Clinical guidelines: their implementation in general practice

MARY CONROY

WILLIAM SHANNON

SUMMARY. In recent years the development of clinical guidelines has received increasing attention from medical educators and those involved in standard setting, and has been initiated at both central and local levels. This review article outlines the current state of knowledge with regard to clinical guideline implementation in medical practice. It deals with the main aspects of the current guideline debate, such as, clinical freedom and doctor autonomy, the importance of ownership in guideline implementation, the effectiveness of guidelines in changing practice and, in particular, the strategies needed to implement clinical guidelines in general practice. Mechanisms of behavioural change that have been recognized as being important for implementation are also discussed. If implementation strategies are not treated as an integral part of the development process then clinical guidelines may fail to achieve their potential in changing clinical practice.

Keywords: protocols; recommendations and guidelines; quality in general practice; patterns of work; literature reviews.

Introduction

CLINICAL guidelines (also known as practice guidelines or protocols of care) set out the optimum management approach for a given condition. They are developed in the belief that they will improve health care outcomes and health service efficiency, and reduce levels of inappropriate practice.[1,2] To be successful, guidelines must be based on valid scientific evidence, be attractive to potential users, and present practical avenues for application.[3] The success of guideline development can be judged by whether awareness and use of recommended guidelines improve, and ultimately by whether clinical practice moves closer to the agreed standards of care, following appropriate audit of that care.[4,5] In recent years the development of clinical guidelines has received increasing attention from medical educators and those involved in standard setting.[3,6–10] Development of clinical guidelines has been initiated at both central and local levels, and numerous potential advantages have been cited in support of the development process;[11] these include a reduction in inappropriate variations in practice, the provision of a more rational basis for referral, a reduction in uncertainty in the management of some conditions, the provision of a basis for continuing medical education, and improved control of health care costs.

This review outlines the current state of knowledge with regard to clinical guideline implementation. The aims of this article are: to review research evidence and current opinion pertaining to clinical guideline implementation; and to review the body of literature dealing with behavioural change in clinical practice, and to examine papers dealing with this subject in light of their possible relevance to the subject of guideline implementation.

M Conroy, MRCGP, MICGP, research fellow and W Shannon, MD, FRCGP, MICGP, professor, Department of General Practice, Royal College of Surgeons in Ireland, Dublin, Republic of Ireland.

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Method

A systematic literature search was carried out. The first search was performed using the MedLine database (1985–1994) and the following keywords: practice guidelines, family practice, quality assurance, social influence/physicians' practice patterns, social influence/knowledge, attitudes, practice. Further papers were obtained through the Royal College of General Practitioners and through the Association of University Departments of General Practice conference workshops held in 1994. An initial appraisal of this first yield of papers was made, and a second yield was obtained by perusal of the reference sections of the first batch of papers, and by use of the *Science citation index* from 1988 to 1994. The reference sections of these papers were examined to identify any further relevant papers.

All papers were then appraised by the authors using standard methodological criteria where possible.[12–15] In some instances where strict criteria could not be used, a consensus was reached by including those papers which cited substantive evidence to support their claims. Consequently, some editorials and discussion papers which were well referenced and written by respected authors in the field of clinical guidelines were also included in order to represent accurately the current thinking and opinion in this area.

Clinical guidelines: conflict with clinical freedom?

Despite a seemingly inherent potential for guidelines to facilitate better practice, many practitioners remain sceptical as to whether guidelines can achieve any clinically significant change.[4] In many ways, the negative issues surrounding the introduction of guidelines are similar to those affecting any new health care development. These include concerns about effectiveness in achieving change, the possible use of guidelines in litigation,[1,16,17] and the possible reduction of clinical freedom in the management of illness by practitioners.[2,18] The term 'cookbook medicine' has been used in this context as a criticism of guidelines.[11]

In a recently published survey, Tunis and colleagues found that many respondents anticipated that guidelines would threaten doctor autonomy and reduce satisfaction with the practice of medicine.[19] The whole issue of clinical freedom and doctor autonomy is always an emotive one, and it is generally accepted that clinical freedom is necessary to allow for individual flair and innovation. However, it may also be used to mask inappropriate and inefficient practice.[20] Patients should have the security of knowing that whatever doctor they consult, he or she will provide them with a certain minimum standard of cost-effective care.[20,21] Guidelines can help to define this standard but they also need to reflect honestly the areas of uncertainty that exist at any given time, in order to avoid stifling healthy innovative practices in clinical care.[22]

