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The Medical Innovation Bill: Still more harm than good

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Abstract

The Medical Innovation Bill continues its journey through Parliament. On 23 January 2015, it was debated for the final time in the House of Lords and with one final amendment, the House moved to support the Bill, which then moved to the House of Commons on 26 January. It will be debated again on 27 February 2015. The Bill's purpose is to encourage responsible innovation in medical treatment. Although this goal is laudable, it is argued that the Bill is unnecessary and has the potential to undermine the very cause it aims to advance. More useful for encouraging responsible innovation is the continued education of health-care professionals on how the law already supports practitioners who look to improve care through responsible innovation.

What is the Medical Innovation Bill?

The Medical Innovation Bill ('the Bill'), (often referred to as the 'Saatchi Bill'), was first introduced into the House of Lords by the advertising mogul Lord Saatchi in 2012. Lord Saatchi's motivation for the Bill was his sense of frustration following his wife's death due to ovarian cancer in 2011 and the limited help available to her through conventional treatment. It is Lord Saatchi's belief that the current law of negligence deters responsible medical innovation for cancer and other medical conditions. According to this view, doctors are, or might be, reluctant to depart from established, conventional treatments for fear of being sued. The stated aim of the original Bill was therefore to remove perceived legal barriers to responsible innovation while at the same time seeking to 'deter reckless irresponsible' changes in medical treatment.

Interestingly, the reference to recklessness has now been removed, and the latest version of the Bill is squarely aimed at impacting on medical practice by permitting departures from 'the existing range of accepted treatments for a condition.' (cl.1(2)). If passed, the Bill would establish a process of consultation between a doctor and one or more appropriately qualified medical colleagues on the decision to use an innovative rather than established treatment (cl.1(3)). If this consultation procedure is followed, and the doctor takes full account of the views obtained in a 'responsible' manner, then the doctor's decision to use an innovative therapy cannot later be held negligent. Debate continues, however, on exactly how the regime envisaged in the Bill would affect the current legal position and medical practice, and whether the changes would be positive.

The Bill has been supported by a vigorous online publicity campaign that asserts that when it comes to medical innovation, doctors' hands are currently 'tied by concerns about professional reputation and potential negligence claims'.¹ Nevertheless, the Bill has proved controversial, with opinions ranging from concern to opposition being expressed by medical bodies (including the General Medical Council² and the British Medical Association³), medical charities and patient groups (including Cancer Research UK⁴), medical defence organisations (the Medical Defence Union and the Medical Protection Society), legal practitioners⁵ and medico-legal academics.⁶

While opponents of the Bill are not against innovation per se, there are legitimate concerns about 'irresponsible' practices that get called 'innovation' but in reality represent unacceptable departures from quality care. At best, these practices amount to harmless quackery, but they could put patients at serious risk. Below, we echo earlier challenges to the need for the Medical Innovation Bill⁷ and argue that current negligence law in the United Kingdom does not hinder responsible medical innovation; indeed, it supports responsible innovation.

The current legal position: Why the Bill is unnecessary

The Bill is unnecessary because there is no concrete evidence to support the assertion that current negligence laws stifle medical innovation. On the contrary, the common law in the United Kingdom explicitly supports medical innovation whilst maintaining safeguards to protect patients.

Under the Bolam test for medical negligence,⁸ a doctor's conduct is evaluated in light of the usual practices or customs within the medical profession. Accordingly, a doctor will not be held negligent in the provision of medical treatment if his or her conduct would be supported by a responsible body of medical opinion. The Bolam test does not, however, confine doctors to treating patients with established therapies. The first use of an innovative therapy is by definition a deviation from established medical practices; yet one which can be accepted under the Bolam test, subject to the proviso that the decision to depart from the standard, established treatment would also be supported by a responsible body of medical opinion.

The ability of the Bolam test to accommodate responsible innovative treatment is best illustrated by *Simms v Simms*.⁹ This case involved an application to the High Court by parents of two incapacitated teenagers suffering from probable variant Creutzfeldt-Jakob disease. The parents sought a judicial declaration that the use of a treatment not yet tested on humans could be in the patients' 'best interests'. Given that no effective treatment or cure had been found and also that an expert witness (an experienced neurosurgeon) supported the use of the proposed treatment on the basis of positive results in the use of the proposed treatments in animal models, it was held to be in the patients' best interests for the treatment to be carried out. Furthermore, it was stated that:

The Bolam test ought not to be allowed to inhibit medical progress. And it is clear that if one waited for the Bolam test to be complied with to its fullest extent, no innovative work such as the use of penicillin or performing heart transplant surgery would ever be attempted.¹⁰

For this very reason, the Bolam test has been interpreted in a flexible manner so as to permit the use of innovative therapies if supported by responsible medical peers.

The current draft of the Bill preserves the Bolam test for negligence in relation to the decision to use an innovative therapy. cl. 2(1)(a) states that the Bill 'does not affect any rule of the common law to the effect that a departure from the existing range of accepted medical treatments for a condition is not negligent if supported by a responsible body of medical opinion'. In this aspect, the Bill is unproblematic. What is contentious is the secondary, alternative route to sanctioning a decision to depart from established medical treatments that the Bill seeks to establish.

Why the Bill is dangerous

Cl. 1 of the Bill lays out a set of procedures for 'responsible innovation' aimed at protecting doctors from negligence claims in relation to a decision to depart from the accepted range of medical treatments. The clause makes reference to the need to consult with other appropriately qualified doctors, 'take full account of the views obtained in a way which any responsible doctor would be expected to take account of such views', obtain any consents required by law, consider risks and benefits of the proposed and the existing medical treatments, and act in a manner that is both accountable and transparent.

