Clinical review

How does evidence based guidance influence determinations of medical negligence?

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"Any doctor not fulfilling the standards and quality of care in the appropriate treatment that are set out in these Clinical Guidelines, will have this taken into account if, for any reason, consideration of their performance in this clinical area is undertaken." Department of Health, 1999.[1]

Evidence based guidance arguably offers the most trustworthy advice available to clinicians concerning medical management. Their authoritative status may explain why clinical guidelines are sometimes prefaced with vague warnings that link guideline compliance with accountability. But how authoritative can guidelines actually be, and does evidence based guidance entirely supplant clinical discretion?

The legal status of evidence based guidance is examined, including whether guidelines from the National Institute for Clinical Excellence (NICE) should be understood to carry special importance in helping courts to decide whether or not allegations of negligence should be upheld.

Summary points

The trustworthiness of clinical guidelines depends on marshalling and interpreting best evidence, which is usually of variable quality and credibility

A tension exists between descriptive tests of medical negligence anchored in customary practice and normative tests, which focus instead on what ought to be done

In the United Kingdom, the Bolam test has not yet been superseded by one that compares an allegedly negligent practice with a medical standard fashioned without reference to a responsible body of practising medical practitioners

Evidence based standards will almost always be Bolam defensible, although some US courts have indicated that slavish compliance with evidence based guidance could be considered substandard, where patients are foreseeably harmed as a consequence

Guidelines do not actually set legal standards for clinical care, but they provide the courts with a benchmark by which to judge clinical conduct

What is evidence?

Evidence is a generic notion of great importance to many practices and enquiries. Cardinal to spying, journalism, historical and scientific research, and the practice of medicine, semantically the term bundles together two approaches to supporting belief, perception, and understanding. Whether evidence refers to marks or indications conspicuous to an observer, to reasoning and judgment about such indications, or to analysis of data arising from experiments, evidence leads on to and supports hypotheses and conclusions, however provisional and conditional.

Evidence—and the more recently minted compound term "evidence based"—refers to reliable observational, inferential, or experimental information forming part of the grounds for upholding or rejecting claims or beliefs. Evidence based medicine (EBM) has not developed a new concept of evidence[2]; its major contribution lies in the emphasis it places on a hierarchy of evidential reliability, in which conclusions related to evidence from controlled experiments are accorded greater credibility than conclusions grounded in other sorts of evidence. Since studies underpinning most medical practices are generally of very variable design and quality—experimental, controlled, blinded or unblinded, uncontrolled, observational, ecological, cross sectional, prospective, retrospective, qualitative, and others—recommendations synthesised from such studies are themselves very variably related to evidence.

Evidence based guidelines claim to be authoritative in the sense of embodying a combination of best evidence and judgment, designed to ensure that recommendations are valid and reliable. For guidance to be binding on clinicians it must be trustworthy.[3] But how trustworthy, clinically, can such guidance actually be? Take, for example, the 2003 UK evidence based guidelines for the management of asthma, which recommend intravenous infusion of 1.2 g of magnesium sulfate over 20 minutes for the treatment of severe life threatening asthma (level 1++ evidence and

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Box 1: Limitations of evidence based guidance that worry clinicians

"There is a fear that in the absence of evidence clearly applicable to the case in hand a clinician might be forced by guidelines to make use of evidence which is only doubtfully relevant, generated perhaps in a different grouping of patients in another country and some other time and using a similar but not identical treatment. This is … to use evidence in the manner of the fabled drunkard who searched under the street lamp for his door key because that is where the light was, even though he had dropped the key somewhere else."[8] (J Grimley Evans, professor of geriatric medicine, University of Oxford, 1995.)

"The 'correct' interpretation of clinical research rests largely on understanding the notion of validity. Although much effort—from both epidemiologists and editors—has been invested in the study of internal validity, comparatively little progress has been made in defining criteria for external validity (generalizability [sic]). The applicability of research data beyond the study population depends on clinical judgment, an inherently slippery art, but an art nonetheless."[9] (R Horton, editor of the *Lancet*, 1995.)