Ownership of clinical guidelines

One of the central issues in the guideline development process to date has been that of ownership. The north of England study of

standards and performance in general practice showed that participation in the development of guidelines encouraged implementation, as compared to guidelines where the target general practitioners had no involvement in the development process.[23] In support of locally developed guidelines, it has been estimated that the Professional Standards and Review Organization in the United States of America spent $100 million financing the development of 100 000 sets of guidelines for the management of myocardial infarction across the country.[24] However, this process of 're-inventing the wheel' has obvious disadvantages in the current economic climate. It should also be remembered that guideline development is a difficult and time-consuming process, and that local groups of physicians often do not have the time, resources and skills needed to produce high-quality, authoritative guidelines.[25,26]

Experience in the Netherlands has shown that the concentration of resources that occurs in the development of central guidelines facilitates a more comprehensive and scientific approach, and consequently centrally developed guidelines may be more valid than those developed locally.[9]

One approach by which these differences could be reconciled, and by which the sense of 'imposition' of central guidelines could be removed, is to encourage local modification of centrally developed guidelines to meet local needs.[26] Involving doctors in the effort to effect change could make change less threatening.[27] Participation in the modification process may also help create the sense of ownership which has been documented as being important in the implementation of clinical guidelines.[7]

Do clinical guidelines work?

As is the case with any new technology, much of the scepticism directed at clinical guidelines is concerned with their effectiveness in actually changing practice. In a review of 59 published evaluations of clinical guidelines that met defined criteria for scientific rigour, all but four detected statistically significant improvements in the process of care after the introduction of guidelines; all but two of the 11 studies that assessed the outcome of care reported statistically significant improvements.[1] The size of the effects seen was variable, but studies that report statistically significant improvement in clinical care suggest that, if the three stages of development, dissemination and implementation are addressed, there is a largely unexplored potential for clinical guidelines to improve such care.[1,28]

The development alone of guidelines does not imply that they will be translated into practice.[29] Experience in the Netherlands indicates that even when doctors know what to do, they often do not perform according to their knowledge and skills.[30] Furthermore, while the dissemination alone of information may increase awareness and predispose to change among the target audience, it is not sufficient to bring about actual behavioural change in the absence of an active implementation strategy appropriate to the setting concerned.[2,4,5,18,26,30-33]

Changing the behaviour of doctors may therefore require interventions beyond a simple educational approach.[34] When one considers the complex influence of attitudes, norms and beliefs on behaviour, the limitations of an information-only approach are not too surprising.[22,35-37] Consequently, doctors may be more likely to change their clinical practice when they perceive new norms for professional behaviour rather than when they simply receive new information.[2] A study which examined the effects of a mailed continuing medical education programme on the management of hypertension by primary care doctors, as part of a randomized controlled trial, showed that this programme did not have a significant effect on the clinical practices of the doctors studied.[38] In contrast, Manning and colleagues found that the use of individualized educational packages, providing feedback on doctors' prescribing behaviour, did have a statistically significant and favourable impact on clinical practice.[39] Another review of 50 randomized controlled trials found that continuing medical education interventions that involved information dissemination alone had little or no effect on health care outcomes.[40] They were also less likely to change doctor behaviour than interventions that used enabling and/or reinforcing methods (defined as facilitation in the practice setting and the use of reminders and feedback). Resources used to prepare large quantities of printed information, which are then sent to doctors, may well be usefully diverted, in part at least, to more effective methods of continuing education. However, while printed materials alone may demonstrate a relatively weak effect on doctors' performance, they may be among the many factors which together effect behavioural change.[40]

Implementation of clinical guidelines

Importance of implementation

The failure of clinical guidelines to achieve their potential in changing clinical practice to date can therefore be attributed, in part at least, to the fact that most current development processes do not treat the implementation of guidelines as an integral part of the development procedure. It is therefore now important to shift the focus from guideline development and to emphasize the need for guideline integration, which encompasses dissemination and implementation strategies, with provision made for evaluation, audit, feedback and outcome measurement.[41] Methods to implement and evaluate clinical guidelines can sometimes lag behind the enthusiasm for setting them, and the obstacles to guideline implementation may not be identified.[42] If the guideline integration process is to work, all elements of the process must be considered at the development stage.

