

Clinical Guidelines

Clinical Guidelines and Evidence-Based Medicine

BCC LAM

Abstract

In recent years, the development of evidence based Clinical Practice Guideline (CPG) has received increasing attention from medical professionals, and has been initiated at both central and local levels. Both the Paediatric Quality Assurance Sub-committee of the Hospital Authority and the Hong Kong College of Paediatricians have formed working groups to develop evidence-based CPG. This review article outlines the potential benefits and harms of CPG for patients and health care professionals. It helps the practitioners to use objective criteria to evaluate the quality of guidelines. It deals with the process of guideline development from selection of topics to dissemination and implementation. Mechanisms of behavioural change that have been recognised as being important for implementation are also discussed. The issues on conflict of clinical freedom and medico-legal implication of clinical guideline are also highlighted. This article aims at improving clinicians' understanding towards CPG and helps to promote an appropriate attitude and culture among Paediatricians towards evidence-based clinical practice.

Key words

Evidence-based clinical practice guideline

Introduction

Clinical Practice Guidelines (CPG) have been defined as "systemically developed statements to assist the practitioner and the patient on decisions about appropriate health care for specific clinical circumstances".¹ Development of clinical practice guidelines is not a new phenomenon. Guidelines have existed in clinical practice for decades subsumed under terms like "protocols of care", "clinical protocols", "position statement" or "principles of practice". Over the recent years, there has been an increasing emphasis on evidence-based clinical practice and the development of evidence-based clinical guidelines. Evidence-based clinical practice is an approach to decision making in which the clinician conscientiously use the current best evidence available in

consultation with the patient to decide upon the options of treatment which suits the patient best.^{2,3} The processes include precisely defining a patient's problem; deciding on information which is required to resolve the problem; conducting an efficient search of the literature; selecting the best and the most relevant studies and applying rules of evidence to determine their validity; and extracting the clinical message and applying it to the patient's problem.⁴

Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience and pathophysiological rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. Traditional medical training on understanding the underlying pathophysiology is also essential to allow the clinician to judge whether the results are applicable to their specific patient at hand. Evidence-based clinical practice also emphasises the needs for physician to be sensitive to and able to determine what patients are really looking for. Evidence-based medicine requires new skills of the physician, including efficient literature searching and critical appraisal skills in evaluating the clinical literature.

In the current era of explosion of knowledge, it almost

Department of Paediatrics, Queen Mary Hospital, Pokfulam Road, Hong Kong, China

BCC LAM (藍章翔) FRCP(Lond), FRCPCH(UK), FHKC Paed

Correspondence to: Dr BCC LAM

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becomes impossible for every clinician to read, search, update and appraise every piece of medical literature, which is increasing at colossal speed everyday. Most clinicians also feel that it is too time consuming to always rely on literature search to guide their every day clinical practice.

Evidence-based CPGs are designed to help practitioners to assimilate, evaluate and implement the ever-increasing amount of evidence on best current practice. They are based on the systematic identification and synthesis of high quality evidence-based on properly designed randomized controlled trials. They are more vigorously grounded in science – not just based on expert opinion or anecdotal experience.⁵ Both the Paediatric Quality Assurance Subcommittee of the Hospital Authority and the Hong Kong College of Paediatricians have formed working groups to develop evidence-based CPG. The primary goal of developing evidence-based CPG is to aim at improving patient care and to maintain good standard of care.

Potential Benefits and Harms of Clinical Practice Guidelines

In spite of the fact that CPG are getting more popular, health care professional are still quite ambivalent towards guidelines. One of the barriers to accept guideline has been a degree of suspicion about the underlying motives of the guideline developers. Medical professions should not accept CPGs developed solely on the basis of financial consideration. Guidelines produced by professional groups aiming at improved patient care usually has higher credibility.⁶ In order for clinicians to understand and make an informed decision to decide whether to follow guidelines or not, it is important for us to realize that guidelines can benefit as well as harm patients, depending on how well they are developed. Woolf et al have written an excellent article on the potential benefits and harms of CPGs which is summarized here.⁷

Potential Benefit for Patients

Guidelines can promote interventions of proven benefit and discourage ineffective ones. Guidelines can also improve the consistency of care, making it more likely that patient will be cared for in a similar manner regardless of where, or by whom they were managed. Guidelines can empower patient to make more informed healthcare choices and to consider their personal needs and preferences in selecting the best option.

