:

- the target groups' awareness and understanding of the content of the guidelines;
- the guidelines' relevance to these groups;
- the extent to which barriers to implementation were overcome;
- the extent to which the guidelines affected or changed clinical practice; and
- whether the guidelines were sufficiently flexible for use in different local and regional circumstances and whether they were interpreted consistently by different providers.

Most importantly, the evaluation plan should be designed to assess whether the guidelines improve health outcomes—that is, the guidelines' validity.

Evaluation requires data on processes, practices and outcomes and these requirements should be taken into account when guidelines are being developed. Areas of concern in terms of confidentiality should be identified. The evaluation plan should also specify areas where more extensive data collection is needed to fill gaps in research identified during the development process and to examine any specific concerns, such as differences in outcomes for different population groups. The plan should seek to establish a process for dealing with these matters.

Guidelines should be evaluated at least once every three years, although in subject areas that are prone to rapid change this may need to occur more frequently.

In short, the evaluation of clinical practice guidelines has six components:

- an assessment of guideline dissemination;
- an assessment of whether or not clinical practice is moving towards the guidelines' recommendations;
- an assessment of whether or not health outcomes have changed;
- an assessment of whether or not the guidelines have contributed to any changes in clinical practice or health outcomes;
- an assessment of the guidelines' impact on consumers' knowledge and understanding; and
- an economic evaluation of the guideline process.

Groups involved in guideline development and implementation will be required to evaluate at least some of these components, but it is unlikely that an individual group would evaluate all six. In the following sections the components are examined in turn, with changes in clinical practice and health outcomes considered together. Guideline developers will also be required to produce a report on the evaluation process.

5.1.1 Evaluation of dissemination

Evaluation of guideline dissemination is very common and relatively straightforward.

How many copies of the guidelines have been requested? How many copies of the guidelines have been mailed out? Of those that were disseminated, how many have been received? opened? read in part? read in full? understood?

How many posters were sent out? How many were displayed in appropriate and prominent places? How many articles have been published, or interviews broadcast, about the guidelines? How many consumer inquiries have there been?

These criteria can be used for assessing whether or not a dissemination strategy has achieved its goals. An indication of the response rates that might be expected can be obtained from the marketing literature.

5.1.2 Evaluation of changes in clinical practice and health outcomes

Ideally, guideline developers would have had access to a national data set that provided evidence of the need for clinical practice guidelines and baseline information for evaluation purposes. The guideline developers themselves may also have collected relevant data, ideally concerned with both clinical practice and health outcomes.

Repeated data analysis and collection should be carried out after the guidelines are disseminated and implemented. Such analysis will allow for continual assessment of changes in patterns of practice in relation to the guidelines and a redefinition of target areas for further promotion. It will also permit an assessment of whether or not health outcomes are improving.

Institutions should also collect data that can be usefully compared against national data. These data can be used in clinical audit and other quality assurance activities and will facilitate assessment of how the guidelines are affecting the routine care being delivered by clinicians and the effects of that care on the health of their patients.

Where possible, existing national, State and Territory and local data sources should be used, for both pre-guideline and post-guideline applications. In other circumstances customised surveys and other initiatives will be required. In many cases the local data collected can be fed back directly into clinical practice.

In providing data for guideline-evaluation purposes, some clinicians may feel it is necessary to seek protection from disclosure of this kind of information under quality assurance legislation. Such legislation exists at Commonwealth and State and Territory levels.

A wide variety of organisations monitor health care and health outcomes. For example, the Australian Council on Healthcare Standards has developed clinical indicators that may provide guidance. The clinical colleges are also collecting data for this purpose.

In some cases it will not be possible to measure health outcomes or the desirable outcomes will be such that immediate feedback is not possible. In these cases it is reasonable to use more immediate proxy measures of outcomes.

For example, mammographic screening programs will be judged effective only if they reduce mortality from breast cancer. Because of the lag time between initiation of screening and the anticipated reduction in mortality, it is reasonable to use a number of proxy measures in the first instance. Among the suitable proxies are tumour size and the degree of lymph node involvement at the time of diagnosis. Should these measures show the scale of improvement expected from the results of the original field trials, it will be reasonable to assume that mammographic screening is on track in terms of providing a benefit to those who take part in the program.

5.1.3 Evaluation of the guidelines' contribution to changes in clinical practice and health outcomes

Section 5.1.2 discusses evaluation of the improvement in clinical practice and health outcomes, which is the goal of clinical practice guidelines. Such assessment, though, does not take account of the contribution guidelines may have made to those improvements.

It is important that the impact of guidelines be assessed. These assessments require complex study designs and will need to be carried out by researchers in collaboration with clinicians, rather than by clinicians alone.

There is a strong recent history of guideline evaluation. A systematic review of 87 studies of the effectiveness of guidelines revealed evidence of changed clinical practice in 81 studies (93 per cent). Of the 17 studies that examined health outcomes, 12 studies (71 per cent) found a measurable improvement (EHCB 1994).

Among possible methods for evaluation of guidelines are the following:

- comparing changes in clinical practice or health outcomes, or both, in areas of exceptionally high guideline promotion with changes in areas of exceptionally low guideline promotion;
- comparing health outcomes in areas of exceptionally high guideline uptake with outcomes in areas of exceptionally low guideline uptake—focus group testing can be useful to elucidate factors that have influenced this uptake.

When evaluating the guidelines it is important to focus on the guidelines themselves, rather than on the clinicians or other service providers. If there is little change in practice, or little adherence to the guidelines, this may be a consequence of a wide range of factors, among them the guideline development, dissemination and implementation process.

5.1.4 Evaluation of consumer guidelines

Consumer guidelines need to be evaluated in addition to the professionals' guidelines.

A number of different approaches to the evaluation of consumer guidelines should be considered:

- the accessibility of the guidelines;
- the clarity and lucidity of the guidelines;

-
- the acceptability of the amount of information contained in the guidelines, particularly compared with the amount of information contained in the professionals' guidelines;
 - the relevance of the guidelines to different groups of consumers; and
 - the overall level of consumer satisfaction (or dissatisfaction) with the guidelines.

In all cases the evaluation needs to be carried out with extensive consumer input and direction.

Examination of the relationship between doctors and the pharmaceutical industry shows that clinicians who perform any research into, or evaluation of, a drug are more likely as a consequence to use that drug (Chren & Landefeld 1994). Generalising from this experience, it would be expected that clinicians involved in evaluating guidelines are more likely to use those guidelines.

5.1.5 Economic evaluation

A number of cost factors relating to guidelines need to be known:

- process costs—the costs of development, dissemination and implementation;
- pre-implementation costs—the costs associated with existing practice patterns, including testing, pharmaceutical and surgical interventions; and
- post-implementation costs—the costs and cost savings resulting from observance of the guidelines. For example, the guidelines may result in the elimination of unnecessary tests or procedures, which may result in lower overall costs as well as better health outcomes.