Every set of guidelines will have specific implementation barriers, and a careful analysis of these should be part of the implementation strategy and of the pilot testing for each new set of standards. Any implementation strategy can be seen to affect either the structure or process of care, and therefore it is important at the outset to identify the barriers to implementation in terms of these.[25,41,43] This can be done by survey or, where possible, by assessing existing performance through observation. A planned campaign is necessary to focus on positive and negative aspects of the behaviour of general practitioners, such as, the desire to be better clinicians, concerns that they may have about inadequate management and clinical uncertainty in their practice. One of the first tasks of anyone planning to introduce change is the demonstration of a performance gap, that is, a sense of dissatisfaction with current practice and a realization that perhaps something should be done. Only when this gap is acknowledged by general practitioners will any real attention be paid to the solutions offered to particular problems.[44] Several likely barriers to implementation have been described,[41] and it is important to establish which ones are regarded by general practitioners as those most important in preventing uptake of a given set of guidelines in their particular situation.

If it is accepted that the provision of information alone is not enough, and that an effective implementation strategy is needed in order to achieve meaningful change, it is useful to review what is known about the factors that encourage use of guidelines in practice. A review of the literature shows that certain interventions work better than others.[41] These include face-to-face education with individual instruction, computer reminder systems and peer review with practice visiting.[10,41,45,46] Emslie and colleagues found that a disease-specific reminder used in the consultation as part of a guideline implementation strategy led to improvements

in the process of care for infertile couples seen in 82 general practices in the Grampian region.[47] Overall there does not appear to be any one ideal strategy or intervention, or at least no evidence of one to date.[27]

General practitioners and practice contexts vary enormously and so a combination of implementation methods may be required.[48] Since those whose behaviour clinical guidelines seek to change are both human and heterogeneous, success in changing clinical practice may depend less on scientific method and more on imagination, flexibility, enthusiasm and the application of certain principles derived from a knowledge of marketing and social influence theory.

Implementation strategies

Any guideline implementation strategy should have an impact at four levels:

- Increasing knowledge, that is, making clinicians aware of the guidelines
- Changing attitudes, such that clinicians agree with and accept the recommendations as a better standard of care
- Changing behaviour, such that clinicians change their clinical practice to conform with the guidelines
- Changing outcomes, by improving patient health and quality of care.[2]

Social influence theory indicates that although the dissemination of information may create awareness and predisposition to change, it is factors such as custom and habit, assumptions and beliefs of peers, prevailing practices and social norms which define and shape the interpretation of information obtained through educational means.[18] Traditional models of general practitioners' decision making suggest that general practitioners may respond to new information by incorporating it into subsequent decision making and clinical practice. In contrast, the social influence, behavioural, model of decision making holds that the judgement and beliefs of peers play major roles in an individual's evaluation of and tendency to act on new information. Customs and habits are therefore formed, and maintained, through the operation of social influences.[18] Norms, values and beliefs vary between settings and over time. Many general practitioners have moved to a new practice setting and discovered that customs and clinical practices vary considerably from those prevailing in a previous setting. As the scientific basis of clinical practice does not vary between settings, the existence of differing practices and customs points strongly to the importance of social influences in determining and changing those practices at a local level.[18] Social influences, because of their role in behaviour, thus offer a potentially valuable basis for implementing practice guidelines and changing general practitioner behaviour, through the use of social influence processes and behavioural change strategies.