Potential Benefits for Healthcare Professionals

Guideline served as a checklist reminding physicians of the elements of appropriate care. It can offer explicit recommendation for clinicians who are uncertain about how to proceed. Guidelines from professional bodies provide authoritative recommendation that reassure practitioners about the appropriateness of their treatment. It blocks the premature introduction of new treatment methods or technologies that show promise but are ultimately of questionable efficacy. It helps to overturn the beliefs of doctors accustomed to out-dated practice. In this regard, it can support the junior doctors to challenge their out-dated seniors. Improvement in consistency of care can support quality improvement activities because agreement on how patient should be treated provides a common point of reference for prospective and retrospective audits of practices. Besides, in the processes of guideline development, clinicians can identify gap in current literature, which helps to generate new research questions and directions.

Potential Harms of Guidelines

Guidelines are only as good as the evidence on which they are based. Science does not always provide clear answers to questions surrounding clinical care. Guidelines are dynamic and evolving, hence they must change to keep pace with new scientific knowledge and technologies.

Recommendations may be wrong (or at least wrong for individual patients). This is because scientific evidence about what to recommend is often lacking, misleading or misinterpreted. There may be lack of resources or time and skill to gather and scrutinize every pieces of evidence. Recommendations may be influenced by the opinions and clinical experience and composition of guideline development group. Consistent practice and reduced variations may come at the expense of reducing individualized care for patients with special needs. Besides, conflicting guidelines from different professional bodies may confuse and frustrate practitioners.⁸ Out-dated recommendations may perpetuate out moded practices and technologies.

Furthermore, attempt to make guideline more explicit and practical (e.g. arbitrary numbers of days on duration of treatment, intervals between screening tests) when supporting evidence may be lacking, does not fully address the complexity of medicine. Recommendations against an intervention may lead providers to stop access to or coverage for services. Imprudent recommendations for costly interventions may displace limited resources that are needed

for other services of greater value to patients.

Guidelines with full recommendations that incorporate clinical expert judgement may not be timely. Amassing the science base is likely to take essentially the same amount of time as it would in EBM activities. Guidelines require the further steps of evaluating the evidence and convening experts to reach some consensus about recommendation followed by open consultation by end-users. Creating a complete guideline may take a year or even longer, in that time, new evidence may have emerged. This was exactly the situation and problem we faced here now, as writing guidelines was still a new challenge for local authors.

Ten Desirable Attributes for Clinical Guidelines

It is important that practitioners are equipped with the ability to evaluate the quality of guidelines. To a certain extent, knowledge of who developed a guideline may be helpful in evaluating its quality. However, even though the development and review procedures used by these professional organization provides some assurance, the quality and validity of a guideline cannot be discerned solely by knowing who has developed it. The use of objective evaluating criteria would be most helpful.⁹⁻¹²

Validity Practice guidelines are valid if they correctly interpret available evidence so that when followed, guidelines lead to improvements in health. Validity can be determined by the assessment of the quality of evidence cited, the means to evaluate the evidence, and the relationship between the evidence and recommendation. Practice guidelines should be accompanied by descriptions of the strength of the evidence and the expert judgement behind them.

Reliability Practice guidelines are reliable if given the same clinical circumstances, another group of experts produces essentially the same statements.

Reproducible Practice guidelines are reproducible if given the same evidence and methods of guideline development, another group of experts produces essentially the same statements.

Clinically applicable Practice guidelines should explicitly state the target population in accordance with the scientific evidence.

Clinically flexible Guidelines should identify the specifically known or generally expected exceptions to their recommendation and discuss how patient preferences are to be incorporated in decision making.

Cost-effectiveness Guideline on intervention should explicitly take into account the cost of interventions so that the limited resources available are used more efficiently. Local modification of internationally developed guidelines in particular should take into consideration local factors that will influence cost-effectiveness.

