NICE head injury guidelines: review of the legal mandate

P Baines

This paper, while reviewing the legal authority held by clinical guidelines, examines the NICE head injury guidelines with respect to the likely consequences of non-compliance. Conversely, the effect on medical practice of rigid adherence to guidelines is also explored. Debate about the appropriateness of NICE head injury guidelines has highlighted the extent to which existing practices will need to change if compliance is to be achieved. Although a degree of resistance remains, there is perhaps a sense of resignation that the management of patients with head injuries will follow nationally prescribed guidance, whether in its current form or following its review next June. There will undoubtedly be those who remain unconvinced of the validity of these guidelines. Despite this, a possible reason for compliance may arise from concerns about the consequences of non-conformity. With the aid of a fictional scenario, this article seeks to remind the reader of the legal authority held by guidelines, the likely consequences of non-compliance and the liability held by their authors should compliance result in an untoward outcome. Finally, consideration is given to the possible long term effects that the adoption of guidelines may have on the medical profession.

GUIDELINES IN PERSPECTIVE

In order to address Dr Y’s concerns, it is useful to put into perspective the range of guidelines he is likely to encounter as a physician. Acknowledged by Plato as long ago as the third century BC, clinical guidelines may assume a wide variety of guises. Notwithstanding their diversity, it is still possible to categorise them into four broad groups (see box 1).

The first of these are the state originated legal documents such as statute. Also included in this group is case law which may influence the medical profession in one of two ways: firstly, through the rulings of individual cases it may determine the legality of a medical practice within a specific set of circumstances, and secondly through general recommendations made by senior judges, such as Lord Scarman’s comments in Gillick v West Norfolk. However, with its reinterpretation in succeeding cases the guidance originating from case law is often seen as transitory in nature.

The second category of guidelines are those issued by the government but which lack independent legal status. These include The Patient’s Charter and circulars issued by either the government or the National Health Service (NHS). Although such statements are open to interpretation by the judiciary, unless tested in court their contents remain broadly aspirational in nature.

Established as the direct result of a Statutory Instrument in February 1999 and amended in July 2002, the National Institute for Clinical Excellence (NICE) can be seen to carry statutory authority. The influence held by the guidelines it produces, however, is less clear. In the absence to date of any rulings conferring on them legal status, their current position probably lies either solely within this second category of guideline, or somewhere between it and the first.

The advice issued by professional bodies represents the third and probably largest source of practical direction to the

Box 1: Categorisation of the source of guidelines

- State originated guidelines
- Statute/statutory instruments
- Codes of practice
- Case law
- Guidelines issued by the government lacking independent legal status
- Circulars
  - The Patient’s Charter
- Professional guidelines
- General Medical Council
- British Medical Association
- Royal Colleges
- Defense unions
- Evidence based research—for example, Cochrane database
- Guidelines issued by an employer
- Contract law
Box 2: Arenas of legal accountability

- Public/criminal liability
  For example: Criminal prosecution by the State
- Private/civil liability
  For example: Private prosecutions using civil law
- Professional liability
  For example: Sanctions by General Medical Council
- Liability to the employer
  For example: Liability arising from contract law

As guidelines issued by different sources may conflict with one another, it is important to understand the hierarchy in which they stand. Usually bearing a direct relationship to the legal consequences of failing to comply, a guideline’s source is often suggestive of this authority. With this in mind it is helpful to remind ourselves of the different arenas in which an individual may be found to have legal accountability. In general terms legal accountability can be divided into four areas given in box 2. These areas are independent of one another, so practitioners may find themselves simultaneously liable to punishment from up to four different bodies. For example, a medical practitioner successfully prosecuted for assault, may simultaneously find him or herself liable to:

- a custodial sentence under criminal law
- pay a fine to the assaulted person following a civil action under the tort of trespass to the person
- professional disciplinary proceedings from the GMC
- disciplinary proceedings from his or her employer.

With similarities apparent between the four areas of legal accountability and the sources of clinical guidelines, the consequences of failing to comply with guidelines will now be explored.

