

Medical Innovation Bill

Guidance note on amendments

1. This guidance note has been prepared in order to assist the reader in understanding the amendments to the Medical Innovation Bill¹ tabled by Lord Saatchi on 8 September 2014.
2. Lord Saatchi's team worked closely with the Department who sought expert legal and clinical advice (including consideration of this issue by Sir Bruce Keogh, NHS England Medical Director) in devising these amendments to work for patients, doctors and lawyers.

The Bill provides an *option* for doctors who want to innovate responsibly

3. **Amendment 12** inserts a new clause into the Bill after clause 1. The effect of subsection (1) of the clause is to emphasise that the *Bolam* test remains unaffected by the Bill. That is the common law test which allows a doctor to show that a responsible body of medical opinion supports his or her actions, thus demonstrating that he or she was not negligent.
4. Subsection (2) goes on to emphasise that it is for the innovating doctor to decide whether to take the steps set out under the Bill or to rely on the existing *Bolam* test as at present; there is no requirement to follow the Bill. Furthermore subsection (2)(b) provides that doctors are not negligent, and thus will not be judged adversely if their actions are later challenged, merely because they have not followed the Bill. What the Bill does is to give doctors another option (in addition to the existing *Bolam* test) for showing that they are acting or have acted responsibly (and thus not negligently).

The Bill ensures that a doctor must act responsibly when innovating

5. **Amendment 2** amends clause 1(2) to emphasise that the protection offered by the Bill applies to the doctor's *departure* from the existing range of accepted treatments for a condition and not just to the decision to do so. The protection therefore covers the decision itself and what the doctor does to put the decision into effect - although the Bill does not provide any protection to the doctor if the decision is implemented incompetently. **Amendment 3** ensures that the Bill only applies to medical treatment.
6. **Amendment 4** amends clause 1(2) to provide that a doctor's departure from the existing range of accepted medical treatments for a condition is not negligent where the decision to depart is taken responsibly. This applies an objective test of responsibility to the doctor's decision and prevents a doctor who acts irresponsibly from relying on the Bill.

The Bill requires a doctor to comply with a number of safeguards

¹ The version of the Bill introduced into the House of Lords by Lord Saatchi on 5 June 2014.

7. **Amendment 5** replaces clause 1(3) of the Bill. New clause 1(3) sets out a list of steps that a doctor must take in order for a decision to be responsible (and thus not negligent).

Peer review

8. New clause 1(3)(a) requires the doctor to obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment. **Amendment 6** inserts new clause 1(4) into the Bill to clarify that a doctor is appropriately qualified if she or he has appropriate expertise and experience in dealing with patients with the condition in question. New clause 1(3)(b) requires the doctor to take full account of those views in a way in which a responsible doctor would be expected to do. This ensures that a doctor cannot ignore views, or give them minimal weight, unless there are reasonable grounds for doing so. This clause provides a critical safeguard in ensuring that there is expert peer review of the doctor's proposal and that the doctor acts responsibly in taking account of that review.
9. These clauses reflect the policy intent of "bringing forward" the *Bolam* test to before treatment is carried out. They seek to do this in a non-bureaucratic way by avoiding the creation of new approval structures or alteration of the remit of existing groups such as Multi-disciplinary team meetings.

Risks and benefits of the proposed treatment, other treatments and no treatment at all

10. New clause 1(3)(d) requires the doctor to consider a number of factors in relation to the proposed treatment. This includes a requirement to consider the risks and benefits that are, or can reasonably be expected to be, associated with the proposed treatment, other accepted treatments and not carrying out any of those treatments. This ensures that the doctor has to consider not only the risks and benefits of the proposed treatment but also how these would compare with other treatments, and with not carrying out any treatment at all. In weighing this up the doctor must apply an objective standard as to what could reasonably be expected in relation to those treatments. This provides a further safeguard for patients, in ensuring that a doctor may not offer an innovative treatment in accordance with the Bill unless she or he has acted in an objectively responsible way.

Notification of responsible officer

11. New clause 1(3) no longer requires a doctor to notify their responsible officer about the proposed treatment. The responsible officer may not have expertise relating to the condition in question and it may be difficult for a doctor to notify them in advance in all cases. The deletion of this provision should reduce bureaucratic burden for doctors without any disadvantage to or loss of protection for patients.

Minor amendments

12. **Amendment 1** removes the reference to "reckless" innovation to ensure that the focus of the Bill is on encouraging responsible innovation in medical treatment and deterring irresponsible innovation.

13. **Amendments 7 to 11** make minor drafting amendments to the Bill as well as changes that are consequential on the other amendments to the Bill.

Short title, commencement and extent

14. **Amendments 13 and 14 amend the current clause 2 of** the Bill. The amendments secure that the Bill comes into force in accordance with regulations made by the Secretary of State, rather than on Royal Assent as under the Bill as introduced. This allows time to prepare for the changes to the law made by the Bill, for example, to produce any guidance that might be helpful. The amendments also enable transitional and saving provision to be made if necessary, again to aid a smooth transition.

8 September 2014