Clinical guidelines: proliferation and medicolegal significance

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Abstract

Guidelines seeking to influence and regulate clinical activity are currently gaining a new cultural ascendancy on both sides of the Atlantic. Statutory agencies may be charged with developing clinical guidelines, and civil courts, in deciding actions in negligence, could be influenced by standards of care expressed in guideline statements. Clinical guidelines are not accorded unchallengeable status: they have been subject to careful scrutiny by British and American courts to establish their authenticity and relevance. In the United States, compliance with clinical guidelines cannot be used as a defence against liability if a physician's conduct is held to have been negligent, and third party organisations can be held liable if their clinical guidelines are found to be a contributory cause of patient harm. Guidelines have not usurped the role of the expert witness in court. The importance the law attaches to customary practice means that atypical or bizarre guidelines are unlikely to be accepted as embodying a legally required standard of clinical care.

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Introduction

Guidelines are increasingly credited with pivotal significance in highly diverse areas of human conduct, and references to all sorts of statements have been accorded the status of "guidelines." In the Arms for Iraq Inquiry, Lord Justice Scott has heard much about whether the government did, or did not, breach its own guidelines in supporting the sale of arms; about who had the authority to make changes to such guidelines, and whether parliament was properly appraised of them. In the Netherlands an informal agreement allowing doctors intentionally to terminate the lives of their patients in accordance with guidelines has been approved by parliament. While intentional killing of another person remains a criminal offence doctors who perform euthanasia according to guidelines drawn up by the Royal Dutch Medical Association are unlikely to be prosecuted, and any doctors who are faced with prosecution can rely upon their adherence to the guidelines as providing an affirmative defence in law.

Clinical guidelines purporting to specify appropriate approaches to the management of numerous medical conditions have appeared in many guises and with increasing frequency over the past twenty years. A recent search of

Index Medicus shows that the annual rate at which the term "guideline" or "protocol" has featured in the titles or abstracts of scientific and medical articles has increased tenfold since 1974. Despite this remarkable ascendancy the development and implementation of guidelines in medicine remain controversial, and the extent to which doctors routinely use guidelines is largely unknown. Viewed by some as a threat to clinical autonomy, and a means of introducing strangers to the bedside,¹ guidelines and their possible legal implications continue to be a source of considerable medical anxiety.²⁻⁴

The *Oxford English Dictionary* defines "guideline" as an aid to manual activity, as in "guideline for a saw." The United States (US) Institute of Medicine captures the more metaphorical aspects of current medical usage in following the *Random House Dictionary's* definition of "guideline" as "a rope or cord that serves to guide one's steps . . . any guide or indication of a future course of action." In the Institute of Medicine's view, clinical guidelines are:

systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.⁵

Those developing, sponsoring, or disseminating guidelines are as diverse as are their motives. In the United Kingdom (UK) they include the Department of Health,⁶⁻⁸ the royal colleges,⁹⁻¹⁴ specialist medical associations,¹⁵⁻¹⁹ purchasing authorities,²⁰ district health authorities,²¹ hospital departments,²² general practitioners,²³ patients' organisations,²⁴⁻³¹ and consensus statements are issued by combinations of these groups.³²⁻³⁴ In the US, in addition to professional and specialist medical associations,³⁵⁻³⁷ guideline developers or sponsors have included health care providers³⁸; third party payers³⁹⁻⁴¹; peer review organisations⁴²; and agencies of, or responsible to, government.⁴³⁻⁴⁴ Professed aims have included:

- Improving health care quality¹²
- Decreasing unnecessary investigation, care, or referral⁴⁵⁻⁴⁶
- Decreasing undesirable variation in treatment³⁴
- Decreasing health care costs by use of review criteria³⁹⁻⁴⁰
- Promoting appropriate use of medical technology¹⁴
- Improving patient awareness of health care needs²⁴⁻²⁵
- Reducing the risks of legal liability in health care delivery⁴⁷

- Incorporating research findings into medical practice.⁴⁸

Clinical guidelines are the commonly chosen vehicle for such diverse purposes because they embody clinical norms judged by their authors to be worth achieving, and against which clinical performance can legitimately be measured. As statements of clinical recommendation, guidelines operate somewhere along a range of "assistance and advice" at one end to "regulation by imposition" of particular clinical practices at the other. Related terms – such as practice policy, protocol, performance measure, and medical review criteria – draw generically upon the notion of guideline and can best be understood as transformed versions of guideline statements for use in various contexts.

