GUIDELINES: PRODUCE, USE, DISUSE AND MISUSE

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INTRODUCTION

Evidence based medicine is the distinctive of doctors who practice modern medicine as compared to the practitioners of complementary medicine. Whilst we are aware that many of the things we practice are still not based on scientific evidence, there is agreement that we should change when evidence becomes available. At the minimum, it should make us uncomfortable and circumspect.

Clinical practice guideline is evidence based medicine in action. Guidelines can be a double-edged sword. Valid guidelines lead to improvement in patient care and increase in cost-effectiveness. Invalid guidelines lead to ineffective intervention and wasteful use of resources[1]. The validity of guidelines is maximized by sound methodology in planning and thoroughness in execution.

Whilst there are many guidelines that are enthusiastically churned out, very few bear fruit. Many do not even go beyond the dissemination phase. It is important for those who contemplate writing guidelines to plan and execute the full cycle of the process down to evaluation and revision. The "fire and forget" approach to guideline writing had generated much skepticism amongst practitioners towards practice guidelines. Table 1 shows a schematic diagram of an ideal practice guideline cycle.

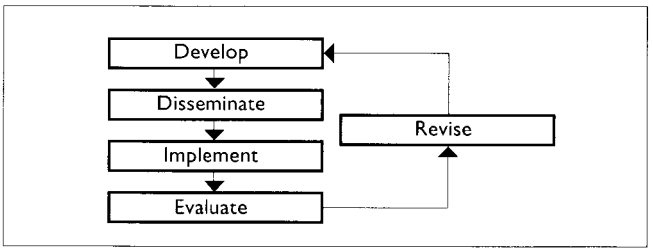

Table 1. Schematic diagram of an ideal practice guideline cycle

HOW ARE GUIDELINES PRODUCED?

Development phase

The common method is to start by gathering a panel of experts, stakeholders and opinion leaders. Issues like compensation for time spent and reimbursement of expenses have to be considered. Good guidelines take a long time to develop. The dedication of the group members is critical to the success of the project.

This is followed by a process of information collection usually in the form of published literature on a subject. Electronic databases have greatly helped the process of searching and collection of relevant information. It is usually good to lay down criteria for accepting or rejecting information. A trained health services researcher is extremely useful in this phase of development. A system of sifting through the evidence should be laid out. The panel then goes through the literature and information collected. It is useful to grade the quality of the information collected. A good way of categorizing the quality of information (Table 2) and the strength of recommendation (Table 3) was devised by the Canadian Task Force on the Periodic Health Examination. This has gained widespread acceptance amongst guideline developers[2]. An adaptation of this, which is used by the North of England evidence based guidelines development project, is an elegant way of implementing the idea to guideline development[1].

The views of the experts are usually merged through consensus development. This often would involve an element of compromise and can be

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Categories of Evidence	
I.	Based on well designed randomized controlled trials, meta-analyses, or systematic reviews.
II.	Based on well designed cohort or case-control studies.
III.	Based on uncontrolled studies or consensus.

Table 2. Categories of evidence

Strength of Recommendations	
I.	Directly based on Category I evidence.
II.	Directly based on Category II evidence or extrapolated from Category I evidence.
III.	Based on uncontrolled studies or consensus

Table 3. Strength of recommendations

affected greatly by group dynamics. The quality of guidelines and perhaps even the outcome of the recommendations adopted are influenced to a great extent by the selection and composition of the panel as well as by the rigor with which the information is gathered and scrutinized.

There are basically two components in the recommendation making process. The first is the creation of consensus among the panel of experts. The second is the formal, systematic review and analysis of gathered information and data. The quality of information is also graded based on the quality of the studies that produced the information. The tendency is to favor high quality information derived from well designed studies. When evidence from the literature is lacking, recommendations are often based on consensus statements of bodies of experts or influential medical peer groups.

