

Has guideline development gone astray?

The move to evidence based medicine has led to a proliferation of guidelines.

R Grol is concerned that many are of poor quality, but **Raymond Gibbons and colleagues** argue that guidelines are important for improving health



R Grol director, Scientific Institute for Quality of Health Care, Radboud University Nijmegen Medical Centre, PO Box 9101, 114, 6500 HB Nijmegen, Netherlands r.grol@iq.umcn.nl

Competing interests: None declared.

YES It is a long time since clinical guidelines were seen as cookbook medicine and a threat to professional autonomy. Nowadays, evidence based guidelines are considered one of the major efforts to improve patient care. Development of guidelines has progressed enormously, with many organisations (including the National Institute for Health and Clinical Excellence in the UK) using validated methods such as the AGREE instrument.¹ Clinical guidelines are valid if they are developed in a rigorous way, independently of vested interests of their developers, and if they support decision making in practice and affect actual care. But are current guidelines meeting these criteria? I have concerns.

For guidelines to have an impact on actual care, they need to be integrated with other quality improvement initiatives, such as performance measurement and quality improvement programmes. This requires intensive collaboration between the organisations responsible for these tasks,² which is lacking in most countries. Expert guideline developers, usually clinicians and epidemiologists, often have very different

aims and interests from those in the quality improvement world. Stakeholders use guidelines for different purposes, also hindering integration and improvement. For instance, policy makers and authorities want to use them for inspection or to contain costs, whereas professional bodies may use them to strengthen their position in the competition with other disciplines.

Another problem is that many guidelines still do not meet the internationally accepted criteria of the AGREE instrument.¹ A recent evaluation of seven depression guidelines from different countries (five of which were issued after the AGREE instrument was published in 2003) showed scores of 25-63% for stakeholder involvement, 1-64% for rigour of development, 0-56% for applicability, and 8-75% for editorial independence.³ New (still unpublished) evaluations of guideline quality show similar findings.

Local influence

Guideline developers are aware that there is a risk of bias in recommendations because appropriate evidence is often lacking. However, even when evidence is available, the final recommendations often reflect personal opinions, local culture, or vested interests of the developers.⁴⁻⁶ A recent Institute of Medicine analysis reports many examples of undue industry influence on

Raymond J Gibbons Arthur M and Gladys D Gray professor of medicine, Division of Cardiovascular Diseases and Internal Medicine, Mayo Clinic, 200 First Street, SW, Rochester MN 55905, USA gibbons.raymond@mayo.edu

Elliott M Antman professor of medicine, Cardiovascular Division, Brigham and Women's Hospital, Boston MA 02115, USA

Sidney C Smith professor of medicine, Division of Cardiology, University of North Carolina, Chapel Hill NC, USA

Competing interests: RJG has done consulting for Molecular Insight Pharmaceuticals, Medscape (heart.org), and Therox; EMA had research support from various companies, has consulted for Sanofi-Aventis, and received lecture fees from Eli Lilly, RJG, EMA, and SCS are all past chairs of the ACC/AHA task force on clinical practice guidelines. RJG and SCS are members of several working groups including the National Heart Lung and Blood Institute clinical guidelines for cardiovascular risk reduction. RJG is a member of the Institute of Medicine Committee on standards for developing trustworthy systematic reviews and clinical practice guidelines.

NO Guideline development in cardiovascular diseases is a well developed process in both the United States and Europe that has enhanced the delivery of proved treatments and improved patient outcomes. It most certainly has not gone astray.

Guidelines for cardiovascular disease

Between 1970 and 2000, life expectancy in the United States increased by six years,¹ with nearly two thirds of that increase, 3.9 years, due to improved outcomes in cardiovascular

“Guidelines are a repository of information for the clinician”

diseases and stroke. Half of the improvement in coronary heart disease mortality was due to improvement in population risk factors; the other half could be attributed to improved evidence based treatment.²

Unfortunately, proved treatment strategies were not consistently applied. Permanent pacemakers were definitely justified in less than half of patients who received one and not justified about 20% of the time.³ Less than half of patients presenting with acute myocardial infarction who had had a previous event and no contraindications were taking aspirin.⁴ Angiotensin converting enzyme inhibitors were used in less than half of eligible patients with heart failure.⁵ Use of treatments known to improve outcomes showed enormous regional variations that could not be explained by patient differences.⁶

In response to these concerns, the American College of Cardiology and American Heart Association started developing clinical practice guidelines 25 years ago. The European Society of Cardiology followed not long

bmj.com This week's poll asks

“Has guideline development gone astray?”

Cast your vote at www.bmj.com/#poll daddy-head

All references are in the version on bmj.com

the development of clinical practice guidelines and makes recommendations to limit conflicts of interests.⁶ Guideline developers sometimes have close ties with the industry.⁷ Another problem is that current methods for translating evidence and professional experiences into recommendations for practice have got less attention and are much less sound and transparent than the methods for finding and grading evidence.

Guideline developers in different countries often come up with different advice, partly because they prefer to use local evidence and partly because normative and cultural opinions have a substantial role in defining good care.^{8,9} This lack of independence and inconsistencies in different guidelines lower the trust that potential users might place in them.

