BMJ 1999;318:527-530 (20 February)

Education and debate

Clinical guidelines

Potential benefits, limitations, and harms of clinical guidelines

This is the first in a series of four articles on issues in the development and use of clinical guidelines

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Over the past decade, clinical guidelines have increasingly become a familiar part of clinical practice. Every day, clinical decisions at the bedside, rules of operation at hospitals and clinics, and health spending by governments and insurers are being influenced by guidelines. As defined by the Institute of Medicine, clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[1] They may offer concise instructions on which diagnostic or screening tests to order, how to provide medical or surgical services, how long patients should stay in hospital, or other details of clinical practice.

The broad interest in clinical guidelines that is stretching across Europe, North America, Australia, New Zealand, and Africa (box) has its origin in issues that most healthcare systems face: rising healthcare costs, fueled by increased demand for care, more expensive technologies, and an ageing population; variations in service delivery among providers, hospitals, and geographical regions and the presumption that at least some of this variation stems from inappropriate care, either overuse or underuse of services; and the intrinsic desire of healthcare professionals to offer, and of patients to receive, the best care possible. Clinicians, policy makers, and payers see guidelines as a tool for making care more consistent and efficient and for closing the gap between what clinicians do and what scientific evidence supports.

As guidelines diffuse into medicine, there are important lessons to learn from the firsthand experience of those who develop, evaluate, and use them.[3] This article, the first of a four part series to reflect on these lessons, examines the potential benefits, limitations, and harms of clinical guidelines. Future articles will review lessons learned about their development,[4] legal and emotional ramifications,[5] and finally their implementation.[6]

Summary points

- Clinical guidelines are an increasingly familiar part of clinical practice
- They have potential benefits and harms
- Rigorously developed evidence based guidelines minimise the potential harms
- Clinical guidelines are only one option for improving the quality of care

Potential benefits of clinical practice guidelines

The principal benefit of guidelines is to improve the quality of care received by patients. Although it has been shown in rigorous evaluations that clinical practice guidelines can improve the quality of care, [7] [8] whether they achieve this in daily practice is less clear. This is partly because patients, doctors, payers, and managers define quality differently and because current evidence about the effectiveness of guidelines is incomplete.

Potential benefits for patients

For patients (and almost everyone else in health care), the greatest benefit that could be achieved by guidelines is to improve health outcomes. Guidelines that promote interventions of proved benefit and discourage ineffective ones have the potential to reduce morbidity and mortality and improve quality of life, at least for some conditions. Guidelines can also improve the consistency of care; studies around the world show that the frequency with which procedures are performed varies dramatically among doctors, specialties, and geographical regions, even after case mix is controlled for.[9] Patients with identical clinical problems receive different care depending on their clinician, hospital, or location. Guidelines offer a remedy, making it more likely that patients will be cared for in the same manner regardless of where or by whom they are treated.

Overview of international activity on guidelines

More details in the form of a full paper are available on the *BMJ*'s website.

Germany, Italy, and Spain—Guidelines are on the rise in Germany and Italy, where a guidelines database is being developed to support national healthcare reform. In Spain, the Catalan Agency for Health Technology Assessment has begun preparing guidelines and teaches methods of guideline

development. Consensus guidelines figure prominently in Catalonian healthcare reform.

Europe

United Kingdom—Guidelines have existed in England for decades; recent years have heightened interest in guidelines as a tool for implementing health care based on proof of effectiveness. Professional bodies, encouraged by the NHS, are producing guidelines for use by providers to improve care and by purchasers to guide contracting and commissioning decisions. The NHS is now using a critical appraisal instrument to determine which guidelines to commend to health authorities. Although historically most British guidelines have derived from consensus conferences or expert opinion, there is growing interest in using explicit methods to develop evidence based guidelines. The Scottish Intercollegiate Guideline Network uses a systematic multidisciplinary approach to prepare evidence based guidelines. National guidelines are converted at the local level into formats that encourage adoption in practice.

The Netherlands—In the Netherlands, the Dutch College of General Practitioners has produced guidelines since 1987, issuing more than 70 guidelines at a rate of 8-10 topics per year. A rigorous procedure involves an analysis of the scientific literature, combined with consensus discussions among ordinary general practitioners and content experts. A systematic implementation programme follows guideline development. Updating of the guidelines has recently begun. Guidelines figure prominently in Dutch health policy.