Social influence strategies are generally mediated through three types of social influence settings: the interpersonal setting where individuals or small groups are targeted; the persuasion setting where moderately sized groups are targeted; and the mass media setting where the target group is very large.[18]

Interpersonal setting. This involves the use of academic detailing, which is akin to the pharmaceutical industry's well-known model of one-to-one contact.[49] It involves a combination of educational visits and information transfer within the context of a well-planned marketing strategy. The effectiveness of this strategy is documented in a large body of marketing research and experience.[50] Some of the most important techniques of such academic detailing include:

- Investigating baseline knowledge and motivation for current clinical practice behaviour
- Defining clear educational and behavioural objectives
- Establishing credibility
- Providing authoritative and unbiased sources of information and presenting both sides of controversial issues
- Stimulating doctor participation in the education process
- Using concise, graphic, educational materials and highlighting and repeating essential messages
- Providing positive reinforcement of improved practices in follow-up visits.[49]

This strategy is most successful when the educators are known to and respected by the target group. This facilitates the transfer of behavioural norms which, together with information transfer, gives a higher likelihood of behavioural change than information transfer alone.[18]

Persuasion setting. In this setting the use of opinion leaders, such as postgraduate education tutors, within the medical community is an important source of norm transfer, since for the average general practitioner research findings are just one of the many inputs that may influence his or her practice decisions. Local opinion leaders have been found to play a key role in shaping local consensus regarding new technologies and thereby in encouraging or blocking new behaviour.[44] Such opinion leaders are seen locally as respected colleagues who embody the norms of the group, and appear competent in evaluating the appropriateness of new technologies.[44] This reinforces the view that although doctors are members of a national or international medical culture, they function largely through their participation in smaller local subgroups.[44] Consequently, norm transfer may best be facilitated through local units.

Opinion leaders play an important role in convincing other general practitioners to become active in the process, rather than passive recipients of practice guidelines.[18,27,50] Lomas and colleagues found a dramatic reduction in the caesarean section rate when opinion leaders were recruited and trained to educate their colleagues with the aim of reducing unnecessary caesarian sections.[29] Consequently, it is intrinsically difficult for information emanating from external or remote sources to affect local clinical practice, irrespective of the esteem with which the source of the information is held.

Mass media setting. Previous attempts at dissemination of guideline information through the mass media (for example, medical newspapers and journals) have with few exceptions failed, even though consumer marketing approaches to the use of the mass media have the potential for effecting behavioural change.[18]

It appears, therefore, that within a given social influence setting a marketing approach should be taken when devising information dissemination campaigns, with the emphasis being on norm as well as information transfer.[18] One method for introducing change, based on experience in industry, emphasizes the importance of obtaining comprehensive background information, identifying barriers to change, negotiating with key individuals such as opinion leaders in the community, achieving agreement on the approach to be used, and evaluating the programme for change.[43] Many of the noted social influence strategies rely on the same underlying behavioural mechanisms and social influence processes, and so a thorough understanding of these mechanisms and processes is necessary to select, use and monitor an effective guideline implementation approach. Before developing an overall approach to guideline implementation, proponents of quality improvement must be willing to consider the details of each strategy relative to the characteristics of a practice setting.[18]

Patterns of influence and interaction vary widely and are cul-

ture-bound. Therefore, the American and British experiences will have some essential differences from the Irish situation. Each country requires its own body of research, and success will depend on being aware of, and adapting to, special features of the local setting. Information on the route and sources of influence on professional decision making is available; this information, which often comes from work carried out in disciplines outside medicine, such as psychology and marketing, could inform the professional bodies responsible for medical education on how to use relevant research findings.[51]

Effective communication for guideline implementation

There is a crucial distinction between first awareness of and decision to use a medical innovation, which suggests an important distinction between variables that inform doctors of new developments and those that persuade doctors to implement them.[50]

The literature on communication directly addresses the issue of communication effectiveness, and distinguishes five attributes of any communication that are consistently important. These are source, channel, message content and format, audience awareness and environment.[50] Some communication variables may play a more influential role than others at a given stage.

The source should be credible and influential. With regard to the channel, personalized interactions involving opinion leaders are the most effective channels.

Once the content of the message is correct, attention to format is one of the most important aspects of guideline development, in that it may directly affect the extent to which the guidelines are read, remembered and used in practice. Attractively designed, user-friendly formats are advocated, with spacious layout and use of graphic aids where possible.[9] The communication should be crisp and persuasive, that is, it should justify the need for change by comparison with existing approaches, norms and concerns.

