Consultation Response

Legislation to encourage medical innovation

April 2014

MPS's response to Legislation to encourage medical innovation: A consultation

Overview

MPS welcomes the debate Lord Saatchi and Michael Ellis MP have ignited by introducing Private Members' Bills with the aim of encouraging responsible medical innovation. Lord Saatchi's work on this issue could lead to some important new thinking about how to further encourage responsible medical innovation.

MPS supports **responsible** innovation in medicine and it is right to have a public conversation about how to best achieve this and to identify and remove barriers.

There should now be an evidence gathering exercise to fully explore what, if any, barriers exist and how these might be dealt with in a proportionate and practical way.

MPS is not convinced that this Bill is needed because:

- We believe that current law protects doctors undertaking responsible medical innovation
- We do not have any evidence that the barrier to responsible medical innovation is a fear of the possibility of clinical negligence claims. Other potential barriers should be explored
- The Bill, as it currently stands, could create some risks

Why the Bill is currently unnecessary

The current law and codes of practice are sufficient legal protection

Responsible innovation as defined in this Bill is likely to meet the existing Bolam/Bolitho tests and therefore adds no value to current case law.

Further evidence gathering is needed

Whether there is currently sufficient medical innovation is not a matter on which MPS is able to comment. However, we have no evidence, nor been made aware, of any concerns that doctors are not being innovative due to a fear of clinical negligence claims.

Before making a change to Primary legislation it would be appropriate to undertake a full review to identify to what extent medical innovation is being held back and what barriers, if any, exist. This evidence gathering could then be used to bring forward recommendations to remove any barriers in a proportionate and well thought through manner.

Furthermore, the draft Impact Assessment (IA) is lacking in detail in some aspects. It is important to have a full understanding of the costs and benefits associated with a potential change in legislation. The IA further indicates that the hypothesis that a 'barrier to improved treatment is the possibility of clinical negligence claims' has not been proven.

Potential non-legal barriers to responsible innovation

As part of a review of potential barriers to responsible medical innovation - if a problem is identified - MPS recommends consideration of the following points:

1) Potential for discipline from regulators

Protecting doctors from action in negligence does not protect them from sanction from their regulator. Ethics are more restrictive than the law and healthcare workers are rightly subject to a number of regulatory and disciplinary proceedings by their regulators. For many doctors, it is the fear of action by a regulator that is a stronger deterrent than the threat of litigation. Regulators have the power to erase doctors from the medical register, or otherwise interfere with their registration, and thus damage their careers.

However, in the same way that responsible innovation is unlikely to fall foul of the Bolam/Bolitho test, it is unlikely that responsible medical innovation would be criticised by a regulator. Conversely a doctor would not be able to rely solely on this Bill to defend fitness to practise allegations at the GMC. More pertinently, refusing treatment to a patient purely because of the fear of litigation might in itself amount to a fitness to practise issue.

2) Medical training

There is an argument that medical training does not encourage medical innovation. Instead it instils a culture which encourages the pursuit of tried and tested medical practice rather than considering innovative alternatives. Whether this is the case or not should be considered.

3) Financial restrictions

As part of the evidence gathering exercise we also believe it would be worth exploring to what extent bureaucracy and complex arrangements for agreeing research and trials may be a barrier to innovation. This could include the role of NICE.

In a similar vein, an additional barrier may be the willingness or ability of the NHS to pay for innovative but unproven treatments. This is a risk identified in the IA 'funding for innovative treatment is not made available by commissioners, meaning that the legislation has little effect[1].' This concern needs to be explored further as it may be a current barrier, rather than one just in the context of this Bill.

4) Clinical negligence claims directed at the employer not the individual

As part of a review into the potential barriers to medical innovation, it is important to note that in the NHS or other employed environments, any claim in clinical negligence is directed at the organisation

[1] Legislation to encourage medical innovation: a consultation, March 2014 P28

(NHS Trust) rather than the individual practitioner. The impact that this has, both on the hypothesis of this Bill and as a potential barrier to medical innovation, should be explored.