THE BREACH OF GUIDELINES

Statute
While statutes carry the greatest of legal authority, where the consequences for non-compliance are not explicitly stipulated by an Act, then criminal or civil proceedings may follow only where there is an associated breach of criminal or civil law. If for example, there is breach of section 58(3) of the Mental Health Act 1983 due to the provision of non-urgent treatment without consent, no specific penalties are stipulated by the Act. However, action may still be taken against the doctor under either criminal law in battery using the Offences Against the Person Act 1861, or as a civil action to recover damages using the tort of trespass. Similarly, even if NICE guidelines were to carry statutory authority, because the consequences of non-compliance are not stated, proceedings may only follow where there has also been an associated breach of criminal or civil law.

The provision of legal precedents in case law rulings provides guidance to the courts and therefore to the medical profession. The consequence of non-compliance with such guidance may in the case of a negligence dispute result in the claim that a doctor has failed in his or her duty of care towards a patient—the relationship between guidelines and the law of negligence being explored in greater detail below.

Governmental guidance lacking legal authority
The legal authority carried by government and NHS circulars is open to interpretation by the courts. The case of *R v North Derbyshire Health Authority ex parte Fisher* highlights such an example, where a health authority was held not to be at liberty to ignore an NHS circular which described the prescribing policy of an expensive drug. However, until the courts decide to take such action and grant it the standing of a case law, most such documents carry only aspirational status, merely stating the aims and hopes of their authors. This reality is infrequently appreciated by the public, who often view such statements as rights which they can enforce. Similarly, *The Patient’s Charter* is not legally enforceable and may arguably serve to increase levels of litigation by unrealistically raising patients’ expectations.

Professional guidance
As the central governing body to the medical profession, the GMC carries both regulatory and disciplinary powers, which ultimately includes the sanction of removing a doctor from the medical register. Guidance issued by the Council tends not to be narrow or prescriptive, instead covering broader ethical and legal issues and allowing practitioners a degree of flexibility in their interpretation.

Guidance from employers
The breach of directions given by an employer may constitute a violation of the contractual terms of employment. If therefore, a hospital trust directs its employees to follow particular guidelines, a failure to do so may instigate internal disciplinary procedures with a sanction of dismissal ultimately available.

GUIDELINES AND THE LAW OF NEGLIGENCE

Returning to the relationship between clinical guidelines and the law of negligence, for a claim to be successful three elements must be satisfied. The first of these is a duty of care and is met merely through attendance at an emergency department. The second is for a breach of that duty to be demonstrated; and thirdly for a causal link to be demonstrated between the breach of duty and actual harm to the patient. For all its shortcomings, NICE has managed to produce a highly sensitive tool for the identification of intracranial injury. Causation may therefore be difficult to disprove where deviation from guidelines results in the delayed diagnosis of a potentially treatable head injury.

With the crux of a negligence case lying therefore in the element of breach, the law requires for the standard of medical care to be reasonable within the individual circumstances of a case. Derived from the case of *Bolam v Friern Hospital Management Committee* (1957), the Bolam standard has for almost half a century formed the basis on which the breach of a duty of care is based. Judged to be that of “the ordinary skilled man exercising and professing to have that special skill”, the test allows each case to be judged on its individual merits, permitting differences in medical opinion.
rather than a rigid adherence to narrowly prescribed practices.

Differences of medical opinion are readily acknowledged and have even been encouraged by the judiciary, who are reluctant to determine which methods of treatment are to be preferred, as Lord Clyde comments in Hunter v Hanley 1956: 

"deviation is not necessarily evidence of negligence. Indeed it would be disastrous if this were so, for all inducement to progress in medical science would then be destroyed. Even a substantial deviation from normal practice may be warranted by the particular circumstances."

The significance held by clinical guidelines is that in advising doctors to practise in one particular manner rather than another, they may be used as a standard against which the practice of other doctors can be judged. The courts have had a dynamic relationship with guidelines over the years, calling for their development and implementation, respecting the direction they provide, overruling high profile ones, and determining the reasonableness of adhering to or deviating from, certain guidelines under specific circumstances. There has been reluctance by the courts, however, to suggest that compliance with a guideline necessarily constitutes reasonable care; or indeed that non-compliance may amount to negligence. Although guidelines may be used in a UK court, there must be the opportunity for them to be subject to a form of cross examination. This is only possible where they are supported by the testimony of an expert when they are unpersuaded of their logical argument, and determining the relevance of expert advice. It would therefore be difficult to envisage the source of guidelines with sufficient authority to be acted upon blindly, and would certainly exceed the seniority of those issued by a department.

