# MEDICINE AND THE LAW

# The role of clinical guidelines in medical negligence litigation: has India made the shift?

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#### Abstract

India has been following English law for certain principles that are well developed in common law. On the issue of medical negligence, India had adopted the principle laid down in the Bolam case which held that a doctor is not negligent if what he has done would be endorsed by a responsible body of medical opinion in the relevant specialty at the material time. This was followed until 2001 when the first reference was made to the Bolitho test.

In time, the Bolam test evolved in the English courts and was made stricter by the Bolitho case. But the Indian courts still follow the Bolam test. Hence this paper will analyse whether India needs to adopt the new test to satisfy the requirements of stricter medical negligence laws and meet the needs of increasing negligence litigation.

#### Introduction

In medical negligence litigation, a key step is for the claimant to prove that the physician failed to meet the required standard of care. The traditional test in law in such cases remains the Bolam test which states that a doctor is not negligent if what he has done would be endorsed by a responsible body of medical opinion in the relevant specialty at the material time (1).

Some commentators believe that this standard was set by the medical profession and evidenced by expert testimony, with minimal court scrutiny, and suggest that stricter evaluation of such opinion would be welcome (2). However, Indian courts have conformed to the test laid down in the Bolam case and have adhered to the same in all medical negligence litigation.

The position in the English courts has now changed. The decision in Bolitho suggests that the court should adopt a more interventionist stance in assessing expert evidence and in setting the standard of care (3). One such approach towards a more objective measure in determining the legal standard of care could be through the use of clinical guidelines. What the court basically meant by suggesting this is that instead of relying on testimony, there should be certain guidelines that the government should adhere to while considering a case of medical negligence, and the guidelines should contain the procedure and conditions for the consideration of the court.

Guidelines are consensus statements developed to assist clinicians in making decisions about treatment for specific

conditions (4). They are systematically developed on the basis of evidence and aim to promote effectiveness and efficiency of healthcare delivery.

The Bolam test has been followed for a long time in India, the principle being used and applied in cases like Suresh Gupta (5, 6). But the question that still remains is whether there has been a shift from this principle to the principle that has evolved in common law and is substantiated in the Bolitho case.

#### The doctrinal shift

The House of Lords ruling in Bolitho signalled a shift away from Bolam (6). It was no longer enough for the standard of care proclaimed by a defendant doctor to be endorsed by a responsible body of peers. In minority judgment comments in Bolitho, it was emphasised that the word "responsible" in the traditional formulation of the Bolam test meant that responsible practice is that which withstands the scrutiny of "logical analysis" from a judicial perspective (7).

The clinical practice, however prevalent within the medical profession, would perhaps be unlikely to withstand logical scrutiny if that practice is contrary to a clear consensus emerging from the evidence base. In his opinion delivered in the Bolitho case, Lord Browne-Wilkinson indicated that experts should direct their minds to the question of comparative risks and benefits in order to reach a defensible conclusion on the matter in question. A clinical conclusion which does not have risk analysis at its heart is not likely to be deemed a responsible conclusion.

Bolitho has called attention to this issue and will therefore take effect not only in determining the logical basis of the course of action offered by the defendant, but also by engaging more forcefully in assessing risk analysis (8). Properly considered clinical guidelines will similarly weigh the risks and benefits. This consonance with doctrinal changes may be a further factor for evidence-based guidelines to play a greater part in medical litigation proceedings.

## **Bolitho in India**

The Bolitho test has been mentioned in the Indian Supreme Court on only two occasions. It was stated in Samira Kohli v Prabha, where the court clearly pointed out that "A beginning has been made in Bolitho v City and Hackney and Pearce v United Bristol Healthcare. We have however, consciously preferred the 'real consent' concept evolved in Bolam." (6, 9)

Similar was the case in Binitha v Lakshmi Hospital where the court did not look into the test at all (10).

### Why Bolitho should be adopted

Unfortunately, medical negligence occurs every day in Indian hospitals and there are believed to be almost a million such occurrences every year. Around one in 10 patients are believed to suffer further as a result of their treatment in hospital and a proportion of these people will go on to claim personal injury compensation through a medical negligence claim (11).

The Bolitho test makes it possible to get quick relief as it increases the burden on the medical practitioner and thus leaves more scope for compensation. Unlike the Bolam test, the Bolitho test says that the court should not accept a defence argument as being "reasonable", "respectable" or "responsible" without first assessing whether such opinion is susceptible to logical analysis (12). However, where there is a body of medical opinion which represents itself as "reasonable", "respectable" or "responsible" it will be rare for the court to be able to hold such opinion to be other than represented. The Bolitho ruling means that testimony for the medical professional who is alleged to have carried out the medical negligence can be found to be

unreasonable, although this will only happen in a very small number of cases.

Looking at the increasing amount of litigation for medical negligence in consumer forums in India, it is high time that the Indian courts adopt the same model and implement it in the larger interests of the public.

#### References

- Bolam v. Friern Hospital Management Committee (1957) 1 WLR 582. [Internet]. [cited 2009 June 9]. Available from: http://www.kevinboone. com/lawglos\_BolamVFriernHospitalManagementCommittee1957.html
- 2. Teff H. The standard of care in medical negligence—moving on from Bolam? Oxford Journal of Legal Studies. 1998;18 (2): 473-84.
- 3. Bolitho v. City and Hackney Health Authority (1997) 4 All ER 771. [Internet]. [cited 2009 June 9]. Available from: http://www.publications.parliament.uk/pa/ld199798/ldjudgmt/jd971113/boli01.htm
- Department of Health. UK. The new NHS, modern, dependable. London: HMSO; 1997.
- 5. Suresh Gupta (Dr) v. Govt. of NCT of Delhi (2004) 6 SCC 422.
- 6. Samira Kohli v. Dr Prabha Manchanda (2008) 2 SCC 1.
- 7. Brazier M, Miola J. Bye-Bye Bolam: a medical litigation revolution? *Med Law Rev*. 2000;8(1): 85-114.
- 8. Foster C. Bolam: consolidation and clarification. *Health Care Risk Report*. 1998 Apr; 4(5):5.
- Samanta A, Samanta J. Legal standard of care: a shift from the traditional Bolam test. Clin Med. 2003 Sept-Oct; 3(5): 443-6.
- 10. Binitha v Lakshmi Hospital (2001) 8 SCC 731.
- 11. Maiti R, M R. Clinical trials in India. *Pharmacol Res*. 2007 Jul; 56(1): 1-10. Epub 2007 Feb 20.
- 12. Indian Medical Association v. V P Shantha (1995) 6 SCC 651.

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