

Law

# Do guidelines have legal implications?

J H Tingle

## Clinical guideline use is increasing

Clinical guidelines are becoming an increasingly common feature of the health care environment in the UK, with health organisations such as the National Institute of Clinical Excellence (NICE), Royal medical colleges, and the universities regularly developing clinical guidelines. The development rate of clinical guidelines has even been termed a “flood” in the area of general medical practice.<sup>1</sup>

Health quality enhancement activity by clinical guidelines has been given a clear boost by government calls for an end to unacceptable regional variations of care and the concept of evidence based care. Clinical guidelines also sit well with other government health care quality enhancement activities such as clinical governance and clinical risk management. The central argument that can be advanced is that, as a matter of sound common sense, if best, reflective, evidence based practice is put into effect, the incidence of untoward incidents must be reduced. Risks can also be more effectively managed and the quality of health improved. Littlejohn and Humphris argue that specific guidelines do improve clinical practice, when introduced in the context of rigorous evaluations.<sup>2</sup>

### THE HEALTH CARE ENVIRONMENT

It is important to remember that clinical guideline development is taking place in a much more health litigation orientated health care environment. More patients are suing than ever before.<sup>3</sup> The National Audit Office announced<sup>3</sup>:

The rate of new claims per thousand finished consultant episodes rose by 72% between 1990 and 1998. In 1999–2000 the NHS received some 10 000 new claims and cleared 9600. At the end of March 2000 there were an estimated 23 000 claims outstanding, with an estimated net present value of £2.6 billion (up from £1.3 billion in 1996–97). In addition, there is an estimated liability of a further £1.3 billion where negligent episodes are likely to have occurred but where claims have not yet been received.

Clinicians practice and develop clinical guidelines in this environment and it seems logical to suggest that they must be prepared to justify the clinical guidelines that they have developed and/or used in a court of law if necessary. A clinical guideline could form part of the evidence of a case and be disclosed.

Many of the main health law solicitor firms now employ nurses as part of their health litigation team. These firms have over the years become much bigger and more specialised. It is now therefore increasingly likely that any clinical guidelines, which were relevant in a case, would be looked at in a law firm by health carers, not just lawyers. Prepare your clinical guidelines on the basis that experts will review them.

### THE NEED FOR A BALANCED PERSPECTIVE

It is important to maintain a balanced perspective on the law relating to clinical guidelines. Lawyers should really have no part to play in the development of clinical guidelines, as they are not clinicians. Clinical guidelines are better reviewed by a hospital multidisciplinary committee, which would include the trust's clinical risk manager, who would be able to spot any possible legal issues, such as consent or capacity.

### DESIGNING CLINICAL GUIDELINES: THE BASIC LEGAL PREMISE

#### A new clinician testing test

The basic legal premise to work from in designing clinical guidelines is the “Bolam principle”, which would be applied in any dispute about the correctness or otherwise of a clinical guideline. Basically, a clinical guideline would be viewed as proper if it satisfied the Bolam test. Lord Browne-Wilkinson stated in *Bolitho v City and Hackney HA* [1998] Lloyd's Rep Med 26 the test:

The locus classicus of the test for the standard of care required of a doctor or any other person professing some skill or competence is the direction to the jury given by McNair J, in *Bolam v Friern Hospital Management Committee* [1957] 1WLR 583,587.

I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of men skilled in that particular art ... Putting it the other way round, 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.

There are many ways to treat patients and any court would look to experts in the medical or nursing professions to help them assess whether the clinical guideline used in the case was proper or not. The views of experts are however not definitive; they may show that a reasonable body of medical opinion may have designed and used a clinical guideline in a certain way, but the judge in the case will have the final say.

### The Bolitho gloss on Bolam

There is a new developing jurisprudence in this area, which is more testing of clinicians than previously was the case. The Lord Chief Justice, Lord Woolf, summed up this approach in a lecture at University College, London<sup>4</sup>:

Until recently the courts treated the medical profession with excessive deference, but recently the position has changed ... The over deferential approach is captured by the phrase “doctor knows best”. The contemporary approach is a much more critical approach. It could be said that doctor knows best if he acts reasonably and logically and gets his facts right.

This, approach can be termed the “Bolitho gloss on Bolam” and can be seen in some detail in *Bolitho v City and Hackney HA* [1998] Lloyd's Rep Med 26.

