

Medical Innovation Bill

House of Lords Third Reading Briefing 23 January 2015

About the BMA

The British Medical Association (BMA) is a voluntary professional association and an independent trade union which represents doctors and medical students from all branches of medicine all over the UK. With a membership of over 153,000, we promote the medical and allied sciences, seek to maintain the honour and interests of the medical profession and promote the achievement of high quality healthcare.

Key messages

- The BMA believes that this legislation is unnecessary and urges peers not to support it. We are not aware of any evidence to suggest that the threat of litigation inhibits innovation or that confusion exists amongst doctors over the circumstances under which they can deviate from standard practice.
- 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') and are logical (The Bolitho Test'). Doctors should act in the patient's best interests, follow General Medical Council (GMC) guidance, particularly on consent, and document their actions fully. Together these provide adequate protection to doctors and patients.
- If there is a need for additional support for doctors, this could be better achieved through professional guidance capable of responding to changing circumstances rather than statute.
- The Bill has been revised a number of times and the proposed amendments now concentrate on preventing 'quackery' rather than the stated aim of the Bill – to encourage responsible medical innovation. We suggest that the Bill is withdrawn and consideration given to identifying other means of increasing medical innovation.



Introduction

The best mechanism to advance medical science is through well-regulated research and clinical trials. However, it can still be necessary and beneficial 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.

We recognise that the Bill was significantly amended at Committee and Report stage however, the BMA concerns about the need for the Bill and how it will operate in practice remain. We suggest that the Bill is withdrawn and alternative, plausible means of increasing innovation in medical practice are explored in detail by an independent body, such as the House of Lords Science and Technology Committee.

The threat of litigation as a barrier to innovation

The BMA is not aware of any evidence that the threat of litigation prevents doctors from innovating (and therefore there is no evidence that the proposed bill will have a positive effect) or that there is confusion or a lack of clarity in the current law. Even if confusion did exist regarding the current law, the most appropriate and effective means of addressing this would be through guidance not primary legislation.

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 Bolam¹ and Bolitho² 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.³ 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.⁴ The *Simms vs Simms*⁵ 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.

The proposed legislation

The Bill seeks to encourage innovation by attempting to grant indemnity for doctors from negligence if they have followed the process prescribed in the Bill before diverting from standard practice. Decisions made following the proposed legislation will likely be tested in the courts. If the courts can intervene and judge a doctor's decision based on the provisions of the Bill this will not therefore achieve the objective of "bringing forward the Bolam test" or provide reassurance for doctors as

intended by the author of the Bill. In the BMA's view, this attempt to provide indemnity before the event is therefore flawed and counter-productive.

The Bill as a whole seeks to codify best practice and legislate for the exercise of judgement with respect to innovative treatment. For the BMA, best practice should be defined in professional guidance. Primary legislation is a crude tool to do this, inflexible and difficult to amend once enacted.

Recording innovative events

We believe it vital for the findings from individual instances of innovative practice to be disseminated to other doctors and researchers. Should the Bill proceed it would be crucial that where any instances of non-standard practice have occurred, the experiences of doctors and patients, any side effects experienced and the success or otherwise of the intervention are shared. However, this could be explored independently of, and without the need for, this Bill.

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For further information, please contact:

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References

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- 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 See also: *Hunter vs Hanley* [1955] SC 200
⁴ *Duffy v Lanarkshire Health Board* 1998 SCLR 1142, 1999 SLT 906, OH
⁵ *Simms vs Simms; A vs A* [2002] 2 WLR 1465; [2003] 1 All ER 669.