In the US, some 20 000 health care standards and clinical practice guidelines are reported to have been issued by over 500 organisations,⁴⁹ and the purchaser/provider split within the NHS can be expected to stimulate a similar proliferation in the UK. Methodological issues involved in guideline development are well reviewed in this issue by Grimshaw and Russell (p 45)⁵⁰ who outline how the results of rigorously conducted outcome trials, meta-analyses of scientific and clinical studies, and systematic literature reviews have all been used, in some measure, to underpin certain guideline recommendations.⁵¹ However, many clinical recommendations continue to be based on the subjective opinions of one or more authors or the consensus view of a group of experts.^{52 53} Clearly, numerous statements of clinical guidance continue to make claim to guideline status, merely by virtue of the term appearing in their titles, their authors taking little heed of the Institute of Medicine's requests that clinical recommendations need to be evidence-based and systematically and transparently developed if they are to be accorded the status of "guidelines."

Whatever their origin, the validity and effectiveness of most clinical guidelines remain untested. A recent study found only 59 reliable evaluations in the accessible world literature.⁵⁴ Given the prodigious level of intervention in the traditional practice of medicine which the profusion of guidelines represents, 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.

Authority of guidelines

Clinical guidelines are commonly couched in language which assumes a tone of authority, displaying a gradient of exhortation from mere option to explicit moral imperative: doctors "may," "should," or "must" follow the proffered advice.⁵⁵ In practice, a mismatch often exists between the moral authority claimed by a guideline and the empirical foundation on which it is actually based. In an attempt to supply users of guidelines with an explicit appreciation of the empirical basis of

its advice, the US Agency for Health Care Policy and Research (AHCPR) has adopted a system by which it grades each of its recommendations according to the strength of the evidence available to the guideline developers.⁵⁶

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The provenance or sponsorship of guidelines can appear sufficient in itself to confer authority.⁵⁷ Guidance from the General Medical Council (GMC), for example, connotes more than mere advice which can be heeded or not at a doctor's discretion, since the GMC is a statutory body which wields disciplinary powers.⁵⁸ Guidelines developed or adopted by prestigious medical organisations may gain wide influence by virtue of the imprimatur of approval which they carry as a result.⁵⁹ Subsequent sponsorship or administrative adoption of such guidelines may appear to confer further credence. Guidelines issued by third party payers who bear no direct clinical or administrative health care responsibilities but who insist on the use of guidelines as a precondition of cost reimbursement depend on a different kind of authority, which is largely economic.

Legal authority

Health care systems in the UK and US are converging in their adoption of guidelines as devices aimed at regulating medical practice. In the US, statute has played an important part in facilitating this development. Greater reliance on professional, self regulatory mechanisms in the UK means there is still a relative paucity of statute in this area, although the situation is beginning to change.

In the UK new Department of Health regulations governing payments to general practitioners spell out an "organised programme" of care for patients with asthma or diabetes.⁶⁰ These requirements, which are backed by a statutory instrument,⁶¹ amount to organisational guidelines for clinical care and indicate how elements from guidelines developed elsewhere can become incorporated into the incentive structure and formal requirements of the NHS.

Another indication of the changing situation in the UK is the GMC's recent decision to apply to parliament for new powers to investigate doctors' professional performance.⁶² The MP Alex Carlile QC, a member of the GMC, has observed:

The first aim of the reform should be to advise, cajole and persuade practitioners who perform badly to improve their standards, and, if necessary in the public interest, to restrict their practise.⁶³

It is envisaged that the new legislation will allow the GMC to discipline doctors who display clear evidence of serious shortcomings

of knowledge, skill, or attitude. In the past the GMC has clearly approved of clinical guidelines⁶⁴ and could, in future, turn to approved guidelines as embodying minimum standards of clinical performance; failure to comply with such guidelines might then be considered substandard care and hence subject to discipline.

In the US, legislation attempting to regulate medical practice by means of guidelines dates from the Peer Review Improvement Act 1982 which established Peer Review Organisations to ensure the quality and cost effectiveness of federally funded health care. These organisations are charged by Congress to develop criteria and norms by which to review all Medicare inpatient treatment programmes and to screen payment claims for evidence of poor quality of care. Their criteria have been criticised as insensitive, and an elaborate and expensive system of appeals has resulted in only a few providers being disqualified from reimbursement.

In 1989 Congress established by statute the AHCPR⁶⁵ to "enhance the quality, appropriateness, and effectiveness of health care services" This statute provides for the establishment of a unit within the AHCPR, the Forum for Quality and Effectiveness in Health Care, composed of physicians, nurses, and patients' representatives, whose brief is to commission clinical guidelines covering prevention, diagnosis, and clinical management of important medical conditions. Each guideline is required to outline specific standards of quality together with clinical performance measures. The forum does not itself develop guidelines (which are not intended to be federal creations) but arranges for their development, updating, and evaluation by contracting with public and private organisations, including professional and specialist medical associations.

