

Legislation to encourage Medical Innovation – a Consultation

This is the response of the NHS Litigation Authority (NHS LA) to the above consultation published by the Department of Health.

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

We do not. However, we are aware of innovation on the part of individual clinicians. For example, various types of metal-on-metal hip replacement were invented by particular surgeons and the ideas were then sold to commercial companies for development. Also, we know of cases where drugs are used by NHS clinicians off-licence when doctors consider that their prescription will be beneficial for individual patients.

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?*

We do not. The General Medical Council provides guidance for clinicians on topics such as consent and research. Further, our view is that the decision in *Bolam* has stood the test of time for over 50 years and has been applied across all categories of professional negligence claim, not merely to cases involving clinicians. The ruling in *Bolam* is very clear and we note that the draft Bill does not seek to overturn it. Support from a responsible body of medical opinion, for *Bolam* purposes, need not be widespread in extent. We know of cases in which the judge concluded that because one eminent expert witness supported the particular treatment at issue, that constituted a responsible body of medical opinion for *Bolam* purposes.

The cover provided by NHS LA under various schemes we administer on behalf of the Secretary of State for Health, in particular CNST (Clinical Negligence Scheme for Trusts) applies whenever innovative treatment is provided by NHS staff in the course of their employment with one of our members. In other words, innovating doctors are covered for professional negligence purposes via the trust's membership of CNST, and we do not withdraw indemnity simply because innovative treatment has been given. NHS clinicians can therefore be assured that their liabilities will be met by NHS LA in these circumstances.

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 believe that this clause, as drafted, is problematical because (3)(b) envisages that responsible innovation could occur even where the proposed treatment “does not or would not have” support from a responsible body of medical opinion. This wording arguably places too great an emphasis upon the opinion of the individual doctor involved. There is no reference to research or to peer review. Both are essential considerations in our view.

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?*

We query use of the phrase "plausible reasons" in (4)(a), because it is not defined and appears to place too great an emphasis on a subjective judgment by the doctor in question. Again, there is no reference to either research or peer review.

We do not fully understand the significance of "opinions or requests expressed...in relation to the patient" under (5)(d). Such opinions could, for example, be those of relatives but in the case of a patient who has capacity, the patient must have the final decision in terms of consent.

We particularly question (5)(e) because this is too subjective in our view. In other words, it is stated that only opinions expressed by colleagues "whose opinions appear to the doctor to be appropriate to take into account" should fall for consideration when determining whether or not a responsible decision has been undertaken. It may well be the case that a valid and relevant opinion from a doctor who disagrees with the clinician proposing treatment is particularly pertinent, but if the proposing doctor has fallen out with that clinician or has strong professional disagreements with him/her, then that second opinion on the present wording does not have to be taken into account. We believe this to be inappropriate.

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?*

We believe that Clause 1(7) as presently drafted is too liberal because the various factors listed only "may be taken into account" when determining whether a responsible decision has been taken. We consider that (7)(a) and (b) are both essential considerations in the process. In relation to (7)(c), we believe that this formulation likewise is too liberal because it uses the word "notification" rather than requiring that the doctor seek permission from his/her responsible officer, which in our view would constitute an improvement to the governance arrangements surrounding innovative treatments. Another factor which might usefully be included in this section is the policy of the doctor's employers on the procedure to be adopted when proposing innovative treatments.

6. *If the draft Bill becomes law, do you have any views on the best ways to communicate its existence to doctors?*

We would suggest via the GMC.

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

We are grateful to note the reference to our safety and learning service in paragraph 3.25 of the consultation. Additional factors which we would recommend are: central registration of all innovative treatments; and a duty on clinicians to report upon the outcome of such treatments.

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

Yes. On page 26 in the box entitled “other key non-monetised benefits by main affected groups”, under (c) it is suggested that there will be a “reduced number of clinical negligence claims as a result of less ambiguity over when it is appropriate to try out an innovative treatment”. This may be the case in the long term, but in the short term there is likely to be litigation on the meaning of individual words and phrases in the Act, should the Bill be passed.

On page 29 in paragraph 20, we believe that this point is picked up although it is described as “‘test case’ legislation”. We believe that the word “legislation” was intended to read “litigation”.

9. *Overall, should the draft Bill become law?*

Our broad view is that existing case-law caters appropriately for cases of innovative treatment. However, the Bill could be beneficial were it to be modified as we have indicated in our responses to questions 3-5; and therefore of the four options given for responses to this question we select the second.