The Impact of Clinical Guidelines and Clinical Pathways on Medical Practice: Effectiveness and Medico-legal Aspects

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Abstract

The 1990s will be remembered as a decade when quality assurance, evidence-based medicine and clinical quality improvement became key issues in the delivery of health care in hospitals and community settings. As public expectations of high quality health care increase in the face of diminishing resources and as accountability and standardisation of clinical practice are demanded by both consumers and professional regulatory bodies, the medical profession has responded with a proliferation of clinical practice guidelines and pathways. The efforts have been spearheaded by the various professional and academic colleges. Despite all the enthusiasm that has been created, there is still uncertainty regarding the clinical effectiveness, validity and medico-legal effects of practice guidelines and clinical pathways. This article focuses on the reasons behind the increasing popularity of clinical guidelines and pathways, a critical appraisal of their effectiveness and the medico-legal implications, effects and consequences of implementing such guidelines in clinical practice.

***Ann Acad Med Singapore* 1998; 27:533-9**

Key words: Evaluation, Evidence-based medicine, Malpractice litigation, Standards of care

Introduction

Guidelines for the management of specified clinical conditions are increasingly being touted as a vital component of the future delivery of health care.[1,2] However, there are many guidelines that have been drawn up which have remained in the closed shelves of many clinics and hospitals. While the process of development of guidelines and clinical pathways can be an intellectually stimulating activity, when it comes to dissemination, implementation and evaluation, most practising clinicians feel uncertainty about the purpose and validity of guidelines. A number of controversial issues still abound in the use of guidelines and pathways. Some argue that guidelines are a fetter on clinical discretion and can lead to the practice of "cookbook medicine". Others have advocated that guidelines ensure the provision of safe and appropriate medical and nursing care.

The subjects of clinical guidelines and clinical pathways are becoming a common discussion point in medical journals because their impact on clinical practice can be potentially significant. In the USA, some 20 000 health care standards and clinical practice guidelines have been issued by over 500 organisations.[3] The growing importance of clinical guidelines has been recognised by the US government. In 1989, the US Congress mandated the establishment of the Agency for Health Care Policy and Research (AHCPR), which has been tasked with the development, dissemination and implementation of national clinical guidelines on important conditions. So far, the AHCPR has developed and disseminated guidelines on a wide variety of clinical conditions such as benign prostatic hypertrophy, cataracts, and the management of pressure sores. Access to a wide variety of clinical guidelines can now be achieved through the Internet with the establishment of web sites such as the US National Library of Medicine's Health Services Technology Assessment Text (HSTAT).

In Singapore, national guidelines have been disseminated for the management of a variety of diseases such as diabetes mellitus (1993) and tuberculosis (1998). In addition, government and restructured hospitals have developed many local guidelines and protocols for use by their own clinical staff. Clinical pathways for specific patient populations have also been developed in several large public hospitals. There are still numerous unresolved issues pertaining to the use and evaluation of clinical practice guidelines and pathways. This paper serves to highlight two important and controversial issues in the use of guidelines and clinical pathways—namely, their effectiveness and medico-legal aspects.

Definitions

In searching the literature on clinical guidelines, it quickly becomes apparent that authors use a variety of

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terms, sometimes interchangeably. According to Farmer,[4] the term clinical guidelines essentially means a recommendation for patient management that identifies one or more strategies for treatment. The American Institute of Medicine defines clinical guidelines as "*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances*".[5]