Although guidelines so produced do not have the force of law, they have been produced as a result of legislation. Congress intended these guidelines to emerge from impressive medical expertise and professional and public consensus, in the hope that they would be quickly and extensively implemented.⁶⁶ It remains to be seen whether the process adopted succeeds in conferring sufficient objectivity and professional legitimacy on the guidelines to give them wide and effective influence.

Potential role of clinical guidelines in litigation

The common law system of tort, which includes actions for medical negligence, evolved from a desire for vengeance for wrongs suffered. By providing compensation to those wronged, tort law 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 and trespass to the person (battery), and exerts powerful regulatory influences on human conduct.⁶⁷ Under UK law* the standard of medical treatment a doctor owes to a patient was established in the case of *Bolam v 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.⁶⁸

This key test has been confirmed by subsequent legal decisions.^{69 70} Although the standard of care is imposed by law, its content is not determined by the courts but is "set by the medical profession . . . [and] is a totally medical proposition erected into a working rule of law."⁷¹ Doctors are required to act in a manner judged reasonable and proper by a body of other responsible doctors. In the *Bolam* case it was decided:

A doctor will not be guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.⁶⁸

Expert testimony helps the court 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.⁷² In the US in areas of practice where a nationally agreed standard of care does not exist, the courts have guarded against the danger of inappropriate testimony by means of a "locality rule."⁷³ This ensures that the appropriate standard of medical care cannot be evidenced by an expert who practises in a part of the country geographically distant from the defendant doctor, or by an expert from an entirely different terrain of practice. Although there is no equivalent rule in the UK, there seems scant legal basis for the anxiety expressed by some – namely, that clinical guidelines created by one group of practitioners for adoption and use by an entirely different group may prove not only inapplicable and clinically inappropriate but might also result in one group of doctors being judged in court by the inappropriate standards of care set by another.^{74 75} Judgement in the *Bolam* case referred to doctors "skilled in *that particular art*" [my emphasis], and these words have been taken in subsequent legal cases to indicate that the standard of care

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* UK law as used throughout is equivalent to law in England and Wales and Northern Ireland and Scotland.

required by law from one sort of practitioner could be different from that required from another.^{76 77} Lord Bridge reiterated this point

in 1985 in his House of Lords judgement in *Sidaway v Governors of Bethlem Royal Hospital*:

The language of the Bolam test clearly requires a different degree of skill from a specialist in his own field than from a general practitioner.⁷⁸

Documentary evidence to establish a standard in court

Written guidelines may be introduced to a UK court by an expert witness as evidence of accepted and customary standards of care. They cannot, however, be introduced as a *substitute* for expert testimony because, with no possibility of challenging such guidelines, the court would view them as hearsay only.⁷⁹ Legislation in some US states does allow a plaintiff to introduce a guideline document in order to establish the proper standard of care, *without* the invariable need for expert testimony.^{57 80 81} However, in conformity with the locality rule for expert testimony, US courts would be unlikely to admit guidelines which demand standards of medical care set by professionally or geographically distant practitioners.

The state legislature in Maine, US, has initiated a five year experimental project to establish statewide, legally validated clinical guidelines admissible in court, which aims at cutting the cost of malpractice premiums and retaining doctors in high risk disciplines within the state.⁸² The process adopted has been set in motion by statute⁸³ but designed by the Maine Medical Association with the approval of the AHCPR and four national medical and surgical associations. Under this legislation, once guidelines and protocols have been developed and adopted by the Maine Licensing and Registration Boards, a doctor may cite the fact of having followed the 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 temporarily becomes, by a process of judicial notice in court, the legally required standard of care. Because the current legislation only allows Maine guidelines to be cited in a doctor's defence, deviation from such a guideline cannot yet be used by a plaintiff as presumptive evidence of negligence by a doctor.⁸⁴ Arguably, the asymmetry between the exculpatory value of guidelines to a doctor, and their lack of inculpatory value to a patient, is unfair and violates the need for "due process and equal protection."⁸⁵ Because this law appears to confer immunity upon doctors who conform with guideline standards, and fails to increase the exposure of those doctors who choose to ignore the guidelines, the Maine legislation may be open to the charge of being unconstitutional.

