

Patient safety and medical innovation

House of Commons Adjournment Debate
Tuesday 9 December 2014

The British Medical Association (BMA) is an apolitical professional association and independent trade union, representing doctors and medical students from all branches of medicine across the UK and supporting them to deliver the highest standards of patient care. We have a membership of over 153,000, which continues to grow each year.

Introduction

This briefing outlines the BMA's views on innovation ahead of the adjournment debate in the House of Commons on patient safety and medical innovation.

Medical Innovation Bill

The BMA has previously briefed peers on the issue of medical innovation ahead of committee stage of the Medical Innovation Bill. We believe that the Medical Innovation Bill is unnecessary and if there is a need for additional support for doctors, this should be done through professional guidance capable of responding to changing circumstances, rather than rigid statute. As such, we have suggested that the Medical Innovation Bill be withdrawn and consideration given to identifying other means of supporting medical innovation. This could be explored by an independent body, such as the Lords science and technology committee.

Existing law

Innovation – the identification of new treatments and the development of new procedures - is at the heart of what it means to be a doctor. We believe that the best mechanism to advance medical science is through well-regulated research and clinical trials. However, it can still be necessary for doctors to explore non-standard treatments with their patients and innovate outside of a research context. Interventions may not always be suitable for full scale clinical trials and not all patients will meet the criteria for enrolment in clinical trials for a new drug or procedure. If there is sufficient justification to believe an untested or unlicensed treatment could be beneficial, doctors should be confident in pursuing these with patients where clinically indicated and in their best interests. The current law allows doctors to innovate and successfully defend a claim of negligence provided they can show their actions were supported by a reasonable body of medical opinion (the 'Bolam Test'¹) and are logical (The Bolitho Test²). Doctors should act in the patient's best interests, follow General Medical Council (GMC) guidance, particularly on consent, and document their actions fully. This provides adequate protection to doctors and patients.



The threat of litigation as a barrier to innovation

The BMA is aware of arguments that the threat of litigation acts as a barrier to innovation. However, the BMA is not aware of evidence that the threat of litigation prevents doctors from innovating or that there is confusion or a lack of clarity in the current law. Other bodies that also had no evidence of this include: the Medical Defence Union³, the National Institute for Clinical Excellence⁴ and the medical Royal Colleges⁵ alongside notable individuals such as Sir Robert Francis QC⁶.

No concrete examples of proposals for beneficial treatment being prevented by the threat of litigation have been provided. If it were the case that the possibility of litigation deterred some doctors from deviating from standard practice, it does not follow that the law is at fault or that all claims to pursue non-standard treatment are equally justified. The law as it stands may, quite rightly, deter doctors from pursuing treatment that would harm their patient without sufficient probability of benefit and would not have the backing of other doctors.

Similarly, it may be the case that some doctors are unclear about how the relevant case law applies to their practice. Again, it does not necessarily follow that the law itself is unclear or needs to be changed. A more appropriate solution would be to provide information and guidance for doctors to improve their understanding and to encourage them to innovate responsibly within the law as it stands.

The BMA would therefore strongly question the necessity and desirability of introducing statute to clarify or change the law in this area. We are also unconvinced that uncertainty exists over the circumstances in which a doctor can safely innovate without fear of litigation.

Current avenues for innovation outside a research pathway

Where it is necessary to pursue innovative treatments and it is not practical to follow a research pathway, doctors are already required to:

- Act in the best interests of their patient
- Follow the detailed guidance from the GMC, particularly on consent
- Maintain good communication throughout the process
- Document actions fully.

It is clear that treatment which is outside of standard practice can be provided in these circumstances and doctors are prepared to explore these options with their patients under the law as it stands. The Bolam⁷ and Bolitho⁸ cases require a doctor to show that their decision has logically based support from a responsible body of medical opinion to successfully defend a claim of negligence – taking into account an objective assessment of what is reasonable in all facts and circumstances.⁹ The BMA has no evidence to suggest that this legal test represents a barrier to innovation. Recent case law has shown that the courts have not held a decision to provide innovative therapy to be negligent provided the doctors have weighed up the available options and the decision could be reasonably and rationally supported.¹⁰ The *Simms vs Simms*¹¹ judgment showed that even risky, innovative treatment, for which there was minimal evidence of effectiveness and which had not been tested on human beings, can be allowed provided it is in the best interests of patients.

December 2014

For further information, please contact:

Stephanie Creighton, Interim head of public affairs and public information

T: 020 7383 6681 | M: 07824 550 771 | E screighton@bma.org.uk

References

¹ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582

² *Bolitho v. City and Hackney Health Authority* [1997] 4 All ER 771

³ Medical Defence Union, [Response to consultation on Medical Innovation Bill](#)

⁴ Department of Health, [Report on the consultation on the Medical Innovation Bill: summary of responses and next steps](#), p13

⁵ Department of Health, [Report on the consultation on the Medical Innovation Bill: summary of responses and next steps](#), p12

⁶ Sir Robert Francis QC, [Comments on the Medical Innovation Bill](#)

⁷ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582

⁸ *Bolitho v. City and Hackney Health Authority* [1997] 4 All ER 771

⁹ See also: *Hunter vs Hanley* [1955] SC 200

¹⁰ *Duffy v Lanarkshire Health Board* 1998 SCLR 1142, 1999 SLT 906, OH

¹¹ *Simms vs Simms; A vs A* [2002] 2 WLR 1465; [2003] 1 All ER 669.