Response form

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Are you responding as an individual or on behalf of an organisation?
If as an individual, are you responding as:
d) other? - I am responding in a personal capacity but as a Professor of Medical Law at the School of Law, University of Leicester
If you are responding on behalf of an organisation, please give the name of the organisation and say who it represents:

The questions posed in the consultation paper 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, I would argue that the current legal situation regarding innovative treatment is similar to that in relation to defensive medicine. A breach of duty (the *Bolam* part of negligence that the consultation refers to) constitutes an act org omission that no reasonable doctor would countenance. A doctor failing to undertake a diagnostic test (or indeed undertaken other that are not required) is not protecting herself from a negligence action but rather encouraging one (see, for example, M. Jones, *Medical Negligence* (4th ed, Sweet and Maxwell, 2008) at p 39). Rather, the doctor's duty is to provide the right amount of tests and no more or less. It is thus at best a reaction based on a false sense of what the law is.

In the same way, a doctor who does not provide innovative treatment when it is appropriate has a false sense of what the law is if she fails to do so through a fear of being sued. Indeed, a doctor who complies with what is proposed in the Bill will *already* be protected from a charge of negligence - so long as the innovative treatment is indeed appropriate.

Indeed, I would argue that the consultation seems to misunderstand what *Bolam* and *Bolitho* actually require of doctors - a point that I return to in question 2.

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. As I mention above, the consultation and the Bill appear to be based on what I consider to be a misreading of *Bolam* and *Bolitho*.

The consultation is correct to say that *Bolam* is based on a responsible body of opinion, but it only requires there to be a reasonable body of opinion that *might* do as the defendant did. This does not mean that the defendant doctor needs to find others that have done what she did, only others that might do so in similar circumstances. This is a very different question, and one that it is more than

appropriate to ask. For example, in the 'vignette' described in the consultation document (Box A), the question of whether other doctors would agree with the analysis of Dr A is surely an absolutely fundamental element in deciding whether or not Dr A's opinion is reasonable or not. A complete lack of support for the decision on the part of Dr A's peers should rightly lead a court to question whether it was indeed an appropriate course of action. Moreover, should Dr A have consulted colleagues within the hospital or outside it, then a body of opinion will be in existence that might have done as Dr A did, thus satisfying the *Bolam* test.

What is concerning about the Bill as it is currently framed is that if Dr A's analysis *was* flawed and thus the advice given to B was similarly erroneous, then it would seem that these proposals would limit B's chances of being able to claim compensation for a doctor having - wrongly - decided to depart from the norm. B's consent would also have been based on erroneous information, thus being an exercise in liberty but would not constitute a truly autonomous choice (see J. Coggon and J. Miola, "Autonomy, Liberty and Medical Decision-Making" (2011) 70 *Cambridge Law Journal* 523).

Furthermore, the Bill displays some circular logic. It seems to wish to limit the need for validation by one's peers in innovative situations (as defined by the individual doctor), but s.1(5) seems to require several instances of 'reasonable' conduct. This would necessarily require a reversion to the *Bolam* test and, therefore, expert evidence. In other words, the effort to escape *Bolam* is unsuccessful if a court is to be able to assess and analyse the doctor's decison-making in relation to the factors in s.1(5).

Bolitho is also important in the sense that it provides the court with clarity in relation to how it uses medical evidence. Lord Browne-Wilkinson in that case made it clear that it would only be in "rare cases" where the evidence in support of what the doctor did lacked "logical force" (in a sense not dissimilar to *Wednesbury* unreasonableness) that it would be appropriate for courts to find for claimants. Thus, doctors are almost certainly safe if they can find some others who are willing to agree with their analysis. Again: if they cannot, a court should rightly be asking why that is the case.

Indeed, the reasons for the judgment in *Bolitho* should not be forgotten. Less than 20 years ago, courts remained very reluctant to question medical practitioners, and they were treated differently to other professions. The law needed to change (see M. Brazier and J. Miola, "Bye Bye *Bolam*: A Medical Litigation Revolution?" (2000) 8(1) *Medical Law Review* 85) - and the reasons for this were

ably described by Lord Woolf just after the *Bolitho* judgment (Lord Woolf, "Are the Courts Excessively Deferential to the Medical Profession?" (2001) 9(1) *Medical Law*

Review 1).

Bolitho thus provides the court with the ability to engage with the doctor's conduct in a critical way, and this is vital if we are to protect patients.

A fundamental issue with this Bill is that, in a way that is similar to the pre-*Bolitho* legal position, it assumes that the doctor's analysis and decisions are correct. There is nothing included within to protect patients from overconfident doctors or those whose reasoning is flawed. Moreover, it does little to protect patients - which in a post-Francis Report atmosphere is something of an omission.

At the very least, safeguards for patients need to be incorporated into the Bill.

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.