Cases in tort featuring clinical guidelines

Courts in the UK acknowledge the importance of reasonable discretion in clinical decision making. The key issue which a court would need to consider in its acceptance of

written guidelines as evidence of the standard of medical care required in a particular case is whether 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 or that non-compliance would be negligent. As Lord President Clyde noted in the *Hunter v Hanley* case in 1955:

In the realm of diagnosis and treatment there is ample scope for genuine difference of opinion and one man is not negligent merely because his conclusion differs from that of other professional men.⁸⁶

A case of alleged brain damage from whooping cough vaccination illustrates this point. In the case of *Loveday v Renton and Wellcome Foundation Ltd* in 1990 the court held that failure to observe contraindication guidelines when administering whooping cough vaccination:

would not in itself constitute negligence because there was a respectable and responsible body of medical opinion that some contraindications should not be observed because the risk of disease outweighed any actual or possible risk from the vaccine.⁸⁷

Mere deviation from a guideline is unlikely to be accepted as evidence of negligence, unless the particular deviation was of a type which no doctor acting with ordinary skill and care would make.⁸⁶ The case of *Cranley v Medical Board of Western Australia*, 1990, involving alleged

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misconduct by an Australian general practitioner, further supports this conclusion. In prescribing injectable diazepam to heroin addicts, Dr Cranley deviated from guidance contained in the Australian *National Methadone Guidelines*; and in pursuing an explicit "harm reduction policy" which was not generally accepted by most drug addiction specialists in Australia at that time, the medical board ruled that he had not adhered to the "orthodox method of treatment," which restricted prescriptions to oral preparations, available at specialist units only. Dr Cranley was duly found guilty of "infamous and improper conduct." On appeal, the Supreme Court of Western Australia noted that there did indeed exist a minority medical opinion in Australia which was both respectable and reputable in support of treating opiate addicts within a harm reduction framework and found, moreover, that the *National Methadone Guidelines* could be understood as reflecting a general harm reduction policy.⁸⁸ Accordingly, the court upheld Dr

Cranley's appeal, finding nothing improper in his practices. In the absence, therefore, of professional consensus that medical practice *should only* conform to a single approach in a particular clinical situation, the fear that clinical guidelines could lead to undesirable uniformity or fossilisation of medical care lacks a legal basis. In the Cranley case, the supreme court reiterated the judgement in *Hunter v Hanley* that once it was established that a respectable minority view existed in support of a particular treatment approach, it was no task for any tribunal to attempt to determine the relative merits of different treatments.

With respect to withdrawal of treatment, the ruling by the House of Lords in the case of *Tony Bland* offers a clear instance in which a court found that written guidelines drawn up by a responsible body of opinion can protect clinicians from liability in the eyes of the law.⁸⁹ The guidelines in question were safeguards to be observed before discontinuing life support to patients in the persistent vegetative state, developed by the medical ethics committee of the BMA after wide ranging consultation, and published as a discussion paper⁹⁰ which took account of possible improvement in such patients in response to treatment.⁹¹ Lord Goff's judgement stated:

study of this document left me in no doubt that, if a doctor treating a PVS [persistent vegetative state] patient acts in accordance with the medical practice now being evolved by the Medical Ethics Committee of the BMA, he will be acting with the benefit of guidance from a responsible and competent body of professional opinion, as required by the Bolam test.⁹²

Lord Goff here accepted that in the clinical circumstances of *Tony Bland*, the BMA guidelines pass the Bolam test because they amount to "guidance from a responsible body of professional opinion," and since this is the standard of care required by law, compliance with the guidelines is compliance with the law. It is important to notice that the judgement contains an appreciation that the guidance was "being evolved," implying that the content of the required standard of care is likely to change over time.

Courts have occasionally found professionally accepted standards of practice deficient, particularly in the matter of how much information patients need to receive before they can validly express informed consent, or dissent, to a procedure.⁹³ In Australia this has led to the creation of guidelines on providing information to patients⁹⁴ and to calls for legislation to ensure that such guidelines are admissible in court actions relating to failure to disclose adequate information.⁹⁵

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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 require. However, it is not clear 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 forty years ago in the *Crawford v Board of Governors of Charing Cross Hospital* case:

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 because he does not at once put into operation the suggestion that some contributor or other might make in a medical journal The time may come in a particular case when a new recommendation may be so well proved and so well known, and so well accepted that it should be adopted, but that was not so in this case.⁹⁶

The four key elements of Denning's test are: proof, dissemination, acceptance, and adoption, each in combination with the notion of wide professional approval over time. The test developed here could be used by a UK court to decide whether a set of clinical guidelines should rightly be viewed as embodying the legally required standard of care.