Clearly expressed Guidelines should use precise definitions, unambiguous language, logical and easy-to-follow modes of presentations.

Multi disciplinary Guideline should be developed by a process that includes participation of representatives of all key disciplines and interests.

Well documented Developers of guidelines should state the objectives and methods and identify the intended users. Guideline should record participants, assumptions and methods and link recommendations to the available evidence.

Regular review Guidelines should state when and how they are to be reviewed. The time frame depends on whether new evidence is anticipated within a period of time.

Development of Clinical Guidelines

There were different methods for development of clinical guidelines. These include informal consensus development, formal consensus development, evidence-based guideline development and explicit guideline development.^{13,14} The Working Group on Clinical Guideline and Evidence-based Medicine recommended evidence-based guideline development which links recommendations directly to scientific evidence of effectiveness. Rules of evidence are emphasized over expert opinion in making recommendations.

Explicit guideline development make recommendation on interventions by assessing the potential benefits, harms, and cost of available interventions, estimating the possible outcomes and patient preferences.^{15,16} This explicit approach is relatively new, though very time and resource demanding,

has gained increased popularity especially by specialty societies.

The processes of guideline development involve a number of steps (Table 1).¹³

Selection of Topic

Guideline development is expensive and very resource demanding. It is important to concentrate effort on those areas likely to produce the greatest improvement in patient care. The three most important selection criteria laid down by the Working Group for prioritizing topics include:-

- 1) Conditions where effective treatment is proven and where evidenced-based clinical information is available.
- 2) Conditions with high degree of public importance i.e. the conditions or services involved are of high volume (prevalence) or high cost (seriousness).

Table 1 Methodologic issues to address in guideline documents

- Selection of topic
- Selection of panel members and chairpersons
- Clarification of purpose
- Assessment of clinical benefits and harms
 - ◆ Admissible evidence
 - ◆ Review process
 - ◆ Evaluation of scientific evidence
- Assessment of expert opinion
- Assessment of public policy issues
 - ◆ Resource limitations
 - ◆ Feasibility issues
- Drafting of document
- Peer review
- Pretesting
- Recommendations of other groups
- Recommendations for research
- Disclaimers
- References

Table 2 Levels of evidence

<i>Level</i>	<i>Type of evidence (based on AHCPR 1992)</i>
Ia	Evidence obtained from meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

- 3) Area known to have a wide variation on clinical practice locally especially when there is a big gap between what clinicians do and what scientific evidence support.

These criterion were similar to those adopted by Scottish Intercollegiate Guidelines Network (SIGN) namely, burden of disease, the existence of variation in practice and the potential to improve outcome.¹⁷

Selection of Guideline Development Panel

The guideline development panel should consist of recognized local experts in general paediatrics and in the related subspecialty field. For guidelines developed by professional organizations like the College of Paediatricians, there should be representatives from both the public and the private sectors. Trainees should also be encouraged to join the guideline development panel to learn the skill of literature search and critical appraisal.

Level of Evidence and Grading System on Recommendation

The Working Group has adopted the definition of types of evidence and grading recommendations that originate from the US agency for health care policy and research (AHCPR) and are being used by the SIGN.¹⁸ This system was also recommended and used by the Royal College of Paediatrics and Child Health (RCPCH)¹² (Tables 2 and 3).

Evidence is graded upon the methodological quality and does not address the applicability of the evidence. Guidelines normally contain many different recommendations based upon different levels of evidence. It is important that users are aware of the level of evidence on which each guideline recommendation is based. The link between guideline

Table 3 Grading of recommendations

<i>Grade</i>	<i>Type of recommendation (based on AHCPR 1994)</i>
A (Levels Ia, Ib)	Requires at least one randomised control trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation
B (Levels IIa, IIb, III)	Requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendation
C (Level IV)	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality

recommendation and the supporting evidence should be made explicit. Separating the strength of the recommendation from the level of evidence helps in situations where extrapolation is required to take the evidence of a methodologically strong study and apply it to the target population. Gradings of recommendation in addition to level of evidence allow more flexibility for future revision. However, it is important to emphasize that the grading does not relate to the importance of the recommendation. Currently, there are discussions on taking account of relevant high quality non-RCTs and qualitative research and to incorporate them into an appropriate grading system.