A clinical pathway or critical pathway is essentially a multidisciplinary care plan that outlines the main clinical interventions that are carried out in the hospital or clinic by the group of professionals responsible for the care of the patient. It is used by health care professionals as a guide to plan, coordinate, deliver, monitor, document and review care concurrently. Pathways embody practice guidelines, while at the same time allowing variations in the activity of the provider and in patient response. Unlike clinical practice guidelines, pathways are commonly developed by a group of doctors, nurses and other allied health professionals for use locally within the same institution or clinic. Pathways are continuously updated and reviewed so that they become a method for evaluating the care provided and form an important component of continuous quality improvement (CQI) in clinical practice. Pathways are therefore peculiar to the working culture, resources and organisation of the health care establishment. Unlike clinical guidelines, clinical pathways define expected or anticipated outcomes of care and are used as a tool for process and outcome audits. Hospital management has also used pathways to minimise average length of stay without compromising on the quality of care provided. As such, clinical pathways have a more immediate and tangible impact on the outcome of patient care. Guidelines are different from pathways in that they are essentially diagnostic and treatment guides or algorithms developed by experts in a specialised field. They are often drafted by adhoc committees who disperse after the guidelines have been disseminated. Clinical guidelines are therefore slow to change. In this paper, the two issues to be discussed are applicable to both clinical pathways and clinical guidelines.

Proliferation of Clinical Guidelines and Pathways

There have been several factors leading to the proliferation of guidelines and pathways. These include a disproportionate rise in health care costs with increasing gross national product (GNP) and the subsequent need for providing more cost-effective care. There are also several reports of unexplained differences in rates of surgical procedures in areas with similar epidemiological and demographic profiles. There is also evidence that a large number of operations are unnecessary.[6] Ferguson[7] estimated that up to 80% of medical treatments may not be effective. While this may be an exaggeration, it serves to point out that there is a lack of sophisticated outcomes data on morbidity and severity of illness for health care providers to determine the effectiveness and quality of the care provided. Similarly, clinical pathways have proliferated because of pressures from payors and consumers for more information regarding their treatment and better coordination of care so that the efficiency of care provision is maximised. This has resulted in shorter length of hospital stays with no compromise in outcomes. As a result, it has been estimated that about 60% of hospitals across the USA have started using clinical pathways.[8] The figure is likely to be higher now. Pathways have also been in use in the United Kingdom (UK) and Australia.

Effectiveness of Clinical Guidelines: Do They Really Work?

There is considerable uncertainty whether clinical guidelines will improve or influence clinical practice. Few evaluations have been carried out using randomised controlled trial methods. Much of the research that has been carried out focus on changes in the process of delivery of care rather than on outcomes. Grimshaw and Russell[9] were the first to publish a rigorous systematic review of evaluations of clinical guidelines in a scientific medical journal. The authors studied and analysed 59 evaluations of guidelines published between 1976 and 1992—24 on specific clinical conditions, 27 on preventive programmes, and 8 on prescribing or laboratory or radiological services. All except 4 of the 59 studies detected significant change in the process of care in the direction proposed by the guidelines. However, the actual sizes of this improvement varied considerably. All but 2 of the 11 studies on patients' outcome found some significant improvement. The authors concluded that explicit guidelines do improve clinical practice, in the context of rigorous evaluations. More recently, the authors increased their evaluation to include a total of 91 studies, of which 81 studies reported significant improvements in the process of care and 12 out of 17 studies showed significant improvements in patients' outcome.[10] There have been fewer published studies that have evaluated the outcomes of using clinical pathways. Most of these have shown a reduction in hospital length of stay and decreased costs without any adverse clinical outcomes.[11,12]

There have been numerous other studies that have been conducted to assess effectiveness of guidelines in a variety of settings. For example, the American Society of Anaesthesiology in 1989 approved standards for preanaesthesia care and intraoperative monitoring. As a result, hypoxic injuries have been reduced dramatically since then. At Harvard Medical School's nine teaching hospitals, the introduction of anaesthesia standards decreased the average loss per anaesthetic by more than half between 1976 and 1987. These loss reductions allowed malpractice insurance premiums to be reduced.