Yet crucially, it would not be necessary for the doctor to have received the support of any of the appropriately qualified doctors consulted. Indeed, even if the medical professionals who expressed a view were firmly opposed, the doctor would not be negligent in the decision to administer the innovative treatment as long as the objections of peers had been fully considered and 'overruled' in a 'responsible' way and the reasons for doing so recorded.

This aspect of the Bill is troubling. Although it may be assumed that the doctor's ultimate decision will be reasonable, responsible and in the patient's best interests if the steps outlined in the Bill are followed, questions arise as to whether this is necessarily the case. If a doctor is unable to find even one suitably qualified medical practitioner who would support the proposed innovative treatment, this would itself cast serious doubts over the appropriateness of the proposed treatment. Nevertheless, the Bill may give rise to the use of untested therapies under precisely such dubious circumstances. By decoupling the negligence standard from the Bolam test and the need to obtain the backing of medical peers, the Bill will thus deprive patients of an important safeguard mechanism, expose them to an ambiguous zone of subjective decision-making and deprive them of adequate legal remedies if they are harmed as a result of exposure to an innovative therapy. Paradoxically, the Bill may also give rise to greater legal uncertainty and a resultant increase in medical negligence litigation.

Other concerns have been raised about how the Bill may encourage potentially dangerous practices under the rubric of 'innovation'. In its current form, the Bill prohibits a doctor from carrying out treatment solely for the purposes of research or for any purposes other than the best interests of the patient, but fails to acknowledge the existence of financial incentives that can encourage practitioners to introduce an experimental treatment as innovative practice rather than undertake the costly and time-consuming burdens of research and formal registration. There are no requirements for practitioners to share any information gathered on the safety and efficacy of an innovation with either the medical community or, indeed, future patients so they may make an informed decision about the potential risks and benefits of an innovative treatment. The Bill does not even define what types of activities constitute 'innovation' or how they differ from, or relate to, clinical research and practice.

A better solution

It is important to make clear that in making these arguments in relation to the Medical Innovation Bill, we are not arguing against medical innovation. Indeed, our position asserts that the law, as it currently stands, encourages responsible innovation, and the Bill undermines both innovation and the systems that are currently in place to protect patients from irresponsible practices. Whilst Lord Saatchi's frustration is entirely understandable, the personal circumstances of individual political leaders are an insufficient justification for instituting changes in the law. This is especially so in situations such as this where existing legal doctrine has provided sufficient support for, and encouragement of, responsible innovation.

As an alternative approach, we should:

1. Accept that innovation is already a very powerful force in biomedicine that has enormous support from governments, the pharmaceutical industry and the general public.
2. Educate health-care professionals on how the law supports innovative practices.
3. Steer innovation in the right direction by refining existing regulatory processes in a cautious and non-polemical way.

To the extent that existing regulatory and guideline-producing bodies might stand in the way of innovation, they could be encouraged to do more to guide responsible innovation by making it a more central part of their remit and by developing guidelines that are more flexible about what might constitute 'standard practice'.

As argued by Sir Robert Francis QC during the Committee hearing: The real obstacles to responsible innovation are not to be found in the Bolam test but in the minefield of regulation and bureaucratic inertia which doctors presumably have to surmount, not to mention the reluctance to fund innovative treatment. Unfortunately, the Bill offers no such solutions to these overriding impediments to innovation.

A public consultation on the issues raised by the Bill was carried out by the Department of Health from February to April 2014, which gathered comments from 70 people, and a further 100 responses sent directly to the Department of Health. Lord Saatchi's online petition, signed by over 16,000 people and supplemented in 2000 cases by additional comments, was forwarded to the Department of Health by Lord Saatchi's team. Despite earlier misgivings on the part of the British government, in a written ministerial statement delivered to the House of Commons on 22 November 2013, the Secretary of State for Health, Jeremy Hunt, offered support for the Bill and the 'need to remove barriers that prevent innovation which can save and improve lives'.

A website set up specifically to oppose the passage of the Bill protests that: 'The Medical Innovation Bill is not needed, removes vital patient protections, risks reckless practice, protects quackery and could harm medical research. Parliament should ensure the Bill is comprehensively reworked or dropped'. We agree with this assertion.

Article Notes

- 1 <http://medicalinnovationbill.co.uk/>
- 2 General Medical Council response to proposed legislation to encourage medical innovation, April 2014, http://www.gmcuk.org/GMC_response_to_proposed_legislation_to_encourage_medical_innovation_April_2014.pdf 56053559.pdf
- 3 'Concerns Medical Innovation Bill allows 'reckless practice'', 15 May 2014, <http://bma.org.uk/news-views-analysis/news/2014/may/concerns-medical-innovation-bill-allows-reckless-practice>
- 4 Cancer Research UK response to proposed Medical Innovation Bill, <https://scienceblog.cancerresearchuk.org/wp-content/uploads/2014/05/Cancer-Research-UK-consultation-response-draft-Medical-Innovation-Bill.pdf>
- 5 Nigel Poole QC, 'Medical Innovation Bill: Re-writing the Law of Medical Negligence' (2014) 3 Journal of Personal Injury Law 129; 'Response of Robert Francis QC to Legislation to Encourage Medical Innovation: A Consultation'.
- 6 'Stop the Saatchi Bill' <http://www.stopthesaatchibill.co.uk/>
- 7 See for example Poole, above n.5.

8 Bolam v Friern Hospital Committee [1957] 1 WLR 582.

9 Simms v Simms [2002] EWHC 2734 (Fam).

10 Para 48.