Ideally, where a desired outcome is determined, a cost-effectiveness analysis should be done. Such analyses require an assessment of all costs incurred in providing the guidelines and the cost-related impact of the guidelines.

Such economic analyses can also assist by providing a comparison of guideline-dissemination and -implementation strategies. In this way it will be possible to assess which strategies are more cost-effective, in addition to improving clinical practice and health outcomes.

5.1.6 Reporting on the evaluation

The results of the evaluation, including any flaws found in the guidelines and their usefulness or otherwise for groups, should be included in a report on the evaluation. Wherever possible, indicators of avoidable outcomes should be provided. Among the avoidable outcomes might be the following:

-
- unforeseen consequences of the guidelines;
 - outcomes that would suggest that the guidelines were not being followed and that would be useful in monitoring the extent to which guidelines were being implemented; and
 - outcomes that would suggest that the guidelines were not being implemented correctly or that the quality of care was poor.

This information could be used in quality assurance processes.

5.2 Revision

When guidelines are developed a date and strategy should be set for their revision. The National Health and Medical Research Council recommends that revision take place at least every three to five years and more often where the subject matter or circumstances are prone to rapid change (NHMRC 1995).

A number of steps are required for revision:

- a multidisciplinary group, from disciplines similar to those of the guideline development group, should assess the guidelines to see whether there is any new evidence that should be incorporated;
- the group should also assess what has been learnt from the evaluation of the dissemination and implementation strategies and incorporate suggested improvements in the further dissemination and implementation of guidelines;
- the group should draw on current practice and experience and on national data that have been informed by the guidelines. Revision should be a coordinated activity, extending beyond the academic literature on clinical practice and health outcomes to incorporate experience, local knowledge and regional and national data; and
- guidelines should state the date of their development and the anticipated revision date.

CHAPTER 6

LEGAL CONSIDERATIONS

6.1 Liability of practitioners

Many practitioners are concerned about their potential legal vulnerability if the patient does not receive treatment specified in clinical practice guidelines. It is certainly possible that guidelines could be produced as evidence of what constitutes reasonable conduct by a medical practitioner for the purposes of assessing whether the practitioner's duty of care had been breached in a medical negligence action.

It is the view of the Health Advisory Committee, which oversaw the preparation of this document (see Appendix F) that the existence of clinical practice guidelines will provide a measure of protection for practitioners who use the guidelines.

In a recent Australian court decision it was held that the Bolam principle—usually summarised as the idea that a doctor is not negligent if they act in accordance with the behaviour of a reasonable body of their peers—is not the only principle to be applied. In *Rogers v Whitaker* (1992) 175 CLR 479 the High Court held that a practitioner had a duty to inform a patient of the risk associated with medical procedures and that the court would assess, on the facts of each case, whether the conduct of the practitioner was reasonable. The High Court pointed out that there is a distinction to be drawn between determining whether a medical practitioner has been negligent in the particular form of the treatment (where professional opinion will be influential) and determining whether a practitioner has been negligent in the provision of all relevant information to a patient.

The *Rogers v Whitaker* case makes it clear that doctors should give information about the risks of any treatment, especially those that may influence a patient's decision. The National Health and Medical Research Council advises all involved in health care to take note of the spirit of the law as well as the letter of the law. Patients should be provided with as much information as they seek, and in a form that is appropriate to their culture and level of education. Doctors should give advice but not coerce: patients should be encouraged to make their own decisions. The use of guidelines should lead to better informed medical decision making by both practitioners and patients.

6.2 Legal liability of guideline developers and bodies supporting guideline development

Normally, a general publication of information, even where negligently collated, does not give rise to liability because the author does not owe a duty of care to the general public at large, although the guideline issuer could be held liable if a relevant close relationship can be established between them and the person who suffers a loss.

If guidelines purport to be a definitive statement of the correct or appropriate procedure there would be a greater risk of liability than if the guidelines are expressly stated to be provided as a general guide subject to the medical practitioner's expert judgment in each case.

Guideline developers need to demonstrate that they have taken reasonable steps to ensure that the guidelines were properly prepared and that they are based on the best information available at the time of publication. The guidelines should clearly state that they are not a definitive statement of the correct procedure; rather, they constitute a general guide to be followed, subject to the medical practitioner's judgment in each case. They should also state the date the guidelines have been issued and make it clear that the information is correct only to that date.

If these procedures are followed it is unlikely that the guideline developers will be exposing themselves to the risk of legal liability.

6.3 Minimum legal requirements for guideline developers

The potential for guidelines to be used as evidence in courts of law depends on the process used to develop them, the extent to which they are evidence-based, the degree of consensus about them, and whether they are up to date.

Guideline developers are unlikely to be held liable for any negative consequences of implementation of the guidelines, particularly if the processes of preparation and the limitations of the guidelines are clearly described. In general, the following principles apply:

- guidelines should be predominantly summaries of the evidence;
- guidelines should have an expiry date;
- an independent review of the guideline development process is recommended;
- areas of disagreement in the guidelines should be acknowledged; and
- guidelines should not be unduly prescriptive and must allow for cases that call for management that differs from what is recommended.

CHAPTER 7

CONCLUSION

The development, dissemination, implementation, evaluation and revision processes described in this document are applicable to a wide range of clinical interventions and disciplines and could also be applied to protocols relating to the use of technology and pharmaceuticals. Users and reviewers of these guidelines are encouraged to contact the National Health and Medical Research Council if they have comments—positive or negative—to make.

The emerging guideline processes are highly complex and depend not only on integration of the activities of all the people involved but also on individual and organisational behaviour change. With the exception of one or two systematic reviews of guideline implementation, the research literature is largely anecdotal, being based on the experiences and impressions of participants and observers.

The research evidence that does exist, however, shows that properly developed clinical practice guidelines can lead to improvements in both clinical practice and health outcomes. But developing the guidelines alone is not enough: they must be disseminated; there must be strategies for implementation; and resources must be set aside for evaluation of the guidelines' impact, which will highlight areas requiring revision, improvement or further development.

In disseminating, implementing and evaluating guidelines, it is preferable, where possible, to use existing networks, facilities and publications rather than to develop new processes. Not only is this less costly: guidelines provided through existing channels and capable of being incorporated in normal practice are more likely to be accepted as part of the routine than anything that requires new structures or changed modes of practice.

What is needed is a systems approach that builds guideline development, implementation and evaluation into the routine processes of care. Organisations such as hospitals, health care regions and divisions of general practice could establish such an approach, integrating the guidelines into their local health care delivery processes. It is important that these activities be coordinated between different groups. A systems approach would be based on four main principles:

- sensible use of resources;
- sustainable infrastructure;
- integration of available resources and strategies; and
- adapting to local needs.

This document provides a range of strategies—from the personal to the general, from those of low intensity to those of high intensity. As a general rule, one-to-one approaches—that is, 'champions' or academic detailing—are most effective, but they are also the most expensive.