Awareness of the different groups within the target audience is essential if an implementation strategy is to be effective. Literature on the diffusion of innovations, that is, the process by which an innovation is effectively communicated through certain channels over time, defines five adopter categories based on the rate at which they take up new innovations.[26] These are innovators, early adopters, an early majority, a late majority, and late adopters.[41] Innovators and early adopters respond to an evidence-based approach and this group often contains the opinion leaders of a given community.[44] The early and late majority groups tend to be more sceptical, more influenced by peers and opinion leaders and more responsive to a facilitative approach. Haines and Jones have described the relationship between the proportion of individuals taking up a new idea and time.[26] This relationship is represented by an S-shaped curve of variable slope, with the innovators and early adopters at the foot of the curve and the late adopters at the end. One reason for this S-shaped curve may be that once the opinion leaders adopt an innovation, they influence their colleagues who rapidly take it up.[26] As most general practitioners will belong to the middle (early and late) majority, any successful implementation strategy must be especially cognizant of any specific needs of this group. The late adopters might require extra stimulus in terms of incentives, resources or official statements by responsible bodies.[41] If an implementation strategy is to be effective, each subset of the target group must be considered when devising the implementation strategy.

The environment in which the communication occurs influences effectiveness; an informal environment is more conducive to achieving change than a formal setting.[50] Personal contacts are the most effective means of communication.

Few, if any, of these considerations are in evidence in the traditional communication of research findings or guidelines. However, the principles underlying the theories of behavioural change and effective communication apply not just in terms of guideline implementation, but in all areas where information is transmitted in the hope of changing the behaviour of doctors, and of improving standards of clinical practice.

Acceptance of clinical guidelines

In choosing an implementation strategy, consideration must be given to how care for the condition is currently organized and to what factors may prevent compliance with the proposed guideline.[52]

The general direction of a recommendation may determine its acceptance depending on whether the primary recommendation is to adopt a new medical practice, discard a current practice, or alter the use of an existing technology. Evidence indicates that new practices may be adopted more rapidly than old practices are discarded.[50] Further research is required to increase understanding of the role of doctor characteristics in the acceptance of medical recommendations.[50]

Evaluation and reinforcement of clinical guidelines

If a guideline implementation strategy is effective in achieving behavioural change, the effects of this change on the quality of patient care must be evaluated. It is also necessary that any effect on behaviour be sustained; to achieve this a reinforcement mechanism is needed. Mechanisms of reinforcement which have been shown to be effective to date include both patient and disease-specific reminders; these may involve checklists that can be incorporated onto guideline summaries or plastic cards.[53,54] It is likely that computers may have an important role to play in providing these reminder systems, and indeed the role of computers in guideline integration must be examined at several levels, such as, the incorporation of guidelines into existing software packages, the facilitation of evaluation, audit and feedback through computerization, and the easy updating of guidelines either when new information becomes available or at recommended time intervals.

Conclusion

If the important rapid changes occurring in medicine are to be communicated to practitioners in an effective and efficient manner, the method of information dissemination must be considered carefully. The possible impact of various sources and channels conveying a particular message must be taken into account, as must the characteristics of the potential recipients and their practice settings.[50] Consequently, the responsibility of guideline integration can be seen to be comprehensive, and extends from the development stage to implementation and review of the guidelines after a recommended period of time. Such responsibility requires time, sustained effort and coordination. To avoid unnecessary duplication of effort, a central agency with responsibility for all guideline integration is needed.[29] This agency would be responsible for the development, implementation, evaluation and updating of guidelines, as well as facilitating and analysing the various factors in the local modification process needed to generate the sense of ownership, which has been shown to be important in the incorporation of guidelines into clinical practice at general practitioner level.

In recent years much time and effort has been expended in the development of practice guidelines for several clinical conditions. The effects of these guidelines on practice will always be

disappointing as long as implementation strategies are not treated as an integral part of the guideline development process.[16] Such implementation strategies will need to be cognizant of the principles of social influence and marketing theory and of the importance of user-friendly formats, norm transfer and modification for local needs, if guidelines are to be taken off the bookshelves and dynamically incorporated into day-to-day clinical practice. A systematic evaluation of the suitability, acceptability, impact and effect of guidelines in actual practice is still lacking. Further research into this whole area would therefore be both appropriate and timely.[9,41]

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Address for correspondence

Dr M Conroy, Department of General Practice, Royal College of Surgeons in Ireland, Mercer's Health Centre, Stephen Street Lower, Dublin, Republic of Ireland.