Lack of applicability

Statements on clinical effectiveness dominate guidelines and assume “ideal patients” without comorbidities. They often do not adequately address issues relevant for everyday care, such as safety and risk management, multidisciplinary collaboration, effect on costs or compliance, and patient self management. The analysis of the seven depression guidelines, for example, showed a focus on drug treatment and limited attention to psychological therapies,

thereafter. The American groups have also used their experience to produce instructions on how to write rigorous guidelines.⁷

Is there evidence that the implementation of practice guidelines led to changes in clinical practice that have improved patient outcomes? Yes.

A project to apply the guidelines improved the delivery of evidence based care in 10 hospitals in southeastern Michigan.⁸ Guideline based care reduced mortality at 30 days by 4.9% and at one year by 5.1%.⁹ The Global Registry of Acute Coronary Events, a multinational cohort study across 14 countries,¹⁰ examined the use of guideline based treatment in 44 372 patients with ST elevation myocardial infarction or non-ST elevation acute coronary syndromes. Use of drug treatments recommended by both the US and European guidelines increased significantly, and this was associated with improved patient outcomes. In ST elevation patients, death decreased by 3.9% and cardiogenic shock by 2.4%; in patients with acute coronary syndrome hospital death decreased by 0.7% and death between hospital discharge and six month follow-up by 1.6%.

In the United States, the Center for Medicare and Medicaid Services sought to improve

“Guidelines often have limited relevance to clinicians and patients”

suicide risk, and social issues.³ In reality half of patients with a chronic condition have at least two problems that may interact, requiring complex care and support.¹⁰ But guidelines are often formulated by mono-disciplinary specialists with specific patient types in mind. Patient and public involvement in guideline development is of growing interest but not standard practice yet, and it is not clear how to incorporate their preferences.^{11,12}

Despite examples of good uptake, audits around the world show that guidelines are, on average, used in only 50-70% of day to day decisions and variation in performance is large.¹³ At least part of the reason for this is that some of the guidelines have limited relevance to clinicians and patients, are written as a handbook and not as a concise set of recommendations for practice (maximum 5-10), or are incompatible with the norms and values of target users.¹⁴ This may make implementation ineffective, particularly when it requires new behaviour and organisational change.¹⁵

the delivery of guideline based therapy by publicly reporting compliance data for individual hospitals. Between 2000 and 2005, compliance with guideline recommended care for myocardial infarction improved from 77.5% to 93.5% and inpatient mortality after a heart attack decreased from 103.8/1000 admissions to 81.7/1000.¹¹

Minnesota has its own guideline development process and quality improvement programme that predates the national effort.¹² Performance measures for outpatient care are publicly reported for all medical practices within the state. Cardiovascular mortality in Minnesota fell by 35% from 1995 to 2005 and is now the lowest of any state.

Development is key

Given this record of success, what are the arguments against guidelines? Firstly, there is concern that many guidelines are based on expert opinion rather than firm evidence.¹³ We agree this is a problem, but the solution is to develop more evidence, not to ignore existing evidence and expert consensus. The process used for developing guidelines is also not always perfect—that is, not all guidelines are created equal. However, various groups

Value for money

Finally, guideline development is time consuming and expensive (€150 000 (£130 000; \$220 000) to €200 000 per guideline in the Netherlands, and more than £400 000 for a NICE guideline). The investments may be worth while if guidelines are clinically relevant and have a wide impact on health care. However, the cost effectiveness of guideline development compared with other methods for improving patient care is unknown.

Guidelines may thus be important for improving patient care, but changes are needed to make them more relevant and effective. Collaboration between all stakeholders—relevant clinicians, scientists, patients, policy makers, quality improvement experts, and others—is essential to identify clinical questions, assess the evidence, draw up workable recommendations and develop related indicators of improved quality of care and programmes for implementation. Procedures must be changed to speed up the development, minimise personal bias in recommendations, and involve patients more actively in the process of both developing and using guidelines. Without such changes, guideline development may increasingly be seen as an expensive but unhelpful and ineffective toy for a happy few.

Cite this as: *BMJ* 2010;340:c306

have set out recommendations that lead to sound and effective guidelines, as the US cardiovascular disease example shows.¹⁴ One of these recommendations is to take steps to ensure that relationships with industry do not contaminate the development process.¹⁵

Some clinicians resent the intrusion of guidelines on their practice.¹⁶ However, guidelines are just that—guidelines; they are not meant to replace patient centred decision making, particularly for very elderly patients and those with multiple comorbidities.¹⁵

The process for development of cardiovascular clinical practice guidelines is itself an ongoing quality improvement effort. Guidelines are a repository of information for the clinician, recommending the use of treatments that have been proved effective and not using treatments that are ineffective and may be harmful. The goal of clinical practice guidelines is to improve the practice of medicine, the quality of care, and patient outcomes. Cardiovascular clinical practice guidelines are already a success story. We believe that the cardiovascular clinical practice guidelines effort is consistent with the highest ideals of medicine, and have felt privileged to have a role in its leadership.

Cite this as: *BMJ* 2010;340:c343