"The extent to which guidelines depend on opinion is disturbing for anyone who believes they should be evidence-based. Guidelines are evidence filtered through opinion. The opinion is crucial—but whose opinion should it be? The NICE committee is made up of a variety of experts in different disciplines who take specific advice from a small number of specialists in the relevant field. These specialists may or may not hold an opinion widely shared by their (equally expert) colleagues."[10] (J Hampton, professor of cardiology, University of Nottingham, 2003.)

grade A recommendation).[4] The *Drug and Therapeutics Bulletin* recently systematically reviewed the value of this treatment and concluded: "The current British Guideline on the Management of Asthma, published jointly by the British Thoracic Society and the Scottish Intercollegiate Guideline Network suggests that a single intravenous dose of magnesium sulphate [sic] should be used for the treatment of patients with acute severe asthma. However, the available data are weak and conflicting and do not justify this unlicensed use of the drug."[5]

Clinical guidelines constantly face challenges from dissenting authoritative reinterpretation of existing evidence and from new, relevant evidence that was unavailable at the time the recommendations were developed. In addition, however evidence based the process of development may be, a guideline may not easily be applied to a particular patient's care (box 1). Clinical guidelines should therefore be understood to command only a provisional title to be believed. Nevertheless, the General Medical Council has announced that doctors should "normally follow guidelines,"[6] and a leading UK barrister in health law has concluded that the effects of guidelines and evidence based medicine combined are that many areas of medicine and surgery, which attract the attention of civil litigators, are or will be governed by clinical guidelines. Increasingly, it will be possible to plead just one particular form of negligence: failing to follow guideline X.[7]

Box 2: What is negligence?

Medical negligence is a composite legal finding, comprising three essential elements. The person bringing the action, the complainant (formerly known as the plaintiff) must show that:

- Firstly, the defendant doctor owed the complainant a duty of care
- Secondly, the doctor breached this duty of care by failing to provide the required standard of medical care
- Thirdly, this failure actually caused the plaintiff harm, a harm that was both foreseeable and reasonably avoidable

Evidence based guidelines could influence the manner in which the courts establish the second element.

Medical negligence

The *Oxford English Dictionary* defines negligence as "a want of attention to what ought to be done or looked after," a failure to match up to required standards of performance (see box 2). Within the common law, a tension exists between descriptive tests of medical negligence, which gauge conduct under scrutiny against the standard of what is done in practice, and normative tests, which focus instead on what ought to be done. The former generally presume that customary professional practice embodies acceptable and legal standards, whereas the latter allow for standards to be determined by other criteria, such as those set forth in statements of good practice or evidence based guidelines.

Negligence is a normative legal doctrine (box 3). The US case of Helling *v* Carey (1974) (see box 4) and that reported by Merenstein (see box 5) show the courts trying to come to grips with whether customary and evidence based standards could be negligent. As far as medical treatment is concerned, courts clearly have the jurisdiction to set standards of clinical care (box 3), but they rarely exercise this power without reference to a test of customary practice.[11]

In the United Kingdom, the standard of care required successfully to defend a negligence claim derives from the case of Bolam *v* Friern Hospital Management Committee (1957): "The test is the standard of the ordinary skilled man exercising and professing to have that special skill."[16] Expert testimony helps

Box 3: Negligence (including medical negligence) is a normative doctrine

"What usually is done may be evidence of what ought to be done … but what ought to be done is set by a fixed standard of reasonable prudence, whether it is complied with or not." Texas & Pacific Railway (1903)[12]

"Courts in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission." Helling *v* Carey (1974)[13]

"It is not the law that if all or most of the medical practitioners in Sydney habitually fail to take an available precaution to avoid foreseeable risk of injury to the patients that none can be found guilty of negligence." Albrighton *v* Royal Alfred Hospital (1980)[14]

Box 4: Helling *v* Carey (1974)

In this much debated US case,[13] two ophthalmologists were successfully sued for failure to diagnose glaucoma before loss of vision in a woman aged 32 years. The doctors had examined the plaintiff frequently over the previous nine years for refraction and contact lens assessments. The court at first instance entered judgment for the defendant doctors after receiving uncontroverted testimony that "the standards of the profession for that speciality do not require a pressure test for glaucoma on patients under 40." The court relied entirely on expert testimony to establish customary practice, and no professionally developed guidelines from a recognised association of ophthalmologists were considered by the court.

