

Clinical practice guidelines and the law



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1. Clinical practice guidelines

Clinical practice has changed immeasurably since 1957 when John Bolam brought his claim against Friern Hospital (1). There is now a wide array of clinical guidelines, codes of practice and clinical protocols. These range from local to national and international guidelines. The medical profession has been cautious about accepting such guidelines, partly through fears that they threaten traditional clinical autonomy, and stifle innovation, so-called “cookbook medicine”.

In addition, several problems have emerged. First, the available guidelines have been of variable quality. Secondly, many clinical guidelines covering the same area have offered conflicting advice. Thirdly, many clinical guidelines did not consider cost-effectiveness. Finally, they were not always published in a readily accessible format.

However, with the advent of new statutory duties to improve the quality of clinical care, through “clinical governance”, underpinned by clinical audit and evidence-based medicine, there has been growing pressure to disseminate authoritative guidelines on a national basis.

For example, the Royal College of Surgeons of England has published guidelines on *Good Surgical Practice* (November 2000), which supplement the General Medical Council’s guidelines on *Good Medical Practice* (1998).

Since 1998 the Royal College of Obstetricians and Gynaecologists has published a series of eight evidence-based guidelines covering a wide range of common conditions, including infertility, menorrhagia, induction of labour and foetal monitoring.

In the wake of the Alder Hey Inquiry, the UK’s Chief Medical Officer published guidelines on *The Removal, Retention and Use of Human Organs and Tissue From Post-mortem Examination* (2001). More recently, the Department of Health has published updated guidelines on *Consent for Examination and Treatment* (2001).

Since March 2000, guidelines covering a wide range of clinical conditions have also been published by the National Institute for Clinical Excellence (2) (“NICE”). These include guidelines on the management of breast cancer, the use of hip prostheses, extraction of wisdom teeth and laparoscopic inguinal hernia repair. A list of useful sources of information is attached. (See Appendix 1)

2. The approach of the English courts to guidelines

The English courts do not uncritically accept guidelines as evidence of responsible or proper practice. Because the maker of a written guideline or protocol is not normally available to give oral testimony, and therefore be cross-examined, such evidence is classed as hearsay. Evidence of common or accepted practice will therefore normally be introduced through the evidence of an appropriate expert, who is entitled to adopt and comment upon relevant literature, including guidelines, as supporting or reinforcing his or her own opinion.

Cross-examination of the expert may extend to the scope of the guidelines, their development, whether they are mandatory or not, known exceptions to their application, and whether any responsible body of medical thought recommends a different approach.

In 1993 Professor Ian Kennedy commented that: *“the role of protocols and guidelines will become more and more important”*. His words remain apt, although in England, clinical practice guidelines do not yet constitute legally binding standards of care, nor have they replaced expert testimony. The approach taken by the courts can be illustrated by the following examples.

In *Loveday v Renton and the Wellcome Foundation* (3) (the pertussis vaccine litigation) Stuart-Smith LJ held that insofar as the claimant sought to rely on contra-indications relating to pertussis vaccine contained in guidelines issued by the DHSS' *Joint Committee on Vaccination and Immunisation* and by the manufacturers as evidence of experts not called as witnesses, the evidence was inadmissible in law (4). The makers of the opinions and the basis for their opinions were unknown, and the evidence could not be tested in cross-examination. Similar objections were made in relation to a series of case reports published in medical journals between 1933 and 1980, which the claimant also sought to rely upon, relating to neurological events after the administration of pertussis vaccine.

In *Cranley v The Medical Board of Western Australia* (5) the Supreme Court of Western Australia allowed a doctor's appeal against findings of misconduct in treating drug addicts under a “harm reduction” treatment policy which included prescription of less harmful drugs such as diazepam, dextropropoxyphene and flunitrazepam for self-administration, including by injection. The Board had criticized Dr Cranley for deviating from “mainstream practice”, as defined in the Australian National Methadone Guidelines, which envisaged the substitution of oral methadone for intravenous heroin.

The Supreme Court held that the Medical Board of Western Australia was wrong in failing to find that there was a reputable minority approving of that policy. It accepted the evidence of Dr Pols, a leading expert in the treatment of addiction, who gave evidence that in appropriate circumstances, parenteral diazepam for self-administration could be prescribed.

In *Early v Newham Health Authority* (6), the 13 year old claimant recovered consciousness while still paralysed from an unsuccessful attempt to intubate her in preparation for appendix surgery. She panicked and was in great distress until she had recovered all of her physical functions. The anaesthetic senior house officer had followed the health authority's written *“Failed Intubation Procedure”* correctly. The guidelines had been drawn up by the hospital's division of anaesthesia, which included eight consultant anaesthetists.