The format in which the practice guidelines are presented in is an important determinant of the quality of the practice guidelines. Developers of guidelines often neglect this aspect. Guidelines are meant to be used. It is a waste of time and resources to produce a perfect guideline that is too cumbersome to be used in real life practices.

Algorithms, charts and tables are very useful aids that allow quick reference and increase the likelihood of the guidelines being used by physicians. The recommendations must be logical and unambiguous. Recommendations are more likely to be accepted if the rationale is explained. This is especially true if they are backed by strong evidence from papers that are listed for verification.

Dissemination

Although the need to disseminate guidelines to the intended users is painfully obvious, many guideline developers give little thought and make no effort to this important area of guideline development. The method by which guidelines are delivered to the users needs careful consideration. Studies have shown that publication of guidelines in journals is the least preferred by users and is unlikely to change medical practice[3]. A more effective way is to deliver the guidelines to the users individually. Publicizing the availability of the guidelines is also important. There is an increasing trend to have guidelines in electronic formats that can be transmitted or downloaded via the Internet.

Implementation

Implementation strategy is the final step towards usage of the guidelines. It is not enough to convince the recipient of guideline of the quality and the validity of the written guidelines. The acid test of the success guidelines lies in whether it is able to convince users to implement the recommendations and change their practice.

Educational events centered on the guidelines had been found to be the most effective way to encourage the adoption of guidelines[4]. The adoption of guidelines is increased when peers and professional bodies endorse them. Endorsement by local opinion leaders is also helpful.

Even when the users had been won over

intellectually, guidelines are often not used because it fails to trigger action at the point of decision making. Old habits are hard to change and a new way of managing problems takes time to become routine. It is therefore very important to have physical reminders and checklists during the early adoption phase. Ideally these reminders should present themselves before the physician at the point of decision making. Such reminders may take the form of a desktop computer programme, charts or tables attached to medical records or special markings that are visually prominent.

Audit projects that are based on the adoption and implementation of specific guidelines are exceptionally effective ways to increase compliance to guideline recommendations.

An effective but potentially problematic tool to increase guideline adoption is to leverage the support of purchaser of health care services. Third party payers, which may include the controller of public funding, can exert a strong influence on the behavior of health care providers. However, this may conflict with the need for clinical autonomy and increase the risk of guidelines being abused and used for purposes other than helping clinical decision making.

Evaluation

The desired end result of practice guidelines is better clinical decision making and improved patient care. Ideally measuring treatment outcome should be a good assessment of the effectiveness of guidelines. Unfortunately, improve outcomes may be difficult to detect because of technical reasons like small sample size, lack of funding, difficulty of recruiting patients and so on. Furthermore even when evaluations show little improvement, it would be difficult to know if the guidelines were giving wrong recommendations or whether there were inadequacies in the dissemination or implementation process. Audit projects are useful ways of assessing whether guidelines have been followed. Clinical decision making before and after guideline implementation can be compared and studied. It could also take the form of goal setting and measuring how progress has been made towards attaining a standard of practice as recommended by the guidelines.

Revision

Since good guidelines are the product of evidence based medicine, they must be constantly revised as more evidence surface in the literature and new knowledge come to light. Similarly, since guidelines are meant to help clinical decision making, they must be revised or improved if evaluation shows that they are not helpful. This final link in the chain of the guideline development process is the most telling feature of whether a particular guideline is truly successful and whether the producers of the guideline were serious minded people.

WHY GUIDELINES ARE DISUSED?

In a random postal survey of 627 general pediatrician members of the American Academy of Pediatrics, it was found that 21% of respondents do not use guidelines at all[5].

In their enthusiasm to be comprehensive, many authors produced guidelines that are too complicated and difficult to use. Authors of guidelines must accept that thoroughness is a virtue in preparation but a vice in crafting. In the management of diseases, there are multiple decision points. It is important to identify major and critical decision points and limit recommendations to these points[6].