Finland and Sweden—In Finland, national and local bodies have issued more than 700 guidelines since 1989. A programme for evidence based guideline development has been started recently. Guidelines in Sweden appear in reports by the Swedish Council on Technology Assessment in Health Care, an internationally consulted technology assessment agency, and in recommendations from other government bodies.

France—In France, the Agence Nationale de l'Accréditation et d'Évaluation en Santé has

North America

Guidelines, protocols, and care pathways developed by professional societies and other groups are common in American hospitals and health plans, where they are used for quality improvement and cost control. Although some evidence based guidelines produced by government panels and medical societies have received prominent attention, many healthcare organisations purchase commercially produced guidelines that emphasise shortened lengths of stay and other resource savings. Canadian health care is largely state funded, but a similar proportion of organisations as in the United States use guidelines. The massive guideline industry in America has created special problems such as information overload. Directories and newsletters have become necessary to monitor the hundreds of guideline topics and sponsoring organisations. Americans have articulated evidence based methods in manuals and other reports. This expertise has not always found its way into actual guidelines—most of which remain rooted in consensus or opinion.

Australia and New Zealand

Guidelines in Australia date to the late 1970s, when the state health authority began endorsing guideline booklets,[2] and they continue on a large scale today. There is an increasing emphasis on the need for evidence based methods.

Guidelines in New Zealand emanate directly from national health policy. New Zealand's

published over 100 guidelines based on consensus conferences or modified guidelines from other countries. It has also developed more than 140 références médicales, guidelines on procedural indications for use in setting coverage policy. The guidelines are disseminated through networks of general practitioners, and their effectiveness is evaluated through local audits.

choosing to restrict services at the point of service through guidelines received international attention in debates about rationing. One guideline on hypertension and a subsequent cholesterol guideline from the New Zealand National Heart Foundation broke new ground methodologically by linking recommendations to patients' absolute risk probabilities rather than to generic treatment criteria .

Clinical guidelines offer patients other benefits. Those accompanied by "consumer" versions (leaflets, audiotapes, or videos in lay language) or publicised in magazines, news reports, and internet sites inform patients and the public about what their clinicians should be doing. Increasingly, lay guidelines summarise the benefits and harms of available options, along with estimates of the probability or magnitude of potential outcomes.[10] Such guidelines empower patients to make more informed healthcare choices and to consider their personal needs and preferences in selecting the best option. Indeed, clinicians may first learn about new guidelines (or be reminded of oversights) when patients ask about recommendations or treatment options.

Finally, clinical guidelines can help patients by influencing public policy. Guidelines call attention to underrecognised health problems, clinical services, and preventive interventions and to neglected patient populations and high risk groups. Services that were not previously offered to patients may be made available as a response to newly released guidelines. Clinical guidelines developed with attention to the public good can promote distributive justice, advocating better delivery of services to those in need. In a cash limited healthcare system, guidelines that improve the efficiency of health care free up resources needed for other (more equitably distributed) healthcare services.

Potential benefits for healthcare professionals

Clinical guidelines can improve the quality of clinical decisions. They offer explicit recommendations for clinicians who are uncertain about how to proceed, overturn the beliefs of doctors accustomed to outdated practices, improve the consistency of care, and provide authoritative recommendations that reassure practitioners about the appropriateness of their treatment policies. Guidelines based on a critical appraisal of scientific evidence (evidence based guidelines) clarify which interventions are of proved benefit and document the quality of the supporting data. They alert clinicians to interventions unsupported by good science, reinforce the importance and methods of critical appraisal, and call attention to ineffective, dangerous, and wasteful practices.