The claimant sued the health authority, claiming that the doctor was incompetent and negligent, and that the guidelines he followed were faulty and flawed. The claim failed. Applying a risk-benefit analysis, Deputy Judge Bennett QC concluded that the small risk of transient consciousness was far outweighed by the avoidance of the far greater risk of injury due to hypoxia. It could not be said that the guidelines were such that no reasonably competent authority would have adopted them.

In *Vernon v Bloomsbury Health Authority* (7) a 48 year-old female claimant suffering from life-threatening bacterial endocarditis developed bilateral and irreversible loss of vestibular function due to a complication of her antibiotic therapy, gentamicin ototoxicity. The claimant received a dosage of gentamicin and duration of treatment in excess of guidelines published, inter alia, in the *British National Formulary*, the *Monthly Index of Medical Specialities* and the manufacturer's data sheet.

Tucker J, accepting the evidence of the defendant's experts, and applying a robust risk-benefit analysis, held that the guidelines were too conservative, and erred on the side of caution. The dosage given and the duration of treatment had been justified in the treatment of a life-threatening condition.

In *Thomson v Blake-James & Others* (8) a GP who failed to adhere to Department of Health guidelines on measles vaccination was found to have been negligent at first instance. One month after birth the claimant had suffered from a suspected seizure, which was felt to be a simple breath-holding attack after in-patient paediatric assessment. The claimant's parents consulted their GP in 1982, when the claimant was five months old, as there had been some bad publicity at that time, particularly regarding the risks of pertussis vaccine. In the light of the history, which the GP reasonably believed was of a seizure, he advised against pertussis and measles vaccination, and recommended a homeopathic preparation.

The GP failed to advise the claimant's parents of the Chief Medical Officer's then guidelines that measles vaccination could be administered to a child with a history of seizures, using special precautions such as anti-convulsants or specific immunoglobulin. The claimant developed wild measles and suffered brain damage. Gage J held that the advice fell short of the standard of care, skill and competence to be expected of a reasonably competent GP, and that this was the cause of the parents' reluctance to have the claimant vaccinated, which was in turn the cause of the damage.

This decision was reversed on appeal. The Court of Appeal held that it was not foreseeable that the GP's failure to mention the alternatives published in the CMO's guidelines would be definitive or likely to be regarded as definitive. The omission could not be regarded as the cause of the parents' decision, when the claimant's mother had been fully aware of the possible alternatives, from later conversations with other GP's.

In *Kent v Griffiths, Roberts and the London Ambulance Service* (9), a pregnant asthmatic patient failed to establish that failure to follow guidelines on the management of asthma published by the *National Asthma Campaign* and in the *British Medical Journal* in 1990 in itself was negligent, since this would involve rejection of clinical judgment on the part of the treating general practitioners. Turner J concluded that:

"...No evidence was led in the case to suggest that the art of general practice had been reduced, in effect, to a "tick box" rubric. All the experts agreed that clinical judgment still had a relevant part to play, even in a case such as this, notwithstanding the existence of guidelines. Accordingly I am satisfied that it is not generally accepted in the profession that even if the BMA (sic) had established guidelines in any given area of medicine, there had to be rigid adherence to them to the exclusion of clinical judgment..."

3. Clinical practice guidelines and risk management

As early as 1994 a leading medical defence organization warned its doctor members that:

"If guidelines have been produced from a respected body and they have been accepted by a large part of the medical profession, a doctor will have to have a strong reason for not following the guidance."

However, the advice given by the BMA to its members in 1996 in "Guidance Notes For Clinical Guidelines" was couched more in terms of good risk management:

“Where clinical guidelines have been developed in a robust manner, which reflects wide consultation and best practice, then it is unlikely that a health professional who follows such guidelines would be held to be negligent for the outcome of the treatment or process used.”

Since the date of these publications the *National Institute for Clinical Excellence* has come into being. NICE guidelines are being disseminated throughout the NHS, and doctors working within the areas to which they apply will be expected to implement them. The *Commission for Health Improvement* (10) (“CHI”), has powers to monitor such guidelines, and to ensure that they are implemented and observed. Clearly such guidelines will be authoritative, and close to the top of any hierarchy of guidelines.

