Clinical Guidelines: Where Next?

RICHARD BAKER* and GENE FEDER†

* Eli Lilly National Clinical Audit Centre, Department of General Practice and Primary Health Care, University of Leicester, Leicester, UK;

† Department of General Practice and Primary Care, St Bartholomew's and the Royal London School of Medicine and Dentistry, University of London, London, UK

In a growing number of countries, guidelines are playing an increasingly important role in assuring the quality of care. Their validity depends on a systematic development process and explicit links between recommendations and underlying evidence. Their role in aiding clinical decision making depends on their developers identifying the key decisions and their consequences; gathering the relevant evidence on the risks and costs of alternative decisions; and presenting the appropriate evidence to make each key decision in a simple and accessible format, possibly electronic. Decision analysis is a potentially powerful tool for clarifying clinical decisions and involving patients directly in the process but its routine use in guidelines is complex and has yet to be fully evaluated. Duplication of guidelines can be avoided by appraising and adapting existing guidelines in local contexts. There is very little evidence available about the impact of guidelines on the doctor-patient relationship. They might have a potentially deleterious effect, but the combination of explicit guidelines eliciting patient preferences and information technology might redress the balance by increasing the role of patients themselves.

THE DEVELOPMENT OF GUIDELINES

Guidelines which explicitly link graded recommendations to research evidence are the benchmark for advancement but their development is costly. In the US, the American Agency for Health Care Policy and Research (AHCPR) has led the way in rigorous guidelines development [1] and their methodology has been adapted in the UK [2]. The AHCPR guidelines for heart failure [3] required a 16 member panel, aided by a six-member team of project staff. A complex sequence of steps was followed, including (i) definition of the guidelines' scope, topics within that scope being rated for importance; (ii) investigation of the five most important topics through a detailed literature search and commissioned systematic reviews in which more than 1000 papers were examined; (iii) writing of recommendations based on this review, followed by discussion of recommendations in an open forum, with appropriate changes being made; (iv) peer review and pilot evaluation. The panel first met in February 1992, the guidelines were eventually published almost two and a half years and many dollars later. The UK and other less wealthy countries would have difficulties in allocating equivalent resources to developing large numbers of guidelines, but less costly approaches are possible, particularly if existing guidelines or systematic reviews are used and updated [4]. It is also more efficient to avoid developing guidelines which are not required. Five criteria can be used to decide whether the development of a guideline could be justified. First, the topic must be of sufficient importance to justify the effort of guideline development. For example, it should affect relatively large numbers of patients or lead...
to substantial morbidity or mortality, with consequent substantial costs to health care services and society as a whole.

Second, the topic must be sufficiently complex to require more than one recommendation, as a single recommendation could be taken directly from one or more good quality research studies or a single systematic review [5]. If the topic is relatively well defined and convincing research evidence is available that gives clear guidance, guidelines would be superfluous. They are more appropriately reserved for topics involving several management decisions and for which there is good evidence, but where that evidence is found in a number of sources and requires assimilation.

Third, there should be evidence that actual care is at variance with evidence about appropriate care. It is self-evident that resources devoted to improving what is already entirely acceptable would be wasted.

Fourth, it may not be justifiable to develop new guidelines if up-to-date, valid versions for the same topic are already available. In these circumstances the available guidelines must be appraised [6]; if they are found for some reason to be inadequate, then the development of new, alternative guidelines may be reasonable. Guideline developers should report which other guidelines they appraised before developing their own and why they decided the others were inadequate. New guidelines may build on the evidence base of older guidelines and adapt them to fit clinical practice in another country. For example, the 1996 UK acute low back pain guidelines explicitly updated the evidence base of the 1994 AHCPR guidelines and adapted the recommendations with accord to the context of British general practice [4].