The best approach to making sure guidelines work would appear to be a mix of strategies suitable for local conditions and developed in concert with local clinicians, consumers and managers. There is no single method for all conditions but all the strategies discussed in this document, if used selectively and in combination, can work. Although effort is required, evidence-based guidelines can and will contribute to improved practice and health outcomes.¹

The guidelines process itself is a continuum and it is expected that this document will be revised as new information becomes available. Since the objective of implementing clinical practice guidelines is to ensure the provision of the best possible patient care and the best possible outcomes from clinical interventions, the incorporation of new knowledge is fundamental to the guidelines' effectiveness.

Best clinical practice ensures that the most appropriate resources are used in the most effective way. This document is designed to contribute to that process and to better health outcomes for all Australians.

¹ The recommended process is endorsed by the National Health and Medical Research Council and is based on the general approach to improving health outcomes agreed to by Australian Ministers responsible for health. It is strongly influenced by the 1992 US Institute of Medicine report, *Guidelines for Clinical Practice: from development to use*, and the work of the US Agency for Health Care Policy and Research, the US Preventive Services Task Force, the UK Clearing House for Information on the Assessment of Health Outcomes and the Cochrane Collaboration, plus the Australian National Health Strategy document entitled *Making It Better* (Harvey 1991) and the wider body of research conducted in the area.

APPENDIX A

DEFINITIONS

- Level of evidence** Study design used as an indicator of the degree to which bias has been eliminated by design (see Appendix B).
- Quality of evidence** The quality of the methods used by investigators to minimise bias in a study design.
- Relevance of evidence** A term encompassing the closeness of the study question to the clinical question, which is determined by the relevance of the outcome measures used and the applicability of study results to other treatments, settings and patients.
- Strength of evidence** The magnitude, precision and reproducibility of the intervention effect; includes the effect size, confidence interval, P value, and the exclusion of clinically unimportant effects. In the case of non-randomised studies, additional factors such as biological plausibility, biological gradient and temporality of associations may be considered.

APPENDIX B

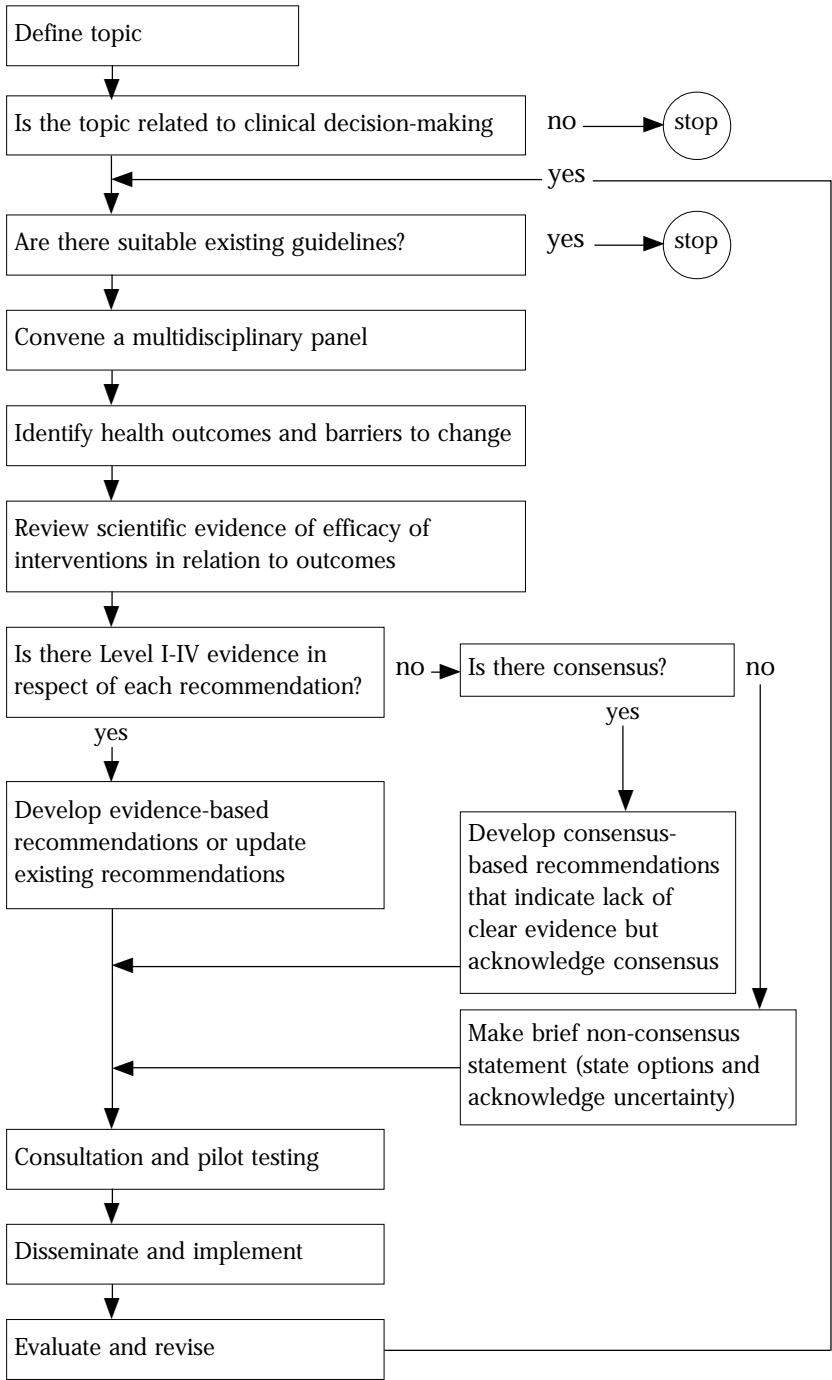
DESIGNATION OF LEVELS OF EVIDENCE

- I** evidence obtained from a systematic review of all relevant randomised controlled trials.
- II** evidence obtained from at least one properly designed randomised controlled trial.
- III-1** evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
- III-2** evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series with a control group.
- III-3** evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
- IV** evidence obtained from case series, either post-test or pre-test and post-test.

These levels of evidence ratings have been adapted from US Preventive Services Task Force (1989), *Guide to clinical preventive services: an assessment of the effectiveness of 169 interventions*, (ed M Fisher), Williams and Williams, Baltimore, Appendix A, p388.

