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.

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. 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, 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. 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. New (still unpublished) evaluations of guideline quality show similar findings.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. A recent Institute of Medicine analysis reports many examples of undue industry influence on guidelines. An expert panel of 15 methodologists recommended abandoning the use of non-validated methods, but this was not implemented in all 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, with nearly two thirds of that increase, 3.9 years, due to improved outcomes in cardiovascular 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.

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

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

“Guidelines are a repository of information for the clinician”

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suicide risk, and social issues. In reality half of patients with a chronic condition have at least two problems that may interact, requiring complex care and support. 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.

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. 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. This may make implementation ineffective, particularly when it requires new behaviour and organisational change.

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.

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. Guideline based care reduced mortality at 30 days by 4.9% and at one year by 5.1%. The Global Registry of Acute Coronary Events, a multinational cohort study across 14 countries, 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 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. Minnesota has its own guideline development process and quality improvement programme that predates the national effort. 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. 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 have set out recommendations that lead to sound and effective guidelines, as the US cardiovascular disease example shows.