No - this is the most concerning section, in particular s.1(3)(b). There seems to be an assumption that the doctor wishing to perform innovative treatment is right, and that the profession is wrong not to support her. But, as I mention above, what if the doctor's analysis is flawed, wrong, or over-hopeful? It is even more concerning that s.1(5) can be satisfied by the doctor concerned merely "considering" the factors. There appears to be little requirement that she is actually fully right. Moreover, and again as mentioned above, surely the fact that the profession does not support the doctor's analysis should give that doctor (and a court) a reason to wonder whether the proposed treatment is right at all.

The solution to this can be found in the existing common law. In the case of *Clark* v *MacLennan* [1983] 1 All ER 416 the court was faced with a scenario that might well occur if this Bill were to become law: a doctor performed an operation on a patient 4 weeks after she gave birth rather than 12 weeks. The doctor could find no others that might have done as he did. The judge suggested that while this would not necessarily demonstrate a breach of duty, the lack of professional support should essentially act to reverse the burden of proof, and it would be for the doctor to convince the court of why the conduct was reasonable rather than for the claimant to convince it that it was not. Making this change would at the very least introduce safeguards for patients that are not currently included in the Bill.

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?

As mentioned above, I feel that the requirement in s.1(5) that the factors need only be "considered" is too weak and assumes that the doctor is correct in her analysis and that others are wrong if they do not support her. I would like to see a far stronger requirement for a doctor to justify departing from what would be the usual treatment.

Also, and again as I mention above, the wishes/consent of the patient cannot really be considered as too reliable an indicator as they would be fundamentally informed by what they were told by the doctor who is proposing the treatment. This can too easily therefore turn into less an exercise in collaborative decision-making and more a case of a patient being led into consenting to a procedure different from the norm due to an enthusiastic or misguided doctor, possibly using flawed clinical reasoning.

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?

These demonstrate the superfluous nature of this Bill - if the doctor complies with this then under the current law she will not be liable in negligence.

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

No.

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

As mentioned above, I do not think that enough thought is given in this Bill to the need to protect patients from flawed decisions by innovative doctors. There is also no sense at all in the Bill that some innovation may not be responsible. For example, there is nothing in the Bill that states that innovation may only be necessary when the established treatments are imperfect.

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

While it is clear that the cost of medical negligence has risen, there is no suggestion, in my view, that this is due to a lack of innovation or that it justifies allowing doctors more discretion. Indeed, the reasons that *Bolitho* was so necessary should not be forgotten (for a flavour of what the law used to be like see I. Kennedy, *Treat Me Right: Essays on Medical Law and Ethics* (Oxford University Press, 1990)). In my view this Bill contains far too few safeguards for patients.

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

Yes / Yes with modifications outlined in response to questions 3-5 / Yes with other modifications (please specify) /No

No.

We also welcome any other comments you wish to make.

While I understand the point that Lady Butler-Sloss was making in relation to *Bolam* stifling innovation, I would respectfully disagree with her. As I mention above, *Bolam* should not be interpreted in this way - and courts have not done so. For example, I would point out that this is not a view shared by Lord Diplock, who said precisely the opposite in the House of Lords in the case of *Sidaway* v *Board of Governors of Bethlem Royal Hospital* [1985]

> "Those members of the public who seek medical or surgical aid would be badly served by the adoption of any legal principle that would confine the doctor to some long-established, well-tried method of treatment only, although its past record of success might be small, if he wanted to be confident that he would not run the risk of being held liable in negligence simply because he tried some more modern treatment, and by some unavoidable mischance it failed to heal but did some harm to the patient. This would encourage "defensive medicine" with a vengeance. The merit of the Bolam test is that the criterion of the duty of care owed by a doctor to his patient is whether he has acted in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion. There may be a number of different practices which satisfy this criterion at any particular time. These practices are likely to alter with advances in medical knowledge. Experience shows that, to the great benefit of human kind, they have done so, particularly in the recent past. That is why fatal diseases such as smallpox and tuberculosis have within living memory become virtually extinct in countries where modern medical care is generally available."

I would argue that there is nothing in this Bill that is not covered by the existing common law, and that the Bill goes too far the other way and thus offers insufficient protection to patients. The reasons for the changes in the law brought by *Bolitho* and, for example, the Mental Capacity Act 2005 should not be forgotten so quickly. In both of these cases, the law was amended to put the protection of patients at the heart of the system, and this Bill comes to close to being a regression from that.

I am certainly not against medical innovation, but do not think that this Bill represents the correct way of encouraging responsible innovation.

About me:

I am a Professor of Medical Law at the School of Law, University of Leicester. I have published widely in the field, including articles on *Bolam* and *Bolitho* (see, for example, "Bye Bye *Bolam*: A Medical Litigation Revolution?" (2000) 8 (1) *Medical Law Review* 85 (with Prof Margot Brazier)).

I am the commentaries editor of the *Medical Law Review*, and serve on the editorial boards of *Clinical Ethics* and *UKCEN*. My full profile and publications list can be found at: http://www2.le.ac.uk/departments/law/people/jose-miola.