APPENDIX C

CLINICAL PRACTICE GUIDELINES FLOW CHART



APPENDIX D

GENERIC OUTCOME MEASURES

Quantity of life	Process-based outcome measures	Quality of life			Satisfaction with care			
<i>Health-related quality-of-life dimensions of health</i>								
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th data-bbox="565 563 653 592">Physical</th> <th data-bbox="747 563 814 592">Social</th> <th data-bbox="908 563 982 592">Mental</th> </tr> </thead> </table>						Physical	Social	Mental
Physical	Social	Mental						
Mortality	Re-admission rates	Measures of impairment	Measures of social support	Measures of depression	Patient satisfaction surveys			
Avoidable premature mortality	Relapses	Disease-specific measures	Measures of disability	Measures of social adjustment				
		Pain scales						
		Measures of functional status						
<i>Measures of handicap</i>								
Multi-dimensional health status profiles and indexes cover many of these dimensions in a single instrument								

Source: UK Clearing House for Information on the Assessment of Health Outcomes (1993).

APPENDIX E

CHECKLIST FOR GUIDELINE DEVELOPMENT

The following checklist is adapted from Woolf (1992):

- selection of topic;
- selection of panel members and chairperson;
- clarification of objectives;
- assessment of projected health outcomes (benefits and harms);
- assessment of scientific evidence;
- assessment, where appropriate, of cost-effectiveness;
- assessment of expert opinion;
- assessment of appropriateness;
- drafting of document;
- consultation;
- pre-testing/piloting;
- recommendations for dissemination, implementation, evaluation and revision; and
- recommendations for research.

APPENDIX F

PROCESS REPORT

Background

The National Health and Medical Research Council published the first edition of *Guidelines for the Development and Implementation of Clinical Practice Guidelines* in 1995. This publication aimed to distil the best aspects of the considerable guideline development work and research being done in Australia and overseas. In September 1997 the National Health and Medical Research Council's Health Advisory Committee undertook to review the document to take account of new research on guideline development and to include new emphases on implementation and system strategies.

The Working Party

A Working Party consisting of Professor Chris Silagy, Professor George Rubin, Professor David Henderson-Smart and Mr Paul Gross undertook to revise the document with the assistance of Professors David Henry and Paul O'Brien and technical writers Mr Ray Moynihan and Ms Melissa Sweet.

The Working Party that developed the first edition consisted of Ms Helen Lapsley (Chair), Mr Roy Harvey, Ms Hilda Bastian, Emeritus Professor Tom Reeve, Professor Chris Silagy, Dr Ian Steven and Associate Professor Peter Woodruff.

The process

Most of the Working Party's work was done out of session, with meetings being used primarily to plan and clarify the task and to analyse and respond to matters raised in consultations.

The report was updated by synthesising the latest evidence on guideline development and making revisions in accordance with feedback from interested parties who had used the document to develop guidelines. A technical writer was contracted to incorporate the revisions and finalise the editing.

The final draft was approved by members of the Health Advisory Committee and endorsed for publication by the National Health and Medical Research Council.

Consultations

Organisations and individuals were asked for their views about the usefulness of the first edition of the *Guidelines*. A questionnaire was sent to about 120 individuals and organisations, including the following:

- members of the Working Party who developed the initial document;

-
- all chairs and members of former working parties developing other guidelines issued by the National Health and Medical Research Council in the previous three years;
 - peak consumer organisations; and
 - relevant branch heads and medical advisers within the Commonwealth Department of Health and Aged Care.

Submissions were received from 25 organisations and individuals during this first stage of public consultations (see Appendix G).

The second stage of public consultation took place during April 1998. The draft revised document was circulated to the individuals and organisations just listed and to the senders of submissions. In addition, the release of the draft revised document was advertised in the national media and the Commonwealth *Gazette*. Twenty-three submissions were received during the second stage of consultation (see Appendix H).

All submissions were carefully analysed by the Working Party and the draft document was amended accordingly.

Dissemination

These revised guidelines will be distributed to:

- clinical colleges;
- academic departments;
- allied health organisations;
- State and Territory health departments;
- public policy makers;
- hospitals;
- consumer and patient groups;
- health economists; and
- professional journals.

They will also be published electronically.

Evaluation and revision

These guidelines reflect existing knowledge and practices at the time of their publication. This is, however, a rapidly changing area, and as new evidence becomes available the guidelines will require further revision in order to remain valid.

APPENDIX G

SUBMISSIONS RECEIVED

October 1997

Professor Hugh Taylor	Royal Victorian Eye and Ear Hospital
Dr Lawrence Brunello	Royal Australian College of Obstetricians and Gynaecologists
Associate Professor Stephen Davis	Royal Melbourne Hospital
Mr L. Apolony	Royal Australasian College of Radiologists
Professor Peter Phelan	Royal Australian College of Paediatrics
Dr C. Aroney	The Prince Charles Hospital
Professor R.C. Bennett	Royal Australasian College of Surgeons
Ms J. Noonan	New South Wales
Associate Professor Peter Woodruff	Queensland
Dr Anthony Arklay	University of Queensland
Dr Roger Goucke	Sir Charles Gairdner Hospital
Professor Geoffrey Donnan	Austin and Repatriation Medical Centre
Ms Merle Fullerton	Northern Rivers ME/CFS/FM Support Association Inc.
Dr Thelma Hunter	Australian Capital Territory
Dr David Wong	Australasian College of Dermatologists
Dr John Vinen	Royal North Shore Hospital
Dr Craig Martin	Health Department of Western Australia
Dr Michael Bollen	Royal Australian College of General Practitioners
Dr Laurence Lau	Royal Australasian College of Radiologists
Mr Charles Curran	Department of Health and Aged Care
Dr Robert Broadbent	Royal Australia and New Zealand College of Psychiatrists
Dr Caroline Crowther	University of Adelaide
Dr Colinh McLeod	Royal College of Pathologists
Dr Jermey Anderson	Monash Medical Centre
Dr Andrew Wilson	New South Wales Health Department

May 1998

Professor Hugh Taylor	Royal Victorian Eye and Ear Hospital
Professor Justin O'Day	St Vincents Medical Centre
Dr John Vinen	Royal North Shore Hospital
Dr Cathy McCarthy	University of Melbourne
Dr Nicholas Clark	Turning Point
Professor R. Bennett	Royal Australasian College of Surgeons
Dr Michael Stanford	Royal Melbourne Hospital
Dr Peter van Asperen	Australian College of Paediatrics
Ms Mary Draper	Royal Melbourne Institute of Technology
Ms Sophie Hill	
Professor Kevin McConkey	University of New South Wales
Dr Andrew Wilson	New South Wales Health Department
Dr Jenny Doust	Australasian Cochrane Centre
Ms Eileen Wilson	Australian National University
Professor Paul Martin	Australian Psychological Society
Dr Sally Redman	National Breast Cancer Centre
Dr Julie Bines	Royal Childrens Hospital, Melbourne
Dr Colin McLeod	Royal College of Pathologists of Australia
Ms Merle Fullerton	Northern Rivers ME/CFS/FM Support Association Inc.
Mr Alan Bansemer	Health Department of Western Australia
Professor Tom Reeve	Australian Cancer Network
Dr John Campbell	Royal Australian College of Obstetricians and Gynaecologists
Dr Ron Tomlins	Royal Australian College of General Practitioners
Professor Chris Del Mar	University of Queensland

APPENDIX H

ECONOMIC APPRAISAL INFORMATION

When comparing the cost-effectiveness of alternative interventions, it is essential that an appropriate comparator be selected. Ideally, this would result in a 'head to head' study comparing the relative benefits and the relative costs of the various treatment options. In practice, though, a treatment 'option' may consist of a combination of several types of treatment, as is the case in the treatment of cancer patients. Furthermore, cost data may not be available for new treatments.