Liability of guideline developers

In the UK the question of third party liability for guideline statements has not yet arisen in court, but it is quite possible that guideline developers could be held negligent if a patient suffered injury as a result of inadequate guidelines (G Burt, Medical Defence Union, personal communication). This question was considered in the US case of *Wickline v California* in 1986, when the court held that:

third party payers . . . can be held legally accountable when medically inappropriate decisions result from defects in the design or implementation of cost containment mechanisms.

The case concerned early discharge of a patient according to treatment guidelines which featured length of stay criteria approved for payment purposes. It was alleged that as a result of early discharge the patient later had to undergo an amputation. The court found that a physician could not claim, as a defence to negligence, that his own clinical judgement had been corrupted by clinical guidelines. Because the patient's physician had complied with the guideline without protest the third party guideline issuer should not be viewed as a proximate cause of injury, the court ruling that:

. . . a physician who complies without protest . . . when his medical judgement dictates otherwise, cannot avoid responsibility for his patient's care.⁹⁷

However, in a more recent case concerning a patient harmed by adherence to review criteria an appeal court found that a doctor's failure to protest against inappropriate review rules did *not* automatically protect the third party from liability. The case involved a depressed patient who committed suicide after early discharge from hospital as a result of a decision by Blue Cross to refuse payment for any further hospital care. The court found that the decision not to approve further hospitalisation "was a substantial factor in bringing about the decedent's demise."⁹⁸

Discussion

Courts in the UK and the US have accepted clinical guidelines as evidence of the customary standards of care but have not accorded them unchallengeable status. Even the most prestigious guidelines have not been treated as

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"holy writ." On the contrary, courts have subjected guideline statements to careful scrutiny in order to establish their authenticity, relevance, current status in terms of generally accepted use, and flexibility of application. With the possible exception of a few US state legislatures, such as Maine, clinical guidelines have not usurped the role of the expert witness in helping a court reach its determination of the legally required standard of care.

In the UK two legal tests stand out as relevant. For a doctor to avoid liability, the Bolam test requires medical treatment to accord with practice accepted as proper by a responsible body of medical opinion. Denning's test in the Crawford case indicates that unless guideline statements carry some special authority as may those issued by the GMC, guidance to clinicians requires to be proven, disseminated, accepted, and adopted, before there is a clear legal requirement upon doctors to follow it.

Contrary to a commonly held medical view, the legal relevance of guidelines may not rest on their scientific credibility. Some guideline developers may hope for an end to interpretative controversies in clinical medicine with the introduction of scientifically based guidelines. Yet it remains a persistent feature of the practice of medicine, in the Institute of Medicine's words, that:

For many clinical conditions and services, the scientific base is limited Where considerable research has been done and good methods have been applied to analyze it, honest clinicians may come to different conclusions using the same evidence.⁵

The common law acceptance of customary practice as the legal measure of the required

standard of medical care is therefore sensible and means that doctors' practices are properly judged by a common professional standard, rather than by the 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. Moreover, before a guideline could be acceptable as evidence of customary practice, the Bolam test requires not merely that the guideline in question should be followed by a significant number of doctors but also that such doctors constitute "a *responsible* body of medical opinion" [my emphasis].

In the US, where a market in health care has operated longer than in the UK, the use of clinical guidelines as mediatory and regulatory tools for shaping health care is highly developed.⁹⁹ US case law has held that compliance with guidelines cannot be used as a defence against liability if a physician's conduct is found to be negligent. It has also found that third party organisations which develop or issue clinical guidelines can be held liable if the guidelines are found to have been a contributory cause of patient harm.

Conclusion

The current economic and cultural climate of health care favours greater use of clinical guidelines of all sorts. Their ascendancy reflects, in part, a changing balance of power between professional stewardship of health care practices and increasing civil regulation. Guidelines do not represent a simple threat to clinical autonomy. Their pervasiveness rather reflects the increasingly complex and collaborative nature of medical practice.

If competently constructed as a result of efforts which take account of scientific evidence, ethical and social values, and the economic implications of treatment, clinical guidelines could exert a consensual influence on medical practice. However, guidelines may also represent factional health care interests. Therefore doctors must remain alert to the wide variety of motives behind the introduction of guidelines and to areas of practice where adherence to guidelines conflicts with their clinical responsibilities towards patients and with the standards of care the law requires. If doctors breach a duty of care towards their patients and injury occurs as a result, then *with* or *without* guidelines, courts in common law jurisdictions will continue to hold them accountable.

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