MPS Briefing

Legislation to Encourage Medical Innovation

June 2014

MPS welcomes the debate this Bill has ignited. We support a responsible, innovative medical profession. There are positive developments to come out of this debate, including the commitment to work with Oxford University to develop a method of data collection and sharing for innovative treatments.

However, we have very serious concerns that the Bill will not achieve what it sets out to achieve. Furthermore, it may inhibit responsible innovation whilst also giving false reassurance to some doctors, who on subsequent objective analysis were found to have innovated irresponsibly causing patient harm.

The Bill is unnecessary

Current law allows doctors acting responsibly to innovate. The Bill recognises the value of current law as it explicitly preserves the current Bolam-Bolitho tests for standards of care as well as the current law on consent. Thus, a doctor acting responsibly with the support of a responsible body of peers and the informed consent of their patient would not be guilty of negligence under the current law.

MPS has extensive experience of issues of clinical negligence and advising doctors on ethical and medicolegal matters. We have never been made aware of any concerns that doctors are failing to be innovative due to a fear of clinical negligence claims.

The Bill is unlikely to be able to deliver what it sets out to achieve

- **It is based on a premise that is incorrect in law**. The briefing note states 'The Bill allows doctors to be certain before they innovate that they have done it in a manner that will be supported and protected by the courts'. This is incorrect in law. This assumes that all Multi-Disciplinary Teams (MDTs) are responsible bodies; however, the decisions of MDTs, just as much as those of individual doctors are subject to the scrutiny of the courts and assessed by reference to the Bolam-Bolitho tests. Accordingly, there is a real and tangible risk that doctors will be falsely reassured. Additionally it will always be possible to challenge through the courts whether the provisions of the proposed legislation were complied with.
- **It fails to recognise other potential barriers to responsible innovation.** By way of example, no thought appears to have been given as to how innovative treatment will be funded. Even with the support of a responsible MDT, Commissioners are unlikely to agree to fund innovative treatment with an uncertain outcome if it means diverting money away from basic care. If the government is serious about encouraging responsible medical innovation, it should undertake a full review to identify to what extent, if any, responsible medical innovation is being held back, what factors are contributing to this, and only then, put forward well thought through recommendations. Primary legislation should only be introduced if it is identified as a solution by an evidence-based analysis of this kind.

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Potential risks created by this Bill

- **The Bill will confuse rather than clarify the law.** The briefing note on the Bill states 'there is a distinct lack of understanding of the Bolam-Bolitho test and the case law around medical negligence'. Whether or not that is the case, creating a law targeted at medical innovation will lead doctors to believe that one law exists for medical innovation and another for established treatments. If there is a lack of understanding of Bolam-Bolitho, it is not an argument for statute to further complicate matters; it is an argument for greater education and understanding about the existing legal position.
- **Prevent proper assessment of potential innovations and thus hold back innovation.** This Bill would create a mechanism allowing doctors to bypass research and development processes necessary to properly evaluate all treatments. There would be a reluctance to undertake full clinical trials on innovative treatments doctors had used under this Bill that had failed on one, maybe two, occasions thereby delaying or even preventing the introduction of good treatments.
- **The brief attached to the Bill claims the Bill will 'empower patients to demand that every possible route should be tried'.** There are two issues arising out of this statement. First, the sad reality of most cases where the Bill might apply is that there is seldom time to try all possible treatments, nor is there likely to be funding for this, and the use of one may in some circumstances preclude the use of another. Second, not every possible route will be Bolam-Bolitho compliant. The combined effect of these issues may lead to a breakdown in the doctor/patient relationship where the doctor is simply not able to deliver what the Bill has led the patient to believe they are entitled to.
- **Open to interpretation.** The proposed safeguards will not prevent practitioners who are well outside of mainstream practice from trying to rely on the Bill. The Bill fails to define what is meant by 'Multi-Disciplinary Team', or 'appropriately qualified colleagues'. Failure to define these terms leaves the Bill open to interpretation. For example, an independent practitioner, working outside established secondary or tertiary care facilities in a setting providing treatments not recognised as mainstream could seek to argue that those working alongside them in that setting are either a MDT or 'appropriately qualified colleagues'. For the reasons set out below, reporting a decision to provide an innovative treatment to the Responsible Officer (RO) may not always be an effective safeguard.
- **The Bill incorrectly assumes a generally well developed MDT structure.** The assumption appears to be that the Bill applies to secondary/tertiary care only, yet 80% of care is provided in primary care. There is virtually no MDT structure in primary care. The General Practitioner would need to rely on the approval of an 'appropriately qualified colleague' and of the RO (see below). It is by no means certain that either would pass the 'responsible body' test.
- **Involvement of the RO could be a false reassurance.** It is not clear whether the RO should be a gatekeeper or will merely record a MDT decision to approve innovative treatment. This would be likely to lead to huge variations in the way in which innovative treatments are sanctioned. It is important to bear in mind that the RO may not be of the relevant specialty so cannot be considered a 'responsible body'. Thus, sanction by the RO might also be a false reassurance, especially outside established primary, secondary and tertiary care settings.

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