Alternatives to removing potential barriers

Above are suggestions for factors that may act as a barrier to medical innovation; below are some suggested solutions to these barriers.

1) Create greater awareness about the existing legal position

A key motivation behind the development of this Bill is to tackle any misconceptions about what the current law allows a doctor to do. The focus for change therefore could be increasing awareness of the position of the Bolam and Bolitho tests. Related to this, greater awareness may also be needed around issues of consent in circumstances of medical innovation.

2) Build an innovative culture in medical training institutions and employers

If it is found that the nature of medical training and/or employers is in some way contributing to a lack of responsible innovation then the focus should be on how these institutions can better build an environment that allows responsible innovation to thrive. Again, a change in legislation would not impact on this. The focus should be culture change.

3) Registering and awareness raising of medical innovations

To ensure there is awareness of innovations that have already been made, any evidence gathering exercise could consider whether the existing system for registering innovations is fit for purpose. Added to this could be consideration of levels of awareness of the current system.

Potential risks created by this Bill

Due to a lack of appropriate safeguards MPS is concerned that risks are created by this Bill as it currently stands. Furthermore, questions have been raised about whether it has the potential to hold back responsible medical innovation, as discussed in the section below.

Lack of appropriate safeguards

The intention is for this Bill to protect patients as well as doctors. However, MPS is concerned that the draft Bill currently lacks appropriate safeguards.

- Clause 1 (4) defines the test for a responsible decision – ‘A responsible decision … is one which is based on the doctor’s opinion that there are plausible reasons why the proposed treatment might be effective’. This is almost exclusively a subjective one made by the innovator. Furthermore in clause 1 (4) (a) - subject to the caveat in 1 (4)(b)(i) - there is no objective test of what is ‘plausible’.
- It is important there is an objective test – which arguably we already have in place following Bolam/Bolitho. Subjective opinion cannot be relied upon in this context.
- Clause 1(7) identifies factors that may be taken into account in determining whether a process satisfies the requirements of clause 1(6). This includes ‘whether the decision has been made

within a multi-disciplinary team' 1 (7)(b). There is no clear definition of what constitutes a multi-disciplinary team. Clarity on this is needed to ensure this safeguard is effective.

- Clause 1 (5)(e) states that for a decision to be responsible the doctor should consider 'opinions expressed by colleagues whose opinions appear to the doctor to be appropriate to take into account.' The consultation asks 'whether the Medical Innovation Bill should only apply when the case has been discussed with clinical colleagues and their recommendations taken into account.' Because this proposal does not require the treating doctor to agree with his colleagues, only take their recommendations into account, it does not add anything to the original proposition. The doctor and colleague could disagree, but that does not have to change the outcome of the proposed test and it remains subjective. On the other hand if everyone was in agreement about offering the innovative treatment then in all likelihood the Bolam test would be satisfied. In which case the proposed law would seem to serve little purpose.

The consultation considers whether the risk of doctors engaging in clinically inappropriate or risky behaviour without sufficient justification will increase with this change. We believe that it increases risk due to the reasons above. The consultation admits that 'it has not been possible to identify the likelihood and scale of these risks[2]'. It is important that thorough analysis is undertaken before there is any change in law.

Impact on Medical Defence Organisations

The consultation lacks full consideration of the impact such a change might have on Medical Defence Organisations. It also lacks full consideration of the impact on indemnifiers including the National Health Service Litigation Authority and the Welsh Risk Pool in respect of treatment carried out under the auspices of the NHS in England and Wales respectively.