Economic appraisal must take such matters into account when examining alternatives. Nonetheless, if the evidence indicates that alternative interventions differ markedly in cost but produce similar health outcomes and have similar levels of acceptability to consumers and practitioners, it is reasonable that guidelines recommend the use of the least costly alternative.

There are many difficulties in incorporating economic appraisals in clinical practice guidelines. One of the most obvious is the scarcity of accurate cost data for many clinical interventions. But, because of the wider resource consequences of clinical decisions, it is important that these and other potential problems be dealt with rather than side-stepped and that economic data be collected when guidelines are being developed and evaluated.

APPENDIX I

IMPLEMENTATION STRATEGIES THAT WORK

Strategies used to influence clinical behaviour

Target	Target group and strategy	
	Individuals	Populations
Patient-centred	Patient participation Patient education ¹ Media campaigns ¹ Public education ¹	Shopping centre screening Mailed reminders ¹
Educational	Traditional continuing medical education Innovative continuing medical education —academic detailing, ‘champions’, individual instruction ¹ Advanced academic training in effective and efficient care Commercial detailing ¹ Task force reports	Evidence-based guidelines ¹ Journal publication of critical appraisal methods Other forms of ‘official policy’ Commercial advertising ¹
Administrative	Reminder systems ¹ Computerised medical records ¹ Peer review Criteria setting Peer assessment Clinical audit ¹	Government regulation ¹ Feedback of practice pattern data ¹ Second opinion programs Review committees
Economic	Clinical budgeting ¹ Decentralised management systems ¹ Removal of items from reimbursement schedules ¹	Differential fee charges ¹ Prospective payment

¹ Strategies that have been shown to be effective.
Source: Adapted from Lomas and Haynes (1988).

APPENDIX J

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL STANDARDS FOR EXTERNALLY DEVELOPED GUIDELINES

Introduction

The National Health and Medical Research Council is keen to see the development of clinical practice guidelines by expert bodies that have identified a need for such guidelines. Where such guidelines are likely to have national application, the Council encourages guideline developers to adhere to national standards for development.

The Council is prepared to endorse guidelines that meet its standards for guideline development. These standards are set out in this appendix.

Guideline developers should bear in mind that some clinical practice guidelines already exist, both in Australia and overseas, so it may be possible to adapt existing guidelines. Should this be done, developers still need to comply with the standards set out in this appendix in order to obtain National Health and Medical Research Council's endorsement. If guidelines do not adhere to these standards or principles they will not receive National Health and Medical Research Council's endorsement. It is expected that guidelines endorsed by the Council would be of national significance and not simply relate to a local matter.

In the first instance, it would be expected that external guideline developers would notify the Council of their intention to develop guidelines. Developers would then be advised of the expected National Health and Medical Research Council's standards and a situation where two separate groups are developing similar guidelines could be avoided (where this information is known to the Council). If the guideline development process is expected to deviate significantly from National Health and Medical Research Council's standards, guideline developers are encouraged to discuss their requirements with the Council.

Developers are asked to submit a final *draft* of the guidelines—not a final, printed 'glossy'—for the Council's consideration.

National significance

Developers should give some supporting rationale explaining their choice of topic. The underlying premise is that a topic would be of national significance and may relate to topics such as the following:

- significant variations in clinical practice for the health care intervention;
- high cost;
- high health burden;
- evidence to support recommendations for practice; and
- an initial assessment of available literature or known guidelines.

Standards for externally produced guidelines

1. Multidisciplinary panel

It is essential that guideline development be overseen by a multidisciplinary panel. Such a panel will consist of expert clinicians in the field, experts in research and health economics, public policy analysts, allied health practitioners and consumer representatives.

In keeping with the multidisciplinary approach, the guideline development process should show evidence of wider consultation, which is also consistent with the spirit of the National Health and Medical Research Council's requirements for public consultation.

2. Scope and coverage of guidelines

The purpose of the guidelines, including their scope and target audience, should be clearly defined.

3. Identification of health outcomes

Outcome measures need to be clearly identified—these can be clinically or socially defined (see Appendix D for a suggested typology).

4. Systematic review of evidence

A systematic review of evidence should include clear statements of the following:

- the aim or aims of the review;
- data sources used to identify evidence;
- data-collection methods—with inclusion and exclusion criteria; and
- characteristics of the primary studies—including methodological quality.

The review should also include:

- a synthesis of the evidence, using meta-analytic techniques where applicable;
- ratings of the level of quality, relevance and strength of the evidence (see Appendixes A and B); and
- a summary of the evidence, including its implications for future research and clinical practice.

5. Consultation

There should be adequate consultation in the development of the guidelines. Consultation can vary—for example, targeted consultations, public advertisements, local workshops, and other face-to-face meetings—and developers can select the most appropriate mechanisms.

In considering externally developed guidelines, the Health Advisory Committee of the National Health and Medical Research Council will require developers to provide a short report of the consultation process, showing who was consulted and how comments were handled.

6. Guidelines

Quality of evidence

- The actual guidelines should include supporting statements of the quality of evidence for key decision points (see Appendix B).
- Where scientific opinion or consensus is lacking this should be stated and details of the differences in expert opinion should be provided.

Flexibility and adaptability

- Guidelines should be flexible and adaptable and take account of differences in target populations, geographical and clinical settings, resources, and patients' values and preferences.

Resource considerations

- Cost information that would assist, where necessary or appropriate, in choosing between interventions should be provided; this may involve cost-effectiveness studies.

7. Revising

The guidelines should contain a statement to the effect that they are based on the best available knowledge at a specific time.

There should be regular monitoring for health outcomes and new information.

The need for review should be stated explicitly, noting that a guideline should be revised at least once every three years. Preferably, the guidelines should be reviewed annually.

8. Implementation plan

An implementation plan should be developed. It should target all potential users and take into account questions of privacy and confidentiality, different patient care settings, and funding and organisational barriers.

9. Evaluation plan

A comprehensive evaluation plan should be developed, identifying how and when the guidelines should be reviewed. The plan should include the mechanisms for revising the guidelines set out in Section 7.

Consideration should be given to probable costs, the involvement of interested parties, and the management of the evaluation.

Proposed measures for evaluating both the guideline development process and the outcomes of guideline implementation should be included.