Fifth, there should be an adequate body of research evidence about the topic concerned. Inevitably, the recommendations of guidelines will always be an interpretation of available research evidence and reflect the values and opinions of the guidelines development panel [7]. However, guidelines must enable the user to distinguish recommendations based largely on evidence from those based largely on opinion. An explicit link between each recommendation and the justification for it is therefore important [7].

THE POTENTIAL OF DECISION ANALYSIS

Despite the recent advances in development methods, the recommendations of many guidelines do not focus directly on specific clinical decisions. Even rarer are statements about the underlying values of the developers (e.g. individual patient needs versus resource constraints) [7], or incorporation of patient preferences, or costs of different treatment options. One strategy for addressing these deficiencies is the adoption of methods which explicitly incorporate cost-effectiveness data and preferences, both of patients and clinicians [8]. Some progress has been made in applying decision analysis to guideline recommendations and although difficulties remain to be resolved before this approach could be used routinely, it does indicate one way forward. Decision analysis takes into account the probabilities of different outcomes consequent upon different decisions and also the preferences of patients for particular outcomes [9-11]. The ability of decision analysis to acknowledge patient preferences is important, as it suggests how guidelines could support decision-making by an individual patient consulting the clinician.

An example of how guidelines can be tailored to individual patients is shown in Fig. 1. It concerns the decision about prescribing an ACE inhibitor or the combination of hydralazine and isosorbide dinitrate (HYD/ISDN) to a patient with heart failure. The AHCPR heart failure guideline contains the recommendation: HYD/ISDN is an appropriate alternative in patients with contraindications or intolerance to ACE inhibitors (strength of evidence = B) [3]. In the case of a patient who has moderate symptomatic hypotension and a cough whilst taking an ACE inhibitor, how is the patient and her family physician to decide whether to accept these side effects or to switch to the hydralazine/isosorbide dinitrate alternative?

The choice that faces the patient is shown in the decision tree, which has been based on the data used in the AHCPR guideline. The option of no treatment — the upper branch from the first box or decision node — would lead to a 47% chance of death within three years. However, if the patient chooses treatment, there is a second decision node indicating the choice to be made between treatments. Treatment with hydralazine/isosorbide would reduce the risk of death at three years to 38%, but treatment with the ACE inhibitor would reduce the risk to 33%.

Does the patient prefer a 33% risk of death although she would experience side-effects, or a 38% risk of death but without side-effects? How big an increase in the risk of death is she willing to accept in order to avoid side-effects? The patient is asked to rate the value or utility to her of life with side-effects and the scale generally employed would score life without side-effects as 1 (most preferred), and death 0 (least preferred). Let us assume that the patient feels that life with side-effects would be less preferable than life without side-effects. Thus, she assigns life with side-effects a score of 0.8. To calculate the utility that can be expected from the different treatment choices, the likelihood of the particular outcomes are combined with the preferences of the patient. Thus, in the case of treatment with hydralazine/isosorbide, the expected utility is (.38 x 0) + (1 - .38) x 1.0 = .62. The expected utility of treatment with ACE inhibitors would be 0.54, therefore, the decision is in favour of the hydralazine/isosorbide option.

Decision analysis needs further development before it could be widely used in guideline development. It is time consuming and there are important methodological problems still to be resolved [12]. However, it can be
FIGURE 1. \( p \) = probability of the particular outcome within three years, \( u \) = the patient's valuation or utility for that outcome on a scale of 0 (least preferred) to 1 (most preferred). The utility that can be expected from making different choices is calculated by combining the probability of different outcomes with the patient's utility for these outcomes. Thus the expected utility from deciding not to treat the heart failure would be \((.47 \times 0) + (.53 \times 1) = .53\). The expected utility of treatment with hydralazine/isosorbide would be \((.38 \times 0) + (.62 \times 1) = .62\). The expected utility of ace inhibitor treatment would be \((.33 \times 0) + (.67 \times .8) = .54\).
of computer-based clinical decision support systems shows that they can improve physician performance [21] and there is evidence that the electronic medical record can improve adherence to complex disease management guidelines [22]. Unfortunately, many guidelines are not compatible with a decision support structure without extensive translation. Returning to the example of the AHCPR cardiac failure guidelines, these proved difficult to incorporate into a network of interactive microcomputer workstations [23]. Despite their explicit format, presented in algorithms, the guidelines contained many ambiguities and lacunae which undermined their translation into an electronic form.