During the development of evidence-based clinical guidelines, consensus statements or expert opinions can still be included provided that they are transparent about the basis for their recommendations and the process by which they are derived.

Peer Review and Pilot Testing

Guidelines should be subject to peer review. The peer review panel should have representatives from local leaders or authority in paediatrics and the related subspecialty. If the guidelines involve more than one discipline, other related specialties should be included. There should be mechanism for open consultation and pilot testing before dissemination and implementation.

Dissemination and Implementation

It is important to set up a dissemination strategy for the guidelines. The guidelines should reach all paediatricians and practitioners practicing in the involved field. Specific educational interventions and continuing medical education

by opinion leaders is an effective means of dissemination.¹⁹

Publication in professional journals will provide another channel of dissemination. Availability of electronic channel e.g. the E-knowledge gateway of the Hospital Authority provide another venue for wide dissemination. However, in order to be successful, dissemination must be reinforced by an appropriate implementation strategy. It is also important to realize that health care professionals can assimilate only a limited number of guidelines at any one time. Hence, the professional organization like the Hospital Authority and the College should coordinate the development and dissemination of guidelines of each specialty at an appropriate pace.

Importance of Implementation

The development of guidelines alone does not imply that they will be translated into practice. Experience indicates that even when doctors know what to do, they often do not perform according to their knowledge and skills.²⁰ Furthermore, while the dissemination of information alone 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.²⁰⁻²²

The failure of clinical guidelines to achieve their potential in changing clinical practice 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 important to put more emphasis on the need for guideline integration, which encompasses dissemination and implementation strategies, with provision made for evaluation, audit, feedback and outcome measurement.²³

Implementation Strategies

Implementation strategy should have impact at the following levels²⁴:-

- Increasing knowledge i.e. making clinicians aware of the guidelines
- Changing attitudes, such that clinician would agree with and accept the recommendations as a better standard of care
- Changing behaviour, such that clinicians would change their clinical practice to conform with the guidelines
- Changing outcome by improving patient health and quality of care

Interpersonal setting It involves a combination of educational visits and information transfer within the context of a well-planned marketing strategy. This is most effective when educators are known to and well respected by the target groups. This facilitates the transfer of behaviour norms which, together with the information transfer, gives a higher likelihood of behavioural change than information transfer alone.

Persuasion setting In this setting, the opinion leaders within the medical community are an important source of norm transfer. 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. Local opinion leaders have been found to play a key role in shaping local consensus regarding new technologies and thereby in encouraging new behaviour.²⁵

Mass media setting Attempts at dissemination of guideline information through the mass media (e.g. medical newspaper, journals, electronic means) are generally not as effective as the other previously discussed means.²⁶

Therefore, no matter which implementation strategies are employed, proponents of quality improvement must consider the details of each strategy relative to the characteristics of the local setting. In order to be successful, guideline must be based on valid scientific evidence, be attractive to potential users and present practical avenues for application. The success criteria can be assessed by whether awareness and use of recommended guidelines has improved the standard of care, and ultimately by whether clinical practice has moved closer to the agreed standard of care.

Monitoring Guideline and Clinical Audit

Guideline developers should also devise criteria for monitoring the extent to which guidelines have been followed. The guideline document should also specify measurable outcomes or end points that can be monitored through clinical audit. Clinical audit describes an evaluation of patient care against defined standard. The Department of Health of NHS of United Kingdom described it as a process of "systematically looking at the procedure needed for diagnosis, care and treatment, examining how associated resources are used, and investigating the effect care has on outcome and quality of life for the patient".²⁷ Undertaking an audit involves collection of relevant patient outcome data, sample selection and analyzing how guidelines influence patient care. This is a very resource demanding process, yet audit forms an integral part of guideline implementation. It also plays an important role in the reinforcement of maintaining practice changes.