Guidelines on baseline foetal monitoring, monitoring with pitocin usage and other practice changes in obstetrics and gynaecology have also helped to improve the outcome of deliveries in hospitals, especially for high risk pregnancies.[13]

There have also been some studies which have reported no significant effect or change as a result of using guidelines. A systematic review of the effectiveness of clinical guidelines on patient outcomes in primary care showed that there was little evidence that such guidelines improved the outcomes although most of the published studies used older guidelines and the sample sizes may have been inadequate to detect small changes in outcome.[14] Another recent study conducted by Hirani and Macfarlane[15] showed that clinical guidelines on the management of severe community-acquired pneumonia have not significantly improved the outcome and mortality from the disease since their implementation. The authors commented that the compliance rate on the use of the guidelines were high among the doctors and the guidelines were found to be practical and relevant. However, there was no reduction in mortality after implementation of the guidelines. It is likely that there could be other factors other than early diagnosis, appropriate antimicrobial treatment and prompt transfer to the intensive care unit that influenced the outcome of the illness. Despite the lack of improvement in the outcome of patients, the authors still believe that guidelines are influential in optimising the management of these patients. Bailey et al[16] showed that an asthma clinical pathway did not significantly reduce the length of stay, but was associated with an increase in the use of metered-dose inhalers which resulted in an estimated cost savings of US$288 000 per year for the institution.

Successful introduction of guidelines and achievement of the desired impact depends very much on the methods used to develop, implement and disseminate the guidelines. These in turn, will determine the acceptability of the guidelines to practising doctors and hence, their compliance with them. Many published reports have suggested that the best guidelines are those that are locally developed, evidence-based, and implemented through patient-specific reminders at the time of consultation. The behavioural factors which influence adherence to guidelines are very complex. Although guidelines may be highly regarded by doctors, this may not equate with implementation.[17,18] For example, it has been observed that clinician confidence in guidelines issued by different organisations is strongly related to the doctor's affiliation with the organisation. It is not the intention of this paper to discuss the strategies for implementation of clinical guidelines and the factors to be considered before doing so. For a more detailed discussion, the reader may refer to various other published articles.[19-21] The intention here is to highlight the point that there is a need for local studies to be done to determine the factors involved in the acceptance and use of published guidelines by doctors in Singapore, which will in turn influence their effectiveness.

Whatever their origin, the validity and clinical effectiveness of many clinical guidelines still remain untested. Given the prodigious level of intervention in the traditional practice of medicine with the profusion of clinical guidelines, the widespread absence of demonstrable links between the professed aims of guidelines and the consequences of their implementation must be seen as a serious flaw in most guideline initiatives. It is therefore imperative that health care professional groups, hospitals and even general practitioners carefully appraise the clinical effectiveness of implementing guidelines in their own settings, taking into account their own resources and organisational constraints. In Singapore, there have been no published studies on the effectiveness of implementation of local or nationally produced clinical guidelines. The time is ripe for such an evaluation to be done if clinical guidelines are to be widely accepted and utilised by the medical profession.

Medico-legal Significance of Clinical Guidelines and Clinical Pathways

Clinical guidelines and pathways represent an attempt by the medical profession to rationalise the practice of medicine based on scientific evidence. Trends show that health care systems in developed countries are converging in their adoption of guidelines as devices aimed at regulating clinical practice. Recent reports point towards an increasing possibility that regulatory bodies and professional organisations could in future, turn to approved guidelines as embodying the minimum standards of clinical performance and failure to comply with such guidelines might be considered substandard care and hence subject to discipline.

The common law system of tort (which prevails in Singapore) includes actions for medical negligence, which evolved from a desire for vengeance for wrongs suffered by victims. By providing compensation to those wronged, tort law is aimed at both deterring wrongdoing and preventing victims themselves from retaliating. This part of the common law allows actions to remedy civil wrongs, such as negligence. Under the Singapore law (as in the UK), the standard of medical treatment a doctor owes to a patient is established in the case of Bolam versus Friern Hospital Management Committee (1957). In the words of Judge McNair: "*The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient that he exercises the ordinary skill of an ordinary competent man exercising that particular art... A man is not negligent if he is acting in accordance with such a practice, merely because there is a body*

of opinion who would take a contrary view."[22] This principle has been upheld in all subsequent court decisions since then. The implications of the Bolam test are far reaching and have bearing on the use of clinical guidelines. It should be noted that although the standard of care can be imposed by law, its content is not determined by the courts, but is set by the medical profession. Doctors are required to act in a manner judged reasonable and proper by a body of responsible doctors.