The Supreme Court of the State of Washington reversed the lower court's decision, holding that: "Irrespective of the standards of the ophthalmology profession … as a matter of law … the reasonable standard that should have been followed … was the timely giving of this simple, harmless pressure test." The rationale for the court's decision included its view that people under 40 years of age were entitled to the same protection as the older age group who, because of the higher prevalence of glaucoma, were offered routine screening by tonometry. The decision was highly controversial at the time, since the number needed to detect one case of glaucoma in the younger age group was calculated to be 25 000, with follow up required for very large numbers of false positives. Very considerable costs were therefore incurred by substituting juridical for the medical customary standard of care. This decision, which does not seem to have set much of a legal precedent, nevertheless, illustrates how courts in common law jurisdictions can set the standards of medical care and screening.

courts decide what is accepted and proper practice in specific situations, ensuring (in theory) that professionally generated standards relating to actual clinical practice are applied by the courts, rather than standards derived from elsewhere, such as from guidelines.[17]

The judge in Bolam recognised that there could be two or more schools of thought regarding proper medical treatment, so doctors can usually rebut a charge of negligence if they have acted in accordance with practice approved by a body of other responsible doctors.[16] In Cranley *v* Medical Board of Western Australia (1990) an Australian general practitioner stood accused of misconduct because he had prescribed injectable diazepam to heroin users, contrary to the then recommendations of the Australian methadone guidelines. The initial court's finding of "infamous and improper conduct" was reversed by the Supreme Court of Western Australia, after it heard of a minority medical opinion that supported treatment of opiate users within a harm reduction framework as followed by Cranley.[18] In this case the court found that a practice outside nationally recognised guidelines was nevertheless acceptable and lawful.

Guidelines and the courts

Guidelines are introduced into courts by expert witnesses as evidence of accepted and customary standards of care, but cannot, as yet, be introduced as a substitute for expert testimony. In court they are treated as hearsay evidence: the mere fact that a guideline exists can neither establish its authority nor support the view that in the circumstances before a court compliance with the guideline would be reasonable and non-compliance negligent. Yet in the United States a study has shown that guidelines play a relevant or pivotal part in the proof of negligence in 6-7% of malpractice actions.[19]

A high proportion of guidelines fall short of meeting quality markers (see box 6), so it is important to prevent poor guidelines from influencing legal standards. However, this very possibility may eventuate because the courts do not generally call experts in guideline methodology to assist them in assessing the robustness and quality of clinical guidelines cited.[20]

If the presumption is that courts should consult clinical guidelines *because* they reflect customary standards of care, then the authority of newly developed guidelines that make recommendations departing from usual practice would be diminished,[22] as would guidelines motivated by cost cutting (see box 4). But if the presumption is that guidelines should be consulted by courts because they provide evidence of standards

Box 5: Daniel Merenstein

Daniel Merenstein[15] reports that while he was a resident on a training programme for family doctors in 1999, a 53 year old man consulted him for a routine health checkup. In the course of the consultation, Merenstein documented discussion of the importance of colon cancer screening, dental care, exercise, improved diet, sunscreen use, and prostate cancer screening. In conformity with the evidence based approach recommended by national clinical guidelines (including those of the American Academy of Family Physicians and the American Urological Association) for screening men over 50 years of age, he discussed the risks and benefits of prostate specific antigen (PSA) estimation, after which the patient elected not to have this measured. The patient later changed doctors and subsequently underwent PSA testing after no discussion of associated harms or benefits. His PSA concentration proved to be very high, the result of advanced prostate cancer (Gleason 8), and he subsequently brought an action against Merenstein and the residency training programme, alleging malpractice.