A study of 12880 clinical decisions made by 61 general practitioners in Netherlands showed that certain attributes in guidelines are more likely to encourage compliance than others. Non-controversial recommendations are favoured over those that are controversial. Specific recommendations are preferred over those that are vague and non-specific. Evidence based recommendations are more readily accepted. Recommendations that demand extra resources, acquisition of new skills and knowledge are less likely to be followed. Likewise recommendations that may provoke negative reactions in patients are not well accepted[7].

HOW GUIDELINES CAN BE MISUSED?

A common complaint heard among practitioner is that guidelines are too many and too complicated. Enthusiasm in embracing evidence based medicine has led to a proliferation of guidelines. It was estimated that in the United Kingdom alone, regional audit programmes produced about 2000 guidelines within a short span of time[8]. This proliferation, which was initially welcome, have now reach a level that it generates negative feelings towards guidelines. Increasingly, there is a feeling among practitioners that some guidelines were written for the sake of writing.

Many physicians feel that guidelines are abused when they are used for purposes other than to guide clinical decision making. A survey showed that 82% of doctors felt that guidelines should not be used in litigation. Seventy seven percent felt that they should not be used in disciplinary actions and 73% felt that usage of guidelines should not be based on the desire to reduce cost[5].

There were also concerns that clinical guidelines may be used like a "cook book". Using clinical practice guidelines in such a fashion would be extremely disastrous in the primary care setting. As we know guidelines are based on population studies. Even the best studies are never perfect in their effort to remove bias and confounding factors. Assumptions are often made in the design of studies as well. Validity of even well designed studies had often been found to be lacking in population sub-groups. Generalizing findings of population studies to an individual with his unique biopsychosocial milieu is even more problematic. Unthinking adherence to guidelines developed by non-clinicians is a recipe for disaster. This have made primary care organizations like the Royal Australian College of General Practitioners to state in its position paper that clinical guidelines should be developed by "practicing clinicians in such a way as to provide useful assistance in practical settings rather than merely as a "recipe" for intervention." [9]

PUTTING THE GUIDE BACK IN GUIDELINES?

Notwithstanding the merits of evidence-based medicine and the attempts at systematic application of methodology, guideline writing remains an inexact science which carries the value judgment of the authors. This is a clearly demonstrated in a study on hypertension guidelines of different countries[10]. Despite drawing data from the same bodies of evidence, different countries came up with different recommendations. Using the guidelines of one country as a standard, up to 50% of patients in another country would have been considered as being treated unnecessarily. This is despite the fact that all the countries studied were fairly similar in terms of culture and economic development.

There is therefore a subjective element and an experiential component in guidelines that cannot be denied. The experience, the value judgment and the special interest of the panel members responsible for crafting of guidelines would have a non-negligible effect on the recommendations of the guidelines. Treatment decisions often depend on weighing the risks and benefits. Different authors or groups of authors would make different value judgment in risk-benefits assessment. What constitute acceptable risk to one may be unacceptable to another.

There is consensus that guidelines must be concise and limit recommendations to major decision points. A conscious attempt must be made to avoid creating guidelines that are so comprehensive that becomes too unwieldy to be used.

CONCLUSIONS

Practice guidelines are the product of evidence based medicine. It is ironic that there seems to be little change in behaviour on the part of guideline developers in the light of mounting evidence that guidelines are ineffective in changing practice behaviour. There are many reasons for the failure of guidelines. It begins with many wrong assumptions that make the whole process invalid before work is even started. Some common incorrect assumptions are:

- Health care resources are unlimited.
- Patients will comply with the recommendations if the physicians say so.
- Physicians will comply if guidelines are delivered.
- Recommendations derived from population studies can be applied to individual patients regardless of their biopsychosocial uniqueness.

Even when guidelines are well written many failed because of a lack of follow-through. It would appear that many guideline developers are more interested in the publication of a guideline than the desired effect that guidelines should have in improving clinical decisions. Guidelines are means to an end and we should question the need of guidelines that do not give serious consideration to practicality issues during implementation.

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