Whilst there is an implication in the illustration (Box D) that by advising their MDO or indemnifier the doctor will be covered, this cannot be taken as read. Any prudent MDO or indemnifier will want to assess the indemnity risk associated with any particular case and come to a reasonable decision on whether or not such a risk exists, the nature and extent of that risk and ultimately if the position taken by the doctor is defensible in law and within regulatory oversight. It is only by careful assessment particularly noting the reliance on subjective rather than objective criteria, can a decision be made on underwriting a risk.

A tool for patients to force the hand of doctors

It is a basic premise in medical law and ethics that a doctor cannot be forced to provide treatment where they believe that it will be of no benefit or where the risks outweigh the benefits. Patients and families might attempt to use this Bill to put pressure on doctors to provide inappropriate treatment in these circumstances.

A shortcut for consent

This Bill does not touch on the issue of consent. While the consultation argues that this Bill does not change the position on consent to treatment it fails to recognise that an overreliance on the protections provided by such a Bill might in some cases result in insufficient attention being placed on the consenting process.

[2] Ibid p29

Patient expectations and communication of the Bill

There is a risk that patients will misunderstand and overestimate what this Bill would do. Patients may unrealistically expect this Bill to effectively authorise widespread introduction of innovative procedures of little real merit and it will be doctors that have to explain otherwise.

A barrier to responsible medical innovation

This Bill could result in more doctors feeling able to pursue 'innovative treatments' in a way that bypasses the tried and tested clinical trials process.

The clinical trials process ensures that innovative treatment, the effect of treatments and their successes or otherwise are correctly reported and recorded. If these systems are bypassed it could mean that important lessons are lost, unsuccessful treatments are unnecessarily repeated and mistakes made.

Summary

MPS warmly welcomes the debate that this proposal has created. In a modern medical system it is right that we ensure that responsible medical innovation can happen. If there are barriers, they should be removed.

However, MPS has seen no evidence that a fear of clinical negligence claims is holding back medical innovation. If medical innovation is being held back, there are probably a number of complex and interrelated causes which need to be fully explored. Any further action should be based on the extent of the problem, what the barriers may be and how to best resolve them in a sensible and proportionate way.

Relevant consultation questions

Question 1 – Do you have experience or evidence to suggest that the possibility of litigation sometimes deters doctors from innovation?

Despite many years of experience in the clinical negligence claims environment we have no evidence that the fear of litigation is holding back innovation in medicine.

Question 2 – Do you have experience or evidence to suggest that there is currently a lack of clarity and uncertainty about the circumstances in which a doctor can safely innovate without fear of litigation?

MPS has no evidence that there is currently a lack of clarity or uncertainty about the circumstances in which a doctor can safely innovate without fear of litigation. Additionally, doctors are currently protected when undertaking responsible innovation. If there is a lack of awareness of the implications of current law this can be solved through education and training; not new law.

Question 7 – To reinforce the Bill, are there things that need to happen to encourage responsible innovation?

MPS is not convinced of the need for this Bill. However it is worthwhile undertaking further evidence gathering to highlight what barriers may exist and ways in which they can be overcome. We make some suggestions in section 1.

Question 9 – Overall, should the draft Bill become law?

MPS is not convinced that there is need for any Bill adding or clarifying protections for doctors undertaking responsible innovation. Furthermore, the Bill as it currently stands creates some risks.

About MPS

MPS is the world's leading protection organisation for doctors**,** dentists and healthcare professionals. We protect and support the professional interests of more than 290,000 members around the world. Our benefits include access to indemnity, expert advice and peace of mind. Highly qualified advisers are on hand to talk through a question or concern at any time.

Our in-house experts assist with the wide range of legal and ethical problems that arise from professional practice. This includes clinical negligence claims, complaints, medical and dental council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

Our philosophy is to support safe practice in medicine and dentistry by helping to avert problems in the first place. We do this by promoting risk management through our workshops, E-learning, clinical risk assessments, publications, conferences, lectures and presentations.

MPS is not an insurance company. All the benefits of membership of MPS are discretionary as set out in the Memorandum and Articles of Association.

CONTACT

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