Expert testimony helps courts ascertain what is accepted and proper practice in specific cases. Credible expert testimony clearly requires a witness to have firsthand experience of the appropriate health care practice. The appropriate standard of care cannot be evidenced by an expert who practices outside of the defendant doctor's area of expertise, i.e. there should be a different degree of skill required of a specialist in his own field compared to a general practitioner.[23] Written guidelines may be introduced to a court by an expert witness as evidence of accepted and customary standards of care. However, they cannot be introduced as a substitute for expert testimony because with no possibility of challenging these guidelines, the court would view them as hearsay only.[24]

The state of Maine, USA, has initiated a revolutionary 5-year experimental project to establish state-wide, legally validated clinical guidelines admissible in court, which aims at cutting the cost of malpractice litigation and therefore retaining doctors in high-risk clinical disciplines within the state.[25] The process adopted has been set in motion by statute, but designed by the Maine Medical Association with the approval of the AHCPR and 4 other national medical and surgical associations. Under this legislation, once guidelines and protocols have been developed by the Maine Licensing and Registration Boards, a doctor may cite the fact that he followed an approved guideline in a particular case as an affirmative defence to a malpractice claim. Under the Maine legislation, the standard of care embodied by the guideline becomes the legally required standard of care. Furthermore, because the current legislation only allows Maine guidelines to be cited in a doctor's defence, deviation from the guideline cannot be used by the plaintiff as presumptive evidence of negligence.[26] Arguably, the asymmetry between the exculpatory value of these guidelines to the doctor and their lack of inculpatory value to the plaintiff may be seen as unconstitutional. It remains to be seen what is the outcome of this 5-year experimental trial. However, since the implementation of legislation, there has not been a single case of malpractice claim that has been filed against a doctor on medical conditions covered by the clinical guidelines. Apparently, plaintiff attorneys are more reluctant to file a lawsuit if they do not expect to achieve any success.

The courts acknowledge the importance of reasonable discretion in clinical decision making. The key issue is whether or not written guidelines can be used as evidence of the standard of care required in a particular case. This is in turn dependent on whether or not the guidelines did in fact embody a consensus standard as represented by customary practice. The mere fact that clinical guidelines exist for the care of a particular condition cannot itself establish that compliance with them would be reasonable in the circumstances and that non-compliance would be negligent. The courts recognise that differences of medical opinion do exist and where each is shown to be respectable, they will not regard as negligent the clinicians who adopt one rather than the other opinion. The court is not entitled to prefer one such opinion to the other. This is known as the Maynard test and comes from the case of Maynard versus West Midlands Health Authority (1984).

In order to satisfy the legal standard of care as stated by the Bolam principle, a clinical guideline must be reflective of a responsible body of medical opinion. If the defendant adhered to a guideline, the burden of proof would be on the plaintiff to prove that the guideline was defective. This is not an easy task. Guidelines are not an immutable representation of the standard of medical care. Medicine is too complicated for that. Both the Bolam principle and the Maynard test show that medicine is by no means an exact science. The clinician is always entitled to argue that the guideline was not appropriate for the patient's condition or that a conscious decision was made to adopt a different, though equally responsible and acceptable approach to the management of the patient's condition. As Hirshfield[27] summarises: "*practice guidelines are just one of many sources of evidence about what the standard of care should be in any given malpractice case.*"

It would clearly be wrong for a doctor to automatically apply a guideline without due consideration of the patient's individual needs and condition. It is reasonable to expect reflective clinical practice and the law demands this. Clinicians must use their own professional judgement and skill and judge the appropriateness of the guideline for that particular case. As West[28] argues: "*the largest component of a physician's training is the development of professional judgement; practice guidelines cannot be permitted to wipe the slate clean and substitute blind adherence to a guideline in favour of professional judgement; physicians must be given latitude and discretion in their approach to treating particular patients, because there are simply too many variables inherent in the treatment of human beings to capture all the alternatives in a single decision tree.*"