The unwillingness of the judiciary to transfer the liability of a negligent act from one party to another is supported by Newick's comments that

"it would be exceptional for the failure of a doctor to administer proper care to be made the responsibility of those who promoted the guideline."

Despite this, in the instance of a doctor following hospital guidelines as in the example of Dr Y, the vicarious liability of the hospital for its employees would in all probability protect the individual from legal action.

**SUMMARY AND THE FUTURE**

Despite the fact that NICE carries statutory authority, the guidelines it produces currently falls short of this status. Even if statutory authority were to be granted to NICE guidelines, it should be remembered that at present no stipulations exist as to the consequences of non-compliance. Therefore, Dr Y would only be subject to criminal or civil proceedings if there had also been an associated breach of criminal or civil law. Although there are no grounds on which criminal proceedings may be instigated, the possibility remains for a civil action in negligence to follow. With the success of the latter heavily dependent on the demonstration of a breach in the duty of care, at present, deviation from guidelines is not in itself _prima facie_ evidence of this.

With an expectation upon doctors to interpret and act independently of guidance, Dr Y should probably be wary that it is the doctor rather than the authors of guidelines who increase their liability in negligence should fault successfully be demonstrated. Dr Y would also be wise to seek clarification from his employer as to the status of local guidelines, ensuring conflict does not arise between commitments to his contract of employment and his own working practices.

The consequence to a medical profession which does not deviate from prescribed guidance may be far reaching. Although already curtailed by Bolitho, compliance with guidelines due to a fear of litigation may eventually remove the Bolam defence entirely due to a lack of variation in practice. The fear of litigation, ironically, becoming a self-fulfilling prophecy.

Arguably of much greater importance than the circumstances of this case, are echoes of the concerns held by Plato more than 2000 years ago: that once the medical profession has dedicated itself to the provision of health care through guidelines, it is committed to continue observing them. For once expertise resides within guidelines rather than the clinician, deviation from such guidance can no longer be justified on the basis of clinical judgement.10
Competing interests: none declared

REFERENCES
2 Gillick v West Norfolk and Wisbech Area Health Authority and Department of Health and Social Security [1986] 1 AC 112.
3 R v North Derbyshire Health Authority ex parte Fisher [1997] 2 Med LR 327
4 Barnett v Chelsea and Kensington Hospital Management Committee [1969] 1 QB 428: Held that a hospital authority which provides a casualty department, owes a duty of care towards persons presenting themselves there complaining of illness.
5 McNair LJ, Bolam v Friern Hospital Management Committee. 2 All ER 1957 118-28 at 122.
6 Hunter v Hanley 1955 SLT 213 1 Div, Clyde LJ, at 217.
9 Re W (a minor), 3 WLR, 1992:758–82.
12 Loveday v Renton (No 2) [1992] 3 All ER 184.
15 Caparo Industries Plc v Dickman [1990] 1 All ER 568–608 at 589.
NICE head injury guidelines: review of the legal mandate

P Baines

doi: 10.1136/emj.2004.019315

Updated information and services can be found at: [http://emj.bmj.com/content/22/10/706](http://emj.bmj.com/content/22/10/706)

These include:

**Email alerting service**
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

**Topic Collections**
Articles on similar topics can be found in the following collections
- Trauma (1047)
- Trauma CNS / PNS (298)
- Guidelines (43)

Notes

To request permissions go to: [http://group.bmj.com/group/rights-licensing/permissions](http://group.bmj.com/group/rights-licensing/permissions)

To order reprints go to: [http://journals.bmj.com/cgi/reprintform](http://journals.bmj.com/cgi/reprintform)

To subscribe to BMJ go to: [http://group.bmj.com/subscribe/](http://group.bmj.com/subscribe/)