Implication of Clinical Guidelines

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. 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, and the possible reduction of clinical freedom in the management of illness by practitioners.

Conflict of Clinical Freedom

Clinicians frequently anticipate that guidelines would threaten doctor autonomy and reduce satisfaction with the practice of medicine. This issue of clinical freedom and doctor autonomy is an emotive one if one can view guideline as a tool for health care decision-making – not a dictate. Even when endorsed by the relevant professional bodies (e.g. the College) or commended by an organization (e.g. the Hospital Authority), clinical guidelines can only assist the practitioner, they cannot be used to mandate, authorize or outlaw treatment options. Regardless of the strength of evidence, it will remain the responsibility of the practicing

clinicians to interpret their application taking account of the needs and wishes of individual patients. Therefore, it is not reasonable to expect 100% compliance with any guideline, since there may be perfectly valid reasons for not complying with a guideline in a given clinical situation. Quality, as reflected in patient outcomes – not rigid compliance – should be the basis for professional accountability. Besides, there must always be room for clinical judgement and patient preference in medical decision-making. Thus, clinicians should view the guideline as a resource – not as pronouncement from high above.

Legal Implication of Clinical Guideline

One of the major concerns of the clinicians on clinical guideline is about the legal status of the guideline and potential litigations resulting from non-compliance. Many clinical guidelines have already been in existence for many years. The use of clinical guidelines has not resulted in increase in number of court cases. Most guidelines, unless issued by a statutory body with legislative power which embody minimum standard of clinical performance, do not have the force of law. When medical-legal issues arise, written guidelines may be introduced as evidence of accepted or customary standard of care. However, they cannot be introduced as substitute for expert opinion who can challenge the guidelines under a specific clinical situation. On the other hand, in places like the United States where most medical liability litigation has taken place, a recent project was initiated to admit legally validated clinical guidelines in court, which aimed at cutting the cost of malpractice premium and helping to retain doctors in high risk disciplines. Under this legislation, once guidelines and protocols have been developed and adopted by the licensing and registration board, a doctor may cite the fact of having followed the guideline in a particular case as an affirmative defense to a malpractice claim. However, deviation from such guideline, cannot yet be used by a plaintiff as presumptive evidence of negligence. Under the common law, the standard of medical treatment a doctor owes to a patient was established in the case of Bolam which is confirmed by subsequent legal decisions.²⁸⁻³⁰ According to Bolam's test, a doctor is not negligent if he acts in accordance with a practice accepted as proper by a responsible body of medical opinion even though other doctors adopt a different practice. Thus, there is ample scope for genuine differences of opinion and a degree of flexibility in argument in medical negligence cases. Therefore deviation from a clinical guideline is unlikely to prove conclusive in a medical negligence action,

unless it can be shown that the guideline is so well established that no responsible doctor acting with reasonable skill would fail to comply with it. Hence, medical-legal issues do not, in principle, represent a barrier to guideline implementation.

Conclusion

Clinical practice guidelines have become a significant tool in the move in health care to the philosophy of evidence-based practice. It is important for the Hospital Authority and the professional organization like the College to promote and involve in the development of guidelines. They should recognize that the development of valid guidelines requires considerable resources. Resources and time need to be made available to enable clinicians to be involved in the development of the local guideline. The Authority should provide technical support for literature review and appraisal, to make provision for continuous medical education, to provide resources and make provision for on going monitoring, evaluation and audit. Central coordination of guideline development could reduce inefficient duplication of guidelines.

Clinicians should view the guideline as a "tool", not a "dictate", nor a magic bullet. Guidelines do not provide solution for every medical dilemma. Unfortunately, many difficult questions in clinical medicine remain difficult because there is no clear answer. The "art of medicine" still plays an important part in every practice. However, the "art of medicine" is not about applying anecdotal experiences to the solution of clinical problems, it is about critically appraising the evidence available and applying it to one individual patient.¹¹ All clinicians should develop an appropriate culture towards evidence-based clinical practice and commitment towards better patient care. Quality as reflected in patient outcome – not rigid compliance should be the basis for professional accountability.

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