10. Endorsement

Externally developed documents would receive time-limited National Health and Medical Research Council endorsement (similar to hospital accreditation processes), the aim being to encourage external bodies to regularly review, evaluate and revise their documents and recommendations. This principle can be seen as a system of continuing quality assurance.

11. Legal considerations

In keeping with advice provided by the Attorney-General's Department, a legal disclaimer should be included in all guidelines. The following is a suggested form of words:

This document is a general guide to appropriate practice, to be followed only subject to the medical practitioner's judgment in each individual case.

The guidelines are designed to provide information to assist decision making and are based on the best information available at the date of publication.

12. Approvals process

The approvals process will involve the following steps:

- notification by the guideline developer to the Secretariat of the Health Advisory Committee of the National Health and Medical Research Council. This notification will include provision of information noted in the introductory section and Section 1 of this appendix;

-
- registration of 'notice to develop' by the Health Advisory Committee Secretariat;
 - regular progress reports from the developer to the Health Advisory Committee Secretariat;
 - draft guidelines submitted to the Health Advisory Committee, which will review the guideline development process. The maximum time from the notice of intent, to provision of the final draft, should not exceed 18 months;
 - establishment of a review panel to review the guideline development process and the content of guidelines. The review panel will be established by the Health Advisory Committee. The number of members will be limited to a maximum of five people although, in exceptional circumstances, the Chair of the Health Advisory Committee may approve a variation to this;

In particular, the review panel will consider submissions received in relation to the second stage of the consultation process and provide advice to the sponsoring organisation and the Health Advisory Committee about amendments that should be made to the draft guidelines. The review panel will be strictly time-limited in its activities. It will be multidisciplinary, recognising the intended audience for the guidelines and will bring together expertise in systematic review and the subject matter under consideration; in addition, one member of the review panel will be a consumer representative;

- provision of the review panel's report to the Health Advisory Committee. Note that, other than in exceptional circumstances, the review process should not exceed two months; and
- consideration by the Health Advisory Committee and a response provided to the guideline developer. If positive, the Committee will recommend to the National Health and Medical Research Council that the guidelines be endorsed.

13. Assessment by the review panel

Draft guidelines submitted will be assessed against the criteria just specified. They will have to meet all criteria to be recommended for endorsement by the National Health and Medical Research Council.

Draft guidelines that do not meet one or more of the criteria will be returned to the guideline developer along with written reasons for the return.

14. Appeals process

Should the guideline developer disagree with the review panel's assessment, the developer is encouraged to write to the Chair of the Health Advisory Committee, setting out the reasons for disagreement.

It would be useful if the guideline developer included any additional evidence or information that would help the Committee respond.

The Health Advisory Committee Secretariat will provide advice on this process.

15. Correspondence

All correspondence should be addressed to:

Health Advisory Unit
Office of the National Health and Medical Research Council
Department of Health and Aged Care
GPO Box 9848 (MDP 50)
Canberra ACT 2601

GLOSSARY

Appropriate care	'That strategy of action which maximises the potential health benefits valued by informed individuals or populations after considering the likely outcomes, their probabilities and their costs' (Harvey 1991, p. 19).
Clinical practice guidelines	'Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances' (Field & Lohr 1990, p. 8).
Comparator	The intervention, drug or therapy most likely to be used as a replacement or substitute by practitioners or prescribers.
Consensus-based guidelines	Clinical practice guidelines based on a guidelines consensus of expert opinion.
Consumer groups	In this document, a broad term covering a variety of consumer groups with general and specific health interests and self-help and support groups.
Economic appraisal	A comparative analysis of alternative courses of action in terms of both costs and consequences; includes cost effectiveness, cost-benefit and cost utility analyses.
Effectiveness	'The extent to which an intervention does more good than harm for the patient when used under "normal" circumstances' (Last 1987, p. 299).
Efficacy	'The extent to which an intervention does more good than harm for the patient when applied under "ideal" conditions' (Last 1987, p. 299).
Evidence-based guidelines	Clinical practice guidelines based on a systematic review of scientific data.
Expert	'A person who by reason of experience and knowledge is entitled to give an opinion upon facts ascertained by himself or herself' (MacNalty 1978).
Health outcome	'A change in the health of an individual, a group of people or population which is attributable to an intervention or a series of interventions' (AHMAC 1993).
Medical review criteria	'Systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services and outcomes' (Field & Lohr 1990, p. 8).

Meta-analysis	A systematic review that employs statistical methods to combine and summarise the results of several studies' (Cook & Guyatt 1994, p. 1327).
Non-consensus based statements	Statements formulated but in relation to which there is disagreement between the parties concerned.
Patients	In this document, people using any clinical service.
Quality assurance	In this document, a systematic approach to assessing the care provided, identifying opportunities for improvement and providing a mechanism for such improvement. Quality assurance should consider medical records, consumer interest and cooperation, administrative processes, staff development, equipment selection and maintenance, and clinical practice guideline development, dissemination, implementation, evaluation and revision.
Randomised controlled trial	Research study where 'participants are allocated at random to receive one of two or more alternative forms of care' with the aim of creating 'unbiased treatment groups for comparison' (Advisory Group on Health Technology Assessment 1992, p. 10).
Reliable/reproducible guidelines	'Guidelines are reproducible and reliable: <ol style="list-style-type: none"> 1. if—given the same evidence and methods for guidelines development—another set of experts produces essentially the same statements; and 2. if—given the same circumstances—the guidelines are interpreted and applied consistently by practitioners (other parties)' (Field & Lohr 1992, p. 30).
Standards of quality	'Authoritative statements of: <ol style="list-style-type: none"> 1. minimum levels of acceptable performance or results; 2. excellent levels of performance or results; or 3. the range of acceptable performance of results' (Field & Lohr 1990, p. 8).
Systematic review	Application of a rigorous scientific approach to the preparation of a review article.
Valid guidelines	'Practice guidelines are valid if, when followed, they lead to the health and cost outcomes projected for them, other things being equal' (Field & Lohr 1990, p. 10).