Clinical guidelines can support quality improvement activities. The first step in designing quality assessment tools (standing orders, reminder systems, critical care pathways, algorithms, audits, etc) is to reach agreement on how patients should be treated, often by developing a guideline. Guidelines are a common point of reference for prospective and retrospective audits of clinicians' or hospitals' practices: the tests, treatments, and treatment goals recommended in guidelines provide ready process measures (review criteria) for rating compliance with best care practices.[11]

Medical researchers benefit from the spotlight that evidence based guidelines shine on gaps in the evidence. The methods of guideline development that emphasise systematic reviews focus attention on key research questions that must be answered to establish the effectiveness of an intervention[12] and highlight gaps in the known literature. Critical appraisal of the evidence identifies design flaws in existing studies. Recognising the presence and absence of evidence can redirect the work of investigators and encourage funding agencies to support studies that fulfill this effectiveness based agenda.

Finally, some uses of clinical guidelines straddle the boundary between benefits and harms. Clinicians may seek secular (and even self serving) benefits from guidelines. In some healthcare systems, guidelines prompt government or private payers to provide coverage or to reimburse doctors for services. Specialties engaged in "turf wars" to gain ownership over specific procedures or treatments may publish a guideline to affirm their role. Clinicians may turn to guidelines for medicolegal protection or to reinforce their position in dealing with administrators who disagree with their practice policies.

Potential benefits for healthcare systems

Healthcare systems that provide services, and government bodies and private insurers that pay for them, have found that clinical guidelines may be effective in improving efficiency (often by standardising care) and optimising value for money.[13] Implementation of certain guidelines reduces outlays for hospitalisation, prescription drugs, surgery, and other procedures. Publicising adherence to guidelines may also improve public image, sending messages of commitment to excellence and quality. Such messages can promote good will, political support, and (in some healthcare systems) revenue. Many believe that the economic motive behind clinical guidelines is the principal reason for their popularity.

Potential limitations and harms of guidelines

The most important limitation of guidelines is that the recommendations may be wrong (or at least wrong for individual patients). Apart from human considerations such as inadvertent oversights by busy or weary members of the guideline group, guideline developers may err in determining what is best for patients for three important reasons.

Firstly, scientific evidence about what to recommend is often lacking, misleading, or misinterpreted. Only a small subset of what is done in medicine has been tested in appropriate, well designed studies. Where studies do exist, the findings may be misleading because of design flaws which contribute to bias or poor generalisability. Guideline development groups often lack the time, resources, and skills to gather and scrutinise every last piece of evidence. Even when the data are certain, recommendations for or against interventions will involve subjective value judgments when the benefits are weighed against the harms. The value judgment made by a guideline development group may be the wrong choice for individual patients.

Secondly, recommendations are influenced by the opinions and clinical experience and composition of the guideline development group. Tests and treatments that experts believe are good for patients may in practice be inferior to other options, ineffective, or even harmful. The beliefs to which experts subscribe, often in the face of conflicting data, can be based on misconceptions and personal recollections that misrepresent population norms.[14]

Thirdly, patients' needs may not be the only priority in making recommendations. Practices that are suboptimal from the patient's perspective may be recommended to help control costs, serve societal needs, or protect special interests (those of doctors, risk managers, or politicians, for example).

The promotion of flawed guidelines by practices, payers, or healthcare systems can encourage, if not institutionalise, the delivery of ineffective, harmful, or wasteful interventions. The same parties that stand to benefit from guidelines—patients, healthcare professionals, the healthcare system—may all be harmed.

Potential harms to patients

The greatest danger of flawed clinical guidelines is to patients. Recommendations that do not take due account of the evidence can result in suboptimal, ineffective, or harmful practices. Guidelines that are inflexible can harm by leaving insufficient room for clinicians to tailor care to patients' personal circumstances and medical history. What is best for patients overall, as recommended in guidelines, may be inappropriate for individuals; blanket recommendations, rather than a menu of options or recommendations for shared decision making, ignore patients' preferences.[15] Thus the frequently touted benefit of clinical guidelines—more consistent practice patterns and reduced variation—may come at the expense of reducing individualised care for patients with special needs. Lay versions of guidelines, if improperly constructed and worded, may mislead or confuse patients and disrupt the doctor-patient relationship.

Clinical guidelines can adversely affect public policy for patients. Recommendations against an intervention may lead providers to drop access to or coverage for services. Imprudent recommendations for costly interventions may displace limited resources that are needed for other services of greater value to patients. The tendency of guidelines to focus attention on specific health issues is subject to misuse by proponents and advocacy groups, giving the public (and health professionals) the wrong impression about the relative importance of diseases and the effectiveness of interventions.