There is already a suggestion that NICE guidelines will form a new “*normative*” framework, providing evidence of the standard of care which doctors ought to conform to. Professor Sir Michael Rawlins, the Chairman of NICE, is reported to have stated that:

“NICE guidelines are likely to constitute a reasonable body of opinion for the purposes of litigationŠdoctors are advised to record their reasons for deviating from guidelinesŠA deviation may not be regarded as logically defensible...”

Thus whilst adherence to NICE guidelines may provide the evidence to sustain a *Bolam* defence, it may be increasingly difficult for a doctor to defend a deviation from NICE guidelines, as a court may refuse to regard the deviation as “logically defensible” (11). This suggests that whilst a claimant will still need to satisfy the burden of proof, a court is likely to draw adverse inferences when a patient suffers harm in the course of departure from guidelines, particularly where the reasons for the departure have not been recorded.

4. Conclusions

Clinical guidelines are now an inescapable part of life for all health care professionals. Increasingly, guidelines reflecting best practice and evidence-based medicine will be emanating from NICE, and will be policed by CHI. Equally important guidelines are being disseminated by the various royal colleges. Guidelines are likely to become increasingly important in the resolution of disputes, as doctors, lawyers, complaints managers and judges learn to rely upon them.

Although each case will turn on its own facts, health care professionals who adhere to guidelines with the authoritative stamp of bodies such as NICE are unlikely to be found guilty of negligence. Compliance with guidelines should also go some way to meeting the new statutory duties to improve the quality of health care. However, compliance with guidelines cannot be regarded as a complete shield to a clinical negligence claim.

It is submitted that authoritative guidelines should represent *minimum standards* of professional practice, particularly in the field of informed consent. Failure to adhere to guidelines cannot be relied upon in itself to establish breach of duty. It is an unreliable sword. However, those who do not adhere to guidelines will be more vulnerable to claims. Guidelines should also prove to be a useful cross-examination tool in such cases.

The search for relevant guidelines and protocols, through requests for disclosure and research, should therefore form a routine but important part of case preparation. In an era where funding through conditional fee agreements is becoming more widespread, this will also be an important element in the assessment of litigation risks.

It follows that medical experts must routinely be asked to consider the existence and relevance of guidelines and protocols in all clinical negligence cases. The attached checklist sets out some suggested questions to assist with the instruction of such experts. (See Appendix 2)

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(1) [1957] 2 All ER118

(2) A Special Health Authority created by powers made under the National Health Service Act 1977. The role of NICE is to provide health professionals in the NHS with the tools to enable them to give high-quality and cost-effective care to their patients.

(3) [1990] 1 Med LR 117

(4) Of course this would not prevent cross-examination on the contents of such documents.

(5) [1992] Med LR 94

(6) [1994] 5 Med LR 214

(7) [1995] 6 Med LR 301

(8) [1998] 5 Lloyd's Rep Med 187

(9) [1999] Medical Litigation Cases 0112

(10) Another new body, created by the Health Act 1999.

(11) See *Bolitho v City & Hackney Health Authority* [1997] 4 All ER 771

APPENDIX 1

USEFUL SOURCES OF INFORMATION AND DETAILS OF PUBLISHED GUIDELINES

1. Guidelines on informed consent

Department of Health Guidelines (April 2001). Available at: www.doh.gov.uk/consent

General Medical Council Guidelines (November 1998). Available at: www.gmc-uk.org/standard/consent.htm

See also "Good Surgical Practice"; Royal College of Surgeons (November 2000) www.rcseng.ac.uk

2. NICE

Available at: www.nice.org.uk

3. Royal College of Obstetricians & Gynaecologists

Available at: www.rcog.org

4. Department of Health Organ Retention Guidelines

Available at: www.doh.gov.uk/orgretentionadvice/index.htm

5. Royal College of Physicians

Stroke guidelines available at: www.rcplondon.ac.uk

6. Royal College of General Practitioners

Guidelines on back pain and type 2 diabetes mellitus available at: www.rcgp.org.uk

7. Cochrane Collaboration - evidence based medicine

APPENDIX 2

GUIDELINES: SUGGESTED QUESTIONS FOR EXPERTS

- How were the guidelines developed?
- When were they published?
- What is the scope of the guidelines?
- Are the guidelines authoritative (eg NICE, royal colleges, CMO/Department of Health)
- Are the guidelines mandatory, or are there permissible exceptions?
- Is there is a responsible/reasonable body of medical opinion which would advocate a different approach?
- Where a doctor has deviated from guidelines, have the reasons for this been recorded in the notes?
- Has the doctor considered the risks and benefits of this course of action, and discussed this with the patient?
- Is the deviation capable of withstanding “logical analysis”?