### LEGAL IMPLICATIONS

The Department of Health<sup>5</sup> has highlighted a number of legal considerations to take into account when developing clinical guidelines:

- (1) The objectives for the clinical guidelines need to be clear, and clearly stated. This will affect their subsequent legal standing
- (2) The intended use and applicability of clinical guidelines should be spelt out clearly, in the introduction
- (3) The guidelines must make clear for whom they are intended
- (4) Clinical guidelines that no longer reflect best practice might conceivably become actionable, and developers need to incorporate specific statements about their validity and review procedure

- (5) They should be constructed in such a way that allows deviation and does not suffocate initiative that might bring about further improvements
- (6) The development of clinical guidelines must involve all the relevant professionals and managers.

### Key legal points

#### Review date?

Point 4 is key, from a legal standpoint, as many guideline developers do not put review dates in guidelines.<sup>2</sup> How do you know that up to date good quality practices are being carried out if the clinical guideline is not being reviewed regularly? The medicine and science may change.

It is an important principle of law that doctors will be judged by the prevailing standards at the time when they carried out their treatment, not when the case comes to trial (*Roe v Minister of Health* [1954] 2 QB 66). Bearing this principle in mind, it is common for legal action, especially about neonatal practice, to occur some considerable time later. It can then be extremely difficult to identify the prevailing range of opinion about acceptable practice from perhaps 10 or more years previously. For this reason it is important that previous versions of clinical guidelines are dated, kept, and filed.

#### Validity?

Validity is also a key factor. Under the Bolam and Bolitho cases judges can be seen to be taking an evidence based approach to assessing expert evidence, which fits in well with government clinical governance and risk management initiatives. Where and what is the evidence used to support the guideline? This may be stated on the reverse of the guideline document.

#### Clinical guidelines do not suspend individual clinical autonomy

Point 5 is also crucial. Clinical guidelines are guidelines and not railway lines. They do not suspend the clinical autonomy of the clinician. A doctor could be negligent if a patient's condition contraindicated the application of the guideline but it was still applied nevertheless. Clinical guidelines do not represent cookbook medicine and many guidelines carry the warning that professional judgement is not suspended when they are used.

#### Failure to follow a clinical guideline does not connote negligence

If a particular clinical guideline would normally have been used in a treatment regime but was not applied in the instant

case, a reasonable explanation is called for. Variances should be analysed as Foster<sup>6</sup> argues:

Clinicians are worried about protocols because they think that failure to follow them will necessarily connote negligence. This is nonsense. The Bolam test does not cease to apply simply because a protocol has been drafted.

#### Develop a clinical guideline audit trail

Developers of clinical guidelines should also develop an audit trail of their development work and be able to say who was involved with the development work and the evidence used. Gosfield<sup>7</sup> states:

Finally, the documentation of the guideline is critical. Every aspect of the guideline's development should be documented. The procedures followed in developing the guidelines, the participants involved, the evidence used, the assumptions and rationales accepted, and the analytic methods employed should be meticulously documented and described.

#### Legal liability of those developing clinical guidelines

On balance, it is an open legal issue whether developers of bad clinical guidelines could be liable to injured patients; much will depend on the facts of the individual case. The courts could take the view that it is not in the public interest to impose a legal duty of care on Royal medical colleges or NICE in regard to their clinical guideline development activity. Conversely, they might take a different view. The Department of Health<sup>3</sup> comments on this point:

It would be difficult to establish that a duty of care is owed to the patient, by the college or professional body issuing the guidelines.

Stern<sup>8</sup> provides a useful and more detailed perspective:

It is possible that liability in negligence might be imposed upon those who publish clinical guidelines if it is found that the clinical guideline caused a particular medical procedure to be adopted and that this in turn caused harm to the patient. Liability would depend upon a finding that it was foreseeable that the guideline could have the effect of modifying the care which clinicians otherwise would provide. This in turn would depend upon factors such as the lapse of time between publication of the

guideline and the allegedly negligent event, the nature of the sanctions imposed for non-compliance or incentives to comply with the guideline, and the degree of specificity of the recommendation in the guideline. Further, the wider the circulation and potential recipients of a particular guideline the less likely it will be found that it was reasonable for clinicians to rely, without more, on the recommendations contained therein.

Clinical guidelines are very important health quality enhancement tools and they need to be viewed as such, as tools, to be picked up and put down as and when professional judgement dictates. Doctors should not be lulled into a sense of false security by having clinical guidelines; medical practice on autopilot should never take place—in the law's view, the professional autonomy of the practitioner always remains.

*Arch Dis Child* 2002;**86**:387–388

#### Author's affiliation

J H Tingle, Centre for Health Law, Nottingham Law School, The Nottingham Trent University, UK

Correspondence to: Mr J H Tingle, Director of the Centre for Health Law, Nottingham Law School, The Nottingham Trent University, NG1 4BU, UK

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