BIBLIOGRAPHY

- Advisory Group on Health Technology Assessment (1992) 'Draft Guidelines on Health Technology Assessment for the Australian Health Technology Advisory Committee' National Health Services, London. Adapted from the report, *Assessing the Effects of Health Technologies: principles, practice and proposals*.
- AHMAC 1993. 'Health Outcomes Seminar: AHMAC Sunshine statement', Communique, February, unpublished.
- Anderson, T.F. & Mooney, G. (1990) 'Medical Practice Variations: where are we?' in T.F. Anderson & G. Mooney (eds), *The Challenges of Medical Practice Variations*, Macmillan, London, pp. 1–15.
- Antman, E.M. et al. (1992) 'A Comparison of Meta-analyses of Randomised Control Trials and Recommendations of Clinical Experts', *Journal of the American Medical Association*, vol. 268, pp. 240–8.
- Bardsley, M. & Cole, J. (1991) 'Measured Steps to Outcomes', *Health Service Journal*, 17 October, pp. 18–20.
- Brown, J.B., Shye, D. & McFarland, B. (1995) 'The Paradox of Guideline Implementation: how AHCPR's depression guideline was adapted at Kaiser Permanente Northwest Region', *Journal on Quality Improvement*, vol. 21, pp. 5–21.
- Chren, M-M. & Landefeld, C.S. (1994) 'Physicians' Behaviour and their Interactions with Drug Companies: a controlled study of physicians who requested additions to a hospital drug formulary', *Journal of the American Medical Association*, vol. 271, no. 9, pp. 684–9.
- Clover, K. et al. (1995) *Project 5: the development of consensus guidelines*, Hunter Access to Surgery Research Project, Hunter Area Health Service, May.
- Conroy, M. & Shannon, W. (1995) 'Clinical Guidelines: their implementation in general practice', *British Journal of General Practice*, vol. 45, pp. 371–5.
- Cook, D.J. & Guyatt, G.H. (1994) 'The Professional Meta-analyst: an evolutionary advantage', *Journal of Clinical Epidemiology*, vol. 47, pp. 1327–9.
- Davis, D.A., Thomson, M.A., Oxman, A.D. et al. (1995) 'Changing Physician Performance: a systematic review of the effect of continuing medical education strategies', *Journal of the American Medical Association*, vol. 274, pp. 700–6.
- Donabedian, A. (1992) 'The Lichfield Lecture: quality assurance in health care—consumers' role', *Quality in Health Care*, vol. 1, pp. 1–5.

-
- Donabedian, A. (1992) 'The Role of Outcome in Quality Assessment and Assurance', *Quality Review Bulletin*, November, pp. 356–60.
- Drummond, M.F. (1980) *Principles of Economic Appraisal in Health Care*, Oxford University Press, Oxford, UK.
- Dunn, E., Norton, P. et al. (1994) 'Disseminating Research/Changing Practice', *Research Methods for Primary Care*, vol. 6, Sage Publications, Thousand Oaks, US.
- Effective Health Care Bulletin (EHCB) (1994) 'Implementing clinical practice guidelines. Can guidelines be used to improve practice?', *Effective Health Care Bulletin*, no. 6, University of Leeds, UK.
- Ellwood, P.M. (1988) 'Shattuck Lecture: outcomes management—a technology of patient experience', *New England Journal of Medicine*, vol. 318, pp. 1549–56.
- Field, M.J. & Lohr, K.N. (eds) (1992) *Guidelines for Clinical Practice: from development to use*, Institute of Medicine, National Academy Press, Washington, DC.
- Field, M.J. & Lohr, K.N. (eds) (1990) *Clinical Practice Guidelines: directions for a new program*, Institute of Medicine, National Academy Press, Washington, DC.
- Fisher, M. (ed.) (1989) *Guide to Clinical Preventive Services: an assessment of the effectiveness of 169 interventions*, US Preventive Services Task Force, Williams and Wilkins, Baltimore, Maryland.
- Forrest, D., Hoskins, A. & Hussey, R. (1996) 'Clinical Guidelines and their Implementation', *Postgraduate Medical Journal*, vol. 72, pp. 19–22.
- Greenhalgh, T. (1997) 'Papers that Summarise Other Papers—systematic reviews and meta-analysis', *British Medical Journal*, vol. 315, pp. 672–5.
- Grimshaw, J.M. & Russell, I.T. (1994) 'Achieving Health Gain through Clinical Guidelines II: ensuring guidelines change medical practice', *Quality in Health Care*, vol. 3, pp. 45–52.
- Grimshaw, J.M. & Russell, I.T. (1993) 'Effect of Clinical Guidelines on Medical Practice: a systematic review of rigorous evaluation', *The Lancet*, vol. 342, pp. 1317–22.
- Grimshaw, J.M., Freemantle, N., Wallace, S. et al. (1995) 'Developing and Implementing Clinical Practice Guidelines', *British Medical Journal*, vol. 4, pp. 55–64.
- Haines, A. & Feder, G. (1992) 'Guidance on Guidelines—writing them is easier than making them work', *British Medical Journal*, vol. 305, pp. 785–6.

-
- Harvey, R. (1991) *Making It Better*, National Health Strategy background paper no. 8, Department of Health and Family Services, Canberra.
- Health Ministers Forum (1994) *National Health Policy*, State Health publication no. P(P) 94-156.
- Health Services Research Group (1992) Outcomes and the Management of Health Care, *Canadian Medical Association Journal*, vol. 147, pp. 1775–80.
- Johnston, M.E., Langton, K.B., Haynes, B. et al. (1994) 'Effect of Computer-based Clinical Support Systems on Clinician Performance and Patient Outcome: a critical appraisal of research', *Annals of Internal Medicine*, vol. 120, pp. 135–42.
- Kane, R.L. & Lurie, N. (1992) 'Appropriate Effectiveness: a tale of carts and horses', *Quality Review Bulletin*, vol. 18, no. 10, pp. 322–6.
- Last, J.M. (1987) *Public Health and Human Ecology*, Appleton & Lange, East Norwalk, Connecticut.
- Lomas, J. (1994) 'Teaching Old (and not so old) Docs New Tricks', in E. Dunn, P. Norton et al. (eds), *Disseminating Research/Changing Practice, Research Methods for Primary Care*, vol. 5, Sage Publications, Thousand Oaks, US.
- Lomas, J. (1993) 'Retailing Research: increasing the role of evidence in clinical services for childbirth', *The Millbank Quarterly*, vol. 71, no. 3, pp. 439–75.
- Lomas, J. (1991) 'Words without Action? The Production, Dissemination and Impact of Consensus Recommendations', *Annual Review of Public Health*, vol. 12, pp. 41–65.
- Lomas, J. et al. (1989) 'Do Practice Guidelines Guide Practice? The Effect of a Consensus Statement on the Practice of Physicians', *New England Journal of Medicine*, vol. 321, pp. 1306–11.
- Lomas, J., Enkin, M., Anderson, G.M. et al. (1991) 'Opinion Leaders vs Audit and Feedback to Implement Practice Guidelines: delivery after previous caesarean section', *Journal of the American Medical Association*, pp. 2202–7.
- Lomas, J. & Haynes, R.B. (1988) 'A Taxonomy and Critical Review of Tested Strategies for the Application of Clinical Practice Recommendations: from "official" to "individual" clinical policy', *American Journal of Preventive Medicine*, vol. 4, pp. 77–97.
- MacNalty, A.S. (ed.) (1978) *Butterworth's Medical Dictionary*, 2nd edn (M. Critchley, Editor-in-chief), Butterworths, London.