There is clearly an onus on doctors to be aware of guideline statements which, in their field of practice, may embody the minimum standard the law may re-

quire. However, it is still unclear how doctors are to recognise which of the many clinical guidelines in existence possess this particular status. The doctors' predicament with regard to the explosion of published materials was appreciated by Lord Denning some forty years ago in the case of Crawford versus Board of Governers of Charing Cross Hospital.[29] Lord Denning ruled: "*It would, I think, be putting too high a burden on a medical man to say that he has to read every article appearing in the current medical press; and it would be quite wrong to suggest that the medical man is negligent if he does not put into operation some contributor's suggestion in a medical journal...*" The 4 key elements of the Denning test are: proof, dissemination, acceptance and adoption. This could be used by a court to decide whether a set of guidelines should be justifiably viewed as embodying the legally required standard of care.

On the flip side of the issue, it could be quite possible that guideline developers could be held negligent if a patient suffered injury as a result of inadequate or erroneous guidelines. This was illustrated in the US case of Wickline versus State of California in 1986.[30] In this landmark case, the California Medicaid (Medi-Cal) programme refused a doctor's request for additional days of patient monitoring on the basis that they were not required under the clinical algorithms developed by Medi-Cal. The patient was discharged and subsequently developed complications. Cost-saving reasons had overridden the doctor's better clinical judgement. The patient in turn sued Medi-Cal for medical negligence in requiring the doctor to discharge the patient against the doctor's better judgement for cost-containment reasons. The court warned that doctors could be held liable where they disregard good clinical judgement by following cost-containment guidelines when the outcome may adversely affect the patient.

Discussion

As in the UK and the USA, courts in Singapore have accepted clinical guidelines as evidence of the customary standards of care, but have not accorded them irrefutable status. In fact, the evidence shows that courts have on numerous occasions, subjected guidelines to careful scrutiny in order to establish their authenticity, relevance, and current status in terms of applicability and flexibility.[31,32] In Singapore, clinical guidelines have not usurped the role of the expert witness in helping the courts reach its determination of the legally required standard of care.

In Singapore, 2 legal tests stand out as relevant with respect to clinical guidelines. For a doctor to avoid liability, the Bolam test requires medical treatment in accordance with practice that is accepted as proper by a responsible body of medical opinion. Denning's test indicates that unless guidelines carry some special authority (e.g. those issued by the Ministry of Health or the Singapore Medical Council), guidance to clinicians requires to be proven through evidence-based research, disseminated, accepted and adopted before there is clear legal requirement upon doctors to follow it. Guidelines have also been increasingly featured in local coroners' inquiries. These have complemented testimonies from expert witnesses.

Currently, the law requires a doctor to practice what is considered acceptable by a responsible body of medical opinion, i.e. a common professional standard rather than a narrower standard of whether a practice can be shown to be scientifically effective. The importance the law usually attaches to customary practice means that atypical or bizarre guidelines are unlikely to be accepted by the courts as embodying the legally required standard of care. Furthermore, the Bolam test requires that the guideline in question should be followed and accepted by a significant number of doctors who must constitute a responsible body of opinion. The practice of evidence-based medicine (EBM) may significantly affect or lead to a change in the litigation decisions concerning clinical guidelines. EBM is the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients. The concept of EBM sits uneasily with the Bolam principle. A responsible minority body of medical opinion can theoretically satisfy the Bolam test. Under the concept of EBM, there is a marked trend towards the acceptance of majority research and clinical care based evidence and practices. This would seem to leave little room for minority clinical practice essentially founded on traditional practice, clinical precedent and experience, but not necessarily rigorous scientific evidence. In the Bolam sense, reasonable practice becomes best practice. It is therefore possible that there could be a judicial drift or even switch from the Bolam principle as the concept of EBM gains momentum. It is therefore important to appreciate that there is this tension between legal and professional care perspectives. Lohr[32] offers some criteria for good practice guidelines: "*The way guidelines are developed can strongly affect their potential for effective use by practitioners, patients and others. Development should be orderly and efficient. Guidelines should be based on the best available science, analysis of that science, and application of consensus panel when rigorous evidence is absent.*"

