

Royal College of Surgeons

Policy briefing



Medical Innovation Bill

House of Lords Briefing

The Royal College of Surgeons welcomes the attempt to clarify the present legal position around medical innovation (the Bolam test). We believe the current draft and recent amendments of the Medical Innovation Bill are vague, lack sufficient detail, and do not reflect some of the risks in surgical innovation. The Government should consider how else they can clarify the current position, including through guidance on when innovative treatment would be considered negligent.

We believe this Bill has been drafted with innovative drug treatments rather than invasive innovative surgery in mind. We have reservations about the Bill's application to surgical practice and we believe it raises more questions than answers. We have outlined some specific concerns which reflect the amendments tabled by Lord Saatchi in September 2014.

We cannot support the present wording of the Bill.

Reliance on consultation with “one or more appropriately qualified doctors”

We are particularly concerned with the proposed clause 1(3)(a) (as proposed by Lord Saatchi's amendments published on 9 Sept 2014) which says a doctor needs to only obtain the views of one or more appropriately qualified colleagues in relation to the proposed treatment. This does not offer sufficient protection to patients; in theory a medical professional could discuss the matter with a colleague who they know to be in agreement or those who may not be in a position to disagree. This is a particular concern for surgery.

Surgical operations can have profound and lasting effects for the patient. While a novel drug may be discontinued in an effort to cease its effects, it can be difficult to 'undo' the effects of invasive surgery. It is only after the risks and benefits have been fully discussed, with the patient and as a medical team, that the decision to operate should be taken.

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The decision to pursue an innovative treatment is most likely to be taken in the event that all conventional avenues have been exhausted, often towards the end of a patient's life. In such circumstances patients and families can be understandably keen to pursue new and untried treatments in an attempt to improve their condition without full knowledge of the side effects. It is imperative in such circumstances that a considered approach is taken to ensure all necessary safeguards are in place.

Furthermore, the term "appropriately qualified" is open to interpretation. We are not convinced it sufficiently describes an experienced professional, expert enough to offer the required level of guidance.

The College believes that any decision to adopt an innovative approach, and thus depart from standard medical practice, should at the very minimum be taken in consultation with a multi-disciplinary medical team.

There will likely be complex circumstances where further arbitration is required, such as cases that present difficult ethical or moral considerations. In such instances there may be value in involving a larger body of expertise, such as a specialty association, that can provide professional guidance. Such bodies could receive and review proposals for innovative procedures to assess whether they are feasible, appropriate and efficacious. Their involvement would arguably be covered by the existing Bolam test.

Use in acute and emergency situations

The Bill must be universally applicable in all clinical scenarios to be practical and to achieve its aims. However, we are concerned the Bill's steps (outlined in the revised Clause 1(3)) are difficult to implement in acute or emergency contexts where an individual is at immediate risk of death or disability. These steps would be difficult to achieve when time is critical. How, for example, would a clinician on night duty be able to seek the required assurances?

Wording of clause 1(4): When innovative treatment can be administered

We are disappointed with the pejorative wording of this clause. It implies a medical professional would conduct themselves for their own professional gain. All physicians are already bound by the Helsinki Agreement, which sets out that "The health of my patient will be my first consideration".

Other considerations for Government

The Government also needs to consider other ways of enhancing innovation in the NHS including:

- Greater use of clinical ethics committees by Trusts to support doctors needing advice around the use of innovations. These are not presently used in all Trusts in the UK, yet they can help to support individual doctors on ethical issues surrounding the provision of patient care, including one-off innovations;
- A reduction in research bureaucracy;

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- More NHS staff and patients encouraged to participate in research;
 - Improving implementation and monitoring of the uptake of innovations, including the monitoring of compliance with NICE approved medicines and devices;
 - Increased funding for surgical research and innovation.