RELATIONSHIP BETWEEN PATIENT AND PHYSICIAN

A particularly important issue in primary care is the impact of clinical guidelines on relationships between practitioners and patients. They may enhance patient involvement in decision making, however, they can also be viewed as the latest medium for organizing medical knowledge for use by the clinician. In quality assurance terms, guidelines as they are presently developed are a manifestation of the absolutist definition of quality [24]. The aggressive implementation of such guidelines may create a new barrier between patient and practitioner. If we are genuinely seeking a more equal relationship based on understanding rather than authority, guidelines could present a problem unless we find satisfactory ways of sharing their recommendations and of rationing their use to prevent them, rather than the patient, dictating the course of consultations. For example, cultural values might be overlooked by clinical guidelines. If the belief of a patient from a particular cultural group is that an illness has a spiritual explanation, advice framed in the context of a western view of medicine and based on research in American or European populations, might have only a limited effect [25].

This issue has not received much attention and the information available is sufficient only to suggest that further investigation is needed. For example, in a study undertaken in family practice, the effects of a computer terminal present during the consultation and programmed to prompt preventive care interventions were investigated [26]. When the computer was used, there was an increase in the number of prevention activities. However, these changes were associated with an increase in the proportion of topics discussed in the consultation that were raised by the doctor and a reduction in those raised by the patient [27]. In an observational study, several patient concerns about computer use in family practice consultations were identified [28]. Patient specific prompts at the time of the consultation may be one of the more effective methods of implementing guidelines but there is a danger that patients may be given less opportunity to express their own concerns.

Finally, although empirical evidence is limited, it could be argued that an over-emphasis on guidelines and clinical decision making might marginalize an important dimension of medical care: the hermeneutic role of the physician, in which we act as witnesses to our patients' experiences and work with them to make sense of their illnesses in the context of the rest of their lives [29,30]. This dimension is difficult to incorporate into conventional guideline recommendations, although the use of evidence from qualitative studies of patients' experiences of illness may draw our attention back to them [31].

CONCLUSIONS

Guidelines are now common and in the future may play an increasingly important role in assuring the quality of care. However, we need to be cautious, particularly in family practice. Guidelines that can be accepted for use must have explicit links drawn between the recommendations they contain and the basis on which they are made, whether research evidence or opinion. If guidelines are to aid clinical decision making, their developers need to identify the key decisions and their consequences; gather the relevant evidence on the risks and costs of alternative decisions; and present the appropriate evidence required to make each key decision in a simple and accessible format. Decision analysis is a potentially powerful tool for clarifying clinical decisions and involving patients directly in the process. However, practical and methodological problems prevent its routine use at present.

The expensive and unnecessary duplication of guidelines for the same topic should be avoided, new guidelines being developed only when fully justified. Furthermore, systems are needed for the appraisal and local adaptation of centrally developed guidelines which ensure that strong recommendations are retained. Once valid and reliable guidelines are available, effective methods of dissemination and implementation are required.

Finally, we need to improve our understanding of how guidelines might influence consultations with doctors. The uninform ed use of guidelines by clinicians might reduce the opportunities for patients to contribute to decisions about their care. However, the combination of explicit guidelines and information technology might increase the role of patients themselves. Efforts to improve guidelines should now focus on the achievement of this objective.

Acknowledgements: Thank you to Rod Jackson for his incisive comments on an earlier draft. This article is based on two papers individually presented by the authors at the ISQua conference in Jerusalem in May 1996.

REFERENCES

Clinical guidelines: where next?