Finally, an issue to consider is the delay between the availability of strong scientific evidence and the subsequent dissemination of clinical guidelines which imply the expected standard of care. A case in point is the introduction of antenatal corticosteroids for the prevention of morbidity in premature infants.[33,34] Corticosteroids were first shown to be effective in reducing serious neonatal mortality and morbidity more than 20 years ago and the same findings were strengthened by at least

13 subsequent randomised trials. However, it was not until 1993 that the Royal College of Obstetrics and Gynaecology recommended to all obstetric units to consider the use of such therapy when the delivery of an infant is likely to be before 34 weeks gestation. The implication here is that even clinical guidelines may be slow to develop and keep pace with the current scientific evidence and professional bodies must therefore be responsive enough to develop guidelines that reflect current best practice. Guidelines must also be reviewed and updated regularly in view of the available evidence from scientific studies. The question of at which point in time during which a doctor may be held negligent for not managing a patient using treatment that has been proven through randomised trials and the eventual issue of clinical guidelines is as yet unresolved.

Conclusions

While there has been a profusion of published guidelines, the paucity of published data on the effectiveness of guidelines is worrisome. Routine planning for the evaluation of guidelines must be part of any guideline-development programme. The American Medical Association has already identified evaluation and revision as the last two steps of an eight-step strategy to incorporate practice parameters into quality assessment, assurance and improvement. To date, scientific evaluations have compared "guideline" with "no-guideline" or "usual care" groups. These are akin to early trials of thrombolysis used to test the efficacy of a drug in the treatment of acute myocardial infarction. After the relative benefit of this drug class over placebo has been proven, subsequent trials compared different thrombolytic agents and different routes of administration. Similarly, the next generation of guideline studies must compare different guidelines factors, e.g. varying development, incorporation and implementation strategies. With the proliferation of use of clinical guidelines and pathways in Singapore, there is an urgent need to evaluate the effectiveness of these treatment strategies and protocols in a scientific manner.

It is hard to draw any hard and fast conclusions about the practical legal aspects of clinical guidelines in Singapore as very little has been written or spoken on these issues. In the USA, where the judicial system is an adversarial one, legal guideline literature is much better developed, although far from conclusive. The fact that guidelines do have legal implications should not deter developers and users of guidelines. All things considered, doctors are probably better off having guidelines than not, as they are at the very least indicative of the care environment and of reflective clinical practice. The courts in Singapore, as in the UK and the USA, do recognise that doctors must act as reflective and autonomous practitioners.

Evidence has shown that guidelines can potentially reduce the number and costs of malpractice litigation.[35,36] Guidelines have the potential to reduce complaints and litigation and can improve record keeping and communication with patients. In addition, clinical pathways, when maximally utilised, can have a profound effect on the prevention of malpractice litigation—the value of the pathway in coordinating care, in ensuring good record-keeping, and clinical documentation, in promoting good communication among care givers and in facilitating communication with patients and their relatives concerning their care.

In 1993, the American Medical Association summed up the stand on clinical guidelines quite succinctly: "*Some physicians are concerned that practice guidelines or parameters will increase their exposure to malpractice liability. In particular, physicians are concerned that they may be automatically liable if they choose, for legitimate medical reasons, not to follow a practice parameter applicable to a patient's condition and an undesired outcome results. Such concerns are unfounded. Practice parameters do not create any new liabilities for physicians, and may in fact, serve to help physicians better control their existing liability risks.*"[37]

If competently constructed, taking into account the available scientific evidence, ethical and social-cultural values of the community and the economic impact of treatment, clinical guidelines can indeed exert a significant impact on medical practice. However, doctors must be careful to evaluate the usefulness of guidelines in their own practice settings. Doctors must remain alert to the wide variety of motives behind the introduction of guidelines, especially where guidelines interfere with the doctor's clinical responsibilities towards the patient. If doctors breach a duty of care towards their patients and an adverse outcome occurs as a result, then with or without guidelines, courts will continue to hold them accountable.

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