for patient safety and justice

Medical Innovation Bill Consultation Team
Department of Health
Medicalinnovationbill@dh.gsi.gov.uk

25 April 2014

Dear Department of Health

Medical Innovation Bill

Thank you for the opportunity to respond to your consultation. We were surprised and disappointed that at no stage were we invited by those behind this Bill to discuss the perceived need for it, and other ways of addressing the perceived problem, before it became a draft Bill. Action against Medical Accidents (AvMA) is, after all, the national charity for patient safety and justice. We have over 30 years' experience of working to improve patient safety, and helping people who have been harmed as a result of inappropriate or sub-standard treatment. We also have considerable expertise in clinical negligence and the law.

The Bill is clearly well-intentioned, and we would like to put on record that we would not like to see any patient denied appropriate treatment because of a fear of litigation. However, we feel the Bill is both unnecessary and may have serious unintended consequences should it become law. It does not even seem to be taken into account that it would lead to patients injured by clinical negligence not being able to access justice in the circumstances described.

We believe the Bill is based on a misunderstanding of how clinical negligence is dealt with by the courts. We are not aware of any case where there has been an unreasonable funding of clinical negligence as a result of innovative medical treatment.

We believe a far better way of dealing with the perceived problems that the Bill attempts to deal with would be to educate doctors in training and post-qualification about the reality of clinical negligence to dispel the myths that might make some feel uneasy about medical innovation.

Given the extremely limited time left for legislation in this parliament, we think there are far greater priorities such as the long awaited and vitally important Bill on Health Professional Regulation.

Our responses to the questions set out in your consultation document are as follows:

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

No. However there is anecdotal evidence to suggest that some doctors' ignorance of how clinical negligence is defined and dealt with in law may deter them from innovation, (so-called "defensive medicine"). This is best dealt with by educating doctors so that they do not feel deterred from innovating because they wrongly, as the Bill does, assume that clinical negligence case law is likely to deem innovative treatment negligent. Doctors have the services of defence organisations such as the Medical Defence Union and Medical Protection Society who try to educate them about such issues, and who can advise them. However, more can be done to explode some of the myths that lie behind this well-intended but unnecessary and dangerous Bill during the course of their training and subsequent career.

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

No

Question 3: Do you agree with the circumstances in which the Bill applies, as outlined in clause 1(3)? If not, please identify any changes you suggest, and give your reasons for them.

We do not think that the Bill is needed at all and in fact may have serious unintended consequences which we describe elsewhere.

Question 4: Do you have any comments on the matters listed in clause 1(4)-(5) on which the doctor's decision must be based for it to be responsible? Are there any that should be removed, or changed, or added, and if so why? For example, should the Bill explicitly indicate that the other treatments mentioned in 1(5) (a)-(c) include treatments offered as part of research studies?

These are completely inadequate safeguards. We note in particular that the individual doctor would be given absolute discretion as to who else's clinical opinions he or she would need to even take account of. Also the emphasis throughout on the individual doctor's opinion. In effect this would be a license for individual doctors to carry out the treatment they want to, provided they are able to persuade the patient that this is the best or only course of action which might (in their individual opinion) help them. We only have to look back to recent scandals such as that of Dr Ian Patterson to see that patients can easily be led into accepting proposed treatment from a doctor which in fact is not clinically appropriate.

Question 5: Do you have any comments on the process set out in clause 1(6)-(7)? Are there any provisions that should be removed, changed or added – and if so, why?

The process is inadequate in that it only requires these factors to be "taken into account" in assessing whether a doctor's decision was carried out in a way in which that individual doctor believes" allows full consideration **by the doctor"** of undefined subjective issues such as the "transparency" and "accountability".

The existing requirement to act in accordance with a responsible body of professional opinion, and operate within the professional code and guidelines produced by the GMC etc, are more than adequate and do not pose the problems which the authors of the Bill assume they do.

Question 6: If the draft Bill becomes law, do you have any views on the best way to communicate its existence to doctors?

The Bill should not become law. The problem (insofar as it exists) of doctors not undertaking treatment which has real potential benefit for patients because of unfounded fear of litigation even if the treatment is clinically justifiable would best be addressed by educating doctors of the real situation with regard to clinical negligence.

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

N/A

Question 8: Do you have any comments and suggestions for inclusion in the draft impact assessment and equality analysis?

Yes. We are shocked that the impact assessment does not take into account two key risks for patients and their families of introducing this legislation:

- Patients (or their next of kin if they die) may be deprived of compensation which they need and deserve due to treatment which under current well-established arrangements would be deemed negligent in a court of law.

- The huge discretion allowed for the individual doctor to decide to provide treatment with totally inadequate safeguards would be likely to harm attempts to improve patient safety and lead to more patients actually being harmed **because of** inappropriate treatment (not just that the treatment may not be "successful"). It would also lead to patients' and families' hopes being unrealistically raised and then dashed.

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

NO

Yours sincerely

Peter Walsh

Peter Walsh
Chief Executive