

ORIGINAL ARTICLE

NICE head injury guidelines: review of the legal mandate

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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.

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Patient X, an 18 year old male is assaulted as he leaves a pub at closing time. He presents to accident and emergency (A&E) two hours later with his Glasgow Coma Scale (GCS) score still reduced at 14. The only other positive finding is a parietal scalp haematoma. Dr Y suspects that the disorientation is due to alcohol intoxication. A skull x ray is taken which does not reveal any abnormality. By now a further hour has passed and the GCS score of patient X is now 15. In accordance with local departmental policy, Dr Y allows X to go home with his mother after issuing instructions regarding head injury. The following morning X is brought back to A&E with a GCS score of 5. A computed tomography (CT) scan is performed immediately revealing an extensive subdural haematoma. Despite surgical intervention patient X makes a poor recovery and will never work.

If NICE guidelines had been followed patient X would have had a CT scan taken during his initial attendance to A&E. With the likelihood that this would have improved X's outcome, Dr Y is concerned about the potential legal repercussions of his decision not to follow NICE guidelines.

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,¹ and secondly through general recommendations made by senior judges, such as Lord Scarman's comments in *Gillick v West Norfolk*.² 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

medical practitioner and includes bodies such as the General Medical Council (GMC), the British Medical Association, Royal Colleges and medical defence organisations. Additionally, the Cochrane Database forms a source of less prescriptive professional guidance, in providing doctors with research based evidence from which they can inform their own practice.

The fourth and final source of guidance is that issued by an employer, which most frequently manifests in the form of 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.³ However, until the courts decide to take such action and grant it the standing of 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.⁴ 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",⁵ 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* 1955⁶:

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,⁷ respecting the direction they provide,⁸ overruling high profile ones,⁹ and determining the reasonableness of adhering to or deviating from, certain guidelines under specific circumstances.¹⁰ 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 witness deemed to have practical clinical experience of the area they deem to cover. Without such representation guidelines lack any legal authority, and are likely to be viewed by the court as hearsay.¹¹

In attempting to demonstrate a negligent breach of duty, not only must deviation from standard practices be demonstrated, but it must also be shown that the course of treatment adopted by a doctor is one which "no professional man of ordinary skill would have taken if he had been acting with ordinary care".⁶ This is exemplified in the case of *Loveday v Renton and Wellcome Foundation*,¹² where a failure to follow guidelines regarding the administration of a vaccine did not in itself constitute negligence, as another responsible body of practitioners could be found to support such a practice. An exception to this defence, however, lies where deviation from recommended practice can be shown to be "obvious folly".¹³

In 1993 the *Bolam* case was reinterpreted by the House of Lords in the case of *Bolitho v City & Hackney Health Authority*. In rejecting the proposition that courts must accept the views of experts when they are unpersuaded of their logical argument, the courts rather than the medical profession were empowered to ultimately determine the constitution of reasonable care. Despite being qualified to apply only to rare cases,¹⁴ the ruling has the potential to significantly strengthen the importance of clinical guidelines, with the possibility of defendants and expert witnesses having to justify to the court significant deviations from standard practice.

Dr Y's departure therefore from NICE head injury guidelines is unlikely to automatically lead to a successful prosecution in negligence. A breach of duty should be defensible using the *Bolam* standard. This should be possible so long as another responsible body of doctors can be found with practices similar to Dr Y's and their actions are not held to constitute obvious folly. Subsequent to the decision in *Bolitho*, however, Dr Y may be required to justify his deviation to the court.

THE LIABILITY OF AUTHORS

With the liability in negligence less substantial than might have been feared, it might therefore seem tempting to

clinicians who disagree with the NICE guidelines to write guidelines for their own department. Before doing so, the clinician should be aware of the extent to which liability lies with the author of a guideline in the event of strict adherence resulting in an untoward outcome. The case of *Caparo Industries plc v Dickman and others* provided an explanation of the relationship between an advisor and advisee, with Lord Oliver stating that a duty only exists where the advice communicated is likely to be acted upon without further independent inquiry.¹⁵ With *Vernon v Bloomsbury Health Authority*¹⁶ demonstrating that even the recommendations of a highly respected medical reference book should not be translated automatically into clinical practice, the courts place an expectation on doctors to act as intermediaries in 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 Newdick's¹⁷ 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.¹⁸

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