Potential harms to healthcare professionals

Flawed clinical guidelines harm practitioners by providing inaccurate scientific information and clinical advice, thereby compromising the quality of care. They may encourage ineffective, harmful, or wasteful interventions. Even when guidelines are correct, clinicians often find them inconvenient and time consuming to use. Conflicting guidelines from different professional bodies can also confuse and frustrate practitioners.[16] Outdated recommendations may perpetuate outmoded practices and technologies.

Clinical guidelines can also hurt clinicians professionally. Auditors and managers may unfairly judge the quality of care based on criteria from invalid guidelines. The well intentioned effort to make guidelines explicit and practical encourages the injudicious use of certain words ("should" instead of "may," for example), arbitrary numbers (such as months of treatment, intervals between screening tests), and simplistic algorithms when supporting evidence may be lacking. Algorithms that reduce patient care into a sequence of binary (yes/no) decisions often do injustice to the complexity of medicine and the parallel and iterative thought processes inherent in clinical judgment. Words, numbers, and simplistic algorithms can be used by those who judge clinicians to repudiate unfairly those who, for legitimate reasons, follow different practice policies. Guidelines are also potentially harmful to doctors as citable evidence for malpractice litigation and because of their economic

implications. Referral guidelines can shift patients from one specialty to another. A negative (or neutral) recommendation may prompt providers to withdraw availability or coverage. A theoretical concern is that clinicians may be sued for not adhering to guidelines although, as discussed in the third paper in this series,[5] this has not yet become an important reality.

Guidelines can harm medical investigators and scientific progress if further research is inappropriately discouraged. Guidelines that conclude that a procedure or treatment lacks evidence of benefit may be misinterpreted by funding bodies as grounds for not investing in further research and for not supporting efforts to refine previously ineffective technologies.

Potential harms to healthcare systems

Healthcare systems and payers may be harmed by guidelines if following them escalates utilisation, compromises operating efficiency, or wastes limited resources. Some clinical guidelines, especially those developed by medical and other groups unconcerned about financing, may advocate costly interventions that are unaffordable or that cut into resources needed for more effective services.

Conclusion

In the face of these mixed consequences, attitudes about whether clinical guidelines are good or bad for medicine vary from one group to another. Guidelines produced by governments or payers to control spiraling costs may constitute responsible public policy but may be resented by clinicians and patients as an invasion of personal autonomy. Guidelines developed by specialists may seem self serving, biased, and threatening to generalists. To specialists, guidelines developed without their input do not contain adequate expertise. Inflexible guidelines with rigid rules about what is appropriate are popular with managers, quality auditors, and lawyers but are decried as "cookbook medicine" by doctors faced with non-uniform clinical problems and as invalid by those who cite the lack of supporting data.

These disparate sentiments and the growing awareness of their limitations and harms have done little to stem the rapid promulgation of guidelines around the world (see box). The unbridled enthusiasm for guidelines, and the unrealistic expectations about what they will accomplish, frequently betrays inexperience and unfamiliarity with their limitations and potential hazards. Naive consumers of guidelines accept official recommendations on face value, especially when they carry the imprimatur of prominent professional groups or government bodies.

More discerning users of clinical guidelines scrutinise the methods by which they have been developed.[4] Moreover, a more fundamental problem is that guidelines may do little to change practice behaviour.[6]

Clinical guidelines are only one option for improving the quality of care. Too often, advocates view guidelines as a "magic bullet" for healthcare problems and ignore more effective solutions. Clinical guidelines make sense when practitioners are unclear about appropriate practice and when scientific evidence can provide an answer. They are a poor remedy in other settings. When clinicians already know the information contained in guidelines, those concerned with improving quality should redirect their efforts to identify the specific barriers, beyond knowledge, that stand in the way of behaviour change.

Acknowledgments

Series editors: Martin Eccles, Jeremy Grimshaw

Funding: The Health Services Research Unit is funded by the Chief Scientist Office of the Scottish Office Department of Health. However, the views expressed are those of the authors and not the funding body.

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