-
- May, F., Gilbert, A., Hurley, E. et al. (1993) 'A Drug and Therapeutics Information Service for Community Medical Practitioners', *Australian Prescriber*, vol. 16, suppl. 1, pp. 49–51.
- McCormick, K.A., Moore, S.R. & R.A. Siegel (eds) (1994) *Clinical Practice Guideline Development: methodology perspectives*, Publication no. 95-0009, Agency for Health Care Policy and Research, US Department of Health and Human Services.
- McGlynn, E.A., Kosecoff, J. & Brook, R.H. (1990) 'Format and Conduct of Consensus Development Conferences', *International Journal of Technology Assessment in Health Care*, vol. 6, pp. 450–69.
- McPherson, K. (1990) 'Why do Variations Occur?' in T.F. Andersen and G. Mooney (eds), *The Challenges of Medical Practice Variations*, Macmillan, London, pp. 16–35.
- Mulrow, C.D. (1994) 'Rationale for Systematic Reviews', *British Medical Journal*, vol. 309, pp. 597–9.
- Mulrow, C.D. (1987) 'The Medical Review Article: state of the science', *Annals of Internal Medicine*, vol. 106, pp. 485–8.
- National Health and Medical Research Council (NHMRC) (1995) *Guidelines for the Development and Implementation of Clinical Practice Guidelines*, 1st edn, Australian Government Publishing Service, Canberra.
- NSW Department of Health (1995) *Evaluation Checklist for Evidence-based Guidelines*, 1st edn, Department of Health, North Sydney.
- Opit, L.J. (1991) 'The Measurement of Health Service Outcomes', in Holland et al. (eds) *Oxford Text Book of Public Health*, 2nd edn, vol. 3, Oxford University Press, Oxford, pp. 159–307.
- Orlowski, J.P. & Wateska, L. (1992) 'The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: there's no such thing as a free lunch', *Chest*, vol. 102, no. 1, pp. 270–3.
- Oxman, A.D., Thomson, M.A., Davis, D.A. et al. (1995) 'No Magic Bullets: a systematic review of 102 trials of interventions to help health care professionals deliver services more effectively or efficiently', *Journal of the Canadian Medical Association*, vol. 153, pp. 1423–31.
- Royal Australian College of General Practitioners (RACGP) (1995) 'Adjudication Criteria for Continuing Medical Education', RACGP, unpublished.

-
- Royal College of General Practitioners (RCGP) (1995) *The Development and Implementation of Clinical Guidelines*, Report of the Clinical Guidelines Working Group, RCGP, London.
- Sackett, D.L. (1995) 'Applying Overviews and Meta-analyses at the Bedside', *Journal of Clinical Epidemiology*, vol. 48, pp. 61–6.
- Sackett, D.L. (ed.) (1994) *The Cochrane Collaboration Handbook*, (CD Rom) – Update Software, Oxford, UK, Issue 1 1999
- Sackett, D.L., Rosenberg, W.C., Muir Gray, J.A. et al. (1996) 'Evidence-based Medicine: what it is and what it isn't', *British Medical Journal*, vol. 312, pp. 71–2.
- Scottish Intercollegiate Guidelines Network (SIGN) (1995) *Criteria for Appraisal for National Use*, Pilot edition, SIGN, September.
- Simes, R.J. & Glasziou, P.P. (1992) 'Meta-analysis and Quality Evidence in the Economic Evaluation of Drug Trials', *Pharmaco Economics*, vol. 1, pp. 282–91.
- Slavin, R.E. (1995) 'Best Evidence Synthesis: an intelligent alternative to meta-analysis', *Journal of Clinical Epidemiology*, vol. 48, pp. 9–18.
- Stocking, B. (1993) 'Implementing the Findings of Effective Care in Pregnancy and Childbirth in the United Kingdom', *The Millbank Quarterly*, vol. 71, pp. 497–521.
- Todd, C. (1995) 'Is There a Role for Academic Detailing in Today's Healthcare System?' *Pharmacoresources*, vol. 38, pp. 3–5.
- UK Clearing House for Information on the Assessment of Health Outcomes (1993) *Issues in Health Outcome Measurement: outcomes briefing*, Introductory issue, Nuffield Institute for Health, Leeds, Spring.
- US Agency for Health Care Policy and Research (AHCPR) (1993) *Program Note: clinical practice guidelines development*, AHCPR publication no. 93-0023, US Department of Health and Human Services.
- US Agency for Health Care Policy and Research (AHCPR) (1991) *Report to Congress: progress of research on outcomes of health care services and procedures*, AHCPR publication no. 91-0004, US Department of Health and Human Services.
- Wensing, M. & Grol, R. (1994) 'Single and Combined Strategies for Implementing Changes in Primary Care: a literature review', *International Journal of Quality in Health Care*, vol. 6, pp. 115–32.

-
- Wise, C.G. & Billi, J.E. (1995) 'A Model for Practice Guideline Adaptation and Implementation: empowerment of the physician', *Journal on Quality Improvement*, vol. 21, pp. 465–76.
- Woolf, S.H. (1992) 'Practice Guidelines, a New Reality in Medicine—11: methods of developing guidelines', *Annals of Internal Medicine*, vol. 152, pp. 946–52.
- Woolf, S.H. (1992) 'Practice Guidelines, a New Reality in Medicine—1: recent developments', *Annals of Internal Medicine*, vol. 150, pp. 1811–18.

Blank facing page to NHMRC back page

The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is a statutory authority within the portfolio of the Commonwealth Minister for Health and Aged Care, established by the *National Health and Medical Research Council Act 1992*. The NHMRC advises the Australian community and Commonwealth; State and Territory Governments on standards of individual and public health, and supports research to improve those standards.

The NHMRC advises the Commonwealth Government on the funding of medical and public health research and training in Australia and supports many of the medical advances made by Australians.

The NHMRC also develops guidelines and standards for the ethical conduct of health and medical research.

The Council comprises nominees of Commonwealth, State and Territory health authorities, professional and scientific colleges and associations, unions, universities, business, consumer groups, welfare organisations, conservation groups and the Aboriginal and Torres Strait Islander Commission.

The Council meets four times a year to consider and make decisions on reports prepared by committees and working parties following wide consultation on the issue under consideration.

A regular publishing program ensures that Council's recommendations are widely available to governments, the community, scientific, industrial and educational groups.

The Council publishes extensively in the following areas:

- Aged care
- Child health
- Clinical practice
- Communicable diseases
- Dentistry
- Drugs and poisons
- Drugs and substance abuse
- Environmental health
- Ethics
- Infection control
- Men's health
- Mental health
- National Health and Medical Research Council
- Nutrition
- Public Health
- Research
- Technology Assessment
- Women's health

A list of current publications is available from:

The Publications Officer
ONHMRC
MDP 50
GPO Box 9848
Canberra ACT 2601

Phone: (02) 6289 1430 (24 hour answering machine)
Toll free: 1800 020 103 (toll-free)
Fax: (02) 6289 1351
E-mail: nhmrc.publications@health.gov.au
Internet: <http://www.health.gov.au/nhmrc>