The nub of the patient's case was that he had been a victim of substandard care. His lawyers successfully argued that the standard of care to be expected when a man over 50 years consults a family doctor for a checkup in Virginia should include routine, PSA testing recommended by the doctor, rather than an offer of PSA estimation in the context of a shared decision making model, in which the patient makes an informed decision whether or not to undergo the test. Four doctors called as expert witnesses testified that, contrary to evidence based guidelines they themselves would not discuss the pros and cons of prostate cancer screening when consulting with men over 50 for health checks but would order a PSA test routinely. The jury seems to have accepted there were two schools of thought concerning responsible and proper practice in these circumstances as it exonerated Merenstein. However, it held the clinic where he worked liable in negligence.

justified in relation to evidence rather than custom, this would radically strengthen the normative dynamic of the law in actions alleging medical negligence. It would also introduce a test of culpable fault much harder for defendants to meet than that represented by the Bolam test (even when modified by Bolitho[23]). The effect would be to propel medical compliance with—possibly slavish obedience to—clinical guidelines.

At a time when only a tiny proportion of guidelines has been shown in rigorous trials to lead to better outcomes, such mass conversion by clinicians may not be desirable. Translating guideline standards into legal standards would tend to deny a role for judgment in using guidelines, which could lead to increased legal scrutiny of guidelines development procedures and their authorship processes.

Discussion

Evidence in medicine refers to information derived from observation, reasoning or experiment linked analytically to conclusions and beliefs. The term "evidence based" does not refer to a new notion of evidence or even to a new conception of its importance—the key contribution of evidence based medicine lies in its ranking of the credibility to be accorded to evidence depending on factors such as the likelihood of bias influencing data collection and interpretation.

Evidence based guidelines are standardised specifications of care that apply to the general condition and not necessarily to the particular clinical situation at hand; they therefore require extrapolation to an individual patient's circumstances. Guidelines are synthesised from many sources of information and may create a false sense of consensus, may mask or underplay controversy, and can rapidly become out of date as a result of new findings. Many guidelines face more or less well grounded degrees of dissent much of the time. Recognition of the role of clinical discretion in taking account of particular circumstances underpins the lack of an administrative or legal requirement that doctors should always follow authoritative guidelines.

Some degree of discretion lies at the heart of clinical judgment, which has to take account of competing influences on decision making such as the patient's choice, healthcare targets, costs, and incentives. But discretion requires to be exercised in accordance with the patient's best interests and within professional bounds. This will often, but not always, entail acting in accord with authoritative guidelines.

Box 6: Quality indicators of clinical guidelines published in peer reviewed journals 1988-98

Of 431 clinical guidelines published in English, listed in Medline, and produced by specialty societies between January 1988 and July 1998, 88% were found to give no information on the searches used to retrieve relevant published studies, 67% did not report any description of the type of stakeholders involved in guideline development or use, and 82% provided no explicit grading of the strength of recommendations.[21]

Although negligence is a normative doctrine (see boxes 3-5), in respect of medical treatment, descriptive legal tests for deciding what constitutes substandard care predominate. In the United Kingdom, the Bolam test has not been superseded by one that compares a treatment offered with a standard fashioned without reference to a responsible body of medical practitioners. Nevertheless, guidelines are highly influential in the way that doctors practise and the manner in which they are to be held accountable.

The creation of NICE, with its dual role of developing authoritative guidelines and of disseminating them through official NHS channels, means that its guidelines are likely to be credited with a distinctive authority medically and therefore legally.[24 25] The current situation has been encapsulated in this way: "Guidelines are no substitute for expert evidence about acceptable practice. Compliance with well recognised guidelines is likely to exculpate (exonerate). Deviation from well recognised guidelines may be Bolam defensible."[7]

Yet Merenstein regrets that "a physician can be put on trial for following national guidelines, the best evidence, the current research, and [can] then be found negligent for not following outdated and unsupported 'community' practices."[26] However, because of the logical gap between the generalities of guideline recommendations and the particularities of a patient's case, a good rule of thumb is that "following evidence based guidelines may generally but not always assure good medical care, and diverging from guidelines does not always signal poor care."[27]

Merenstein's experience has attracted further research and commentary, based on study of the judge's notes and interviews with three members of the jury of the case.[28] Although the clinic in which Merenstein worked had no written policy for conducting health checks in men over the age of 50, the particular patient concerned had had previous estimations of prostate specific antigen (PSA) undertaken at previous checkups in the same clinic. Both these considerations may have weighed with the Virginian jury, who found the clinic negligent for having operated a substandard system of health maintenance checks (perhaps because without a policy it could not sufficiently guard against PSA testing being entirely dependent on which doctor a patient happened to consult) and yet exonerated Merenstein.

Conclusion

As we have seen, it is not beyond the bounds of possibility that, in very particular circumstances, adherence to evidence based guidance associated with harm to patients could be deemed inappropriate and even negligent by the courts, but such cases remain rare and have generally not set legal precedents.

Evidence based guidelines set normative standards such that departure from them may require some explanation, but they do not constitute a *de facto* legal standard of care. They take the finder of fact (judge in the United Kingdom, jury in the United States) to a very definite starting place—namely to justified, advocated medical standards—from which to make an assessment of questionable conduct, and this represents quite a departure for the process of adjudication

hitherto adopted by the courts, which has relied almost exclusively on expert witnesses setting normative boundaries. Because *bona fide* guidelines carry a presumptive status that means clinicians should generally follow them and if not should take account of them, courts now have available to them the added information and wisdom that guidelines embody.

The bottom line so beloved of EBM readers is: guidelines do not actually set legal standards for clinical care but they do provide the courts with a benchmark by which to judge clinical conduct.

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Early lessons

When politicians wish to avoid answering a difficult question, the fact that the precise situation has not yet actually arisen is grasped as a legitimate excuse for avoiding a response. In clinical practice, however, this is often the very question that one should be prepared to answer.

I was taught this by my first surgical teacher in the late 1950s. Before then, it had seemed that my job as a junior surgical trainee was simply to make arrangements for my chief's decisions to be carried out. But my surgical teacher was different. He actually asked me what I thought should be done for almost every patient on the ward round. If ever it was a question of waiting for the result of an investigation, he would ask, "And what do you think we should do if it's negative?"

If he agreed with what I suggested, then we did it, provided the patient agreed, which they almost always did in those days. If not, he tested me and usually demolished my logic. It was a new experience, and ward rounds became more focused and valuable for me. It soon became a habit and self discipline, and for the first time I felt I was part of a team.

Not that he was "knife happy," a syndrome that we on the lower decks quickly learnt to recognise in some of our seniors. He was discriminating but clearly enjoyed a kind of aggressive defence in discussing clinical decision making. I recall that in discussions about a patient who had been undergoing seemingly endless investigations, he remarked, "The efforts made to avoid operating on this patient have been truly heroic."

In his view, it was the essence of clinical practice that, with reasonable reservations, one should have a defensible view about what should be advised for a patient in the light of the prevailing situation. Often decisions must be made without all the information one would like to have, and in this respect, as he was fond of pointing out, they are akin to many other decisions made in life, including proposals of marriage.

He also taught me was to avoid giving an opinion without having seen the patient. Often a letter or telephone description of a particular clinical situation was very different from the reality. A 90 year old patient with colonic cancer and heart failure might become a testing surgical challenge when found to be a sharp eyed and vigorous retired head teacher. Whenever he was asked about a specific patient in a hospital corridor consultation, he would usually say, "Well let's go and have a look now."

I remain grateful to him for teaching me so many of the fundamentals of good clinical practice. I only wish I could say that I always lived up to them.

David Crosby *retired surgeon, University Hospital of Wales*

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