NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE
Response to consultation questions on the Medical Innovation Bill

Summary points

The consultation document on the Medical Innovation Bill rightfully highlights the important balance between encouraging appropriate testing of new treatments, and safeguarding patients from risky, potentially harmful experimentation. NICE is very supportive of initiatives to encourage innovation and also mindful of the need to protect patients from harm. With this balance in mind, there are four main points to emphasize, detailed below.

- NICE has not been made aware of any evidence that doctors are deterred from appropriate innovation by fear of litigation. We are aware, however, of many examples where doctors are successfully innovating under the existing law. This consultation may uncover concern that fear of litigation exists as a deterrent but, if not, further investigation into this issue would make the case for change more robust.

- Within the current law there are two key factors that determine the lawfulness of any medical treatment: whether the patient has given informed consent to the treatment; and the over-riding duty on doctors to act or make recommendations on the basis of the patient’s best interests.

- Introducing new legislation that makes it easier for doctors to try new treatments, without evidence that doctors are deterred by fear of litigation, may therefore pose a potential risk to patients of inappropriate experimentation.

- To support the need for ongoing innovation to identify and disseminate new treatments that improve outcomes for patients, NICE would recommend that this is encouraged within the existing legal framework. Mechanisms for stimulating innovation might include:

  o facilitating opportunities for research through formal trials, for example by better access to information and better funding

  o improved data collection about innovative treatments through an expansion of registries and other methods for ongoing data collection.

  o An online portal, perhaps supported by an expert advice service, to provide doctors with information about potential new treatments and current evidence to underpin them;
If there is felt to be a particular uncertainty around appropriate treatment options at the end of life or where standard treatments have been ineffective, guidance could be developed by the GMC to assist clinicians. This is also an issue which potentially may be covered within Clinical Guidelines on particular conditions.

Responses to specific questions

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

In the range of work that NICE undertakes to support the uptake of innovative technologies, we have not been made aware that fear of litigation is deterring doctors from innovation. We are always clear with practitioners that, while guidelines reflect the best evidence, they should not be rigidly followed with every patient, irrespective of differing clinical conditions and individual circumstances.

A review of the published medical literature, searching all the main databases, identified no reports that doctors are deterred from innovative practice by fear of litigation. One publication from 2008 highlighted the approach that surgeons should follow to introduce innovative techniques within the current legal framework.¹

We are aware, however, of the risks to which patients are exposed when they do not receive effective, evidence-based treatments. It is important that vulnerable patients are protected from this risk, while also being given the opportunity to try innovative new treatments. Careful consideration should therefore be given before introducing new legislation that might inadvertently increase the risk of harm to patients.

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?

NICE has not received any information to suggest that doctors are uncertain about how to innovate safely because of the risk of litigation. Where there is uncertainty about the process, we are aware that doctors seek advice from their defence society to understand how to test new treatments within the existing legal framework. The current system provides safeguards for patients from inappropriate treatment, and protects doctors from the risk of litigation should patients consider they have been put at risk by inappropriate treatments.

To ensure doctors are not confused about how to innovate within the current legislation, the mechanisms could be clarified and communicated to the profession through a number of routes, including GMC advice, Royal Colleges and through the NICE website.

**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 consider that clause 1(3) may put patients at significant risk of inappropriate innovation. Clause 1(3), by effectively removing the Bolam test, takes away an important mechanism for protecting patients from poor medical care. The Bolam test has been important in many legal cases of poor practice, none of which relate to anything that could otherwise be described as 'appropriate innovation'.

Clause 1(3) also appears to be at odds with 1(4)(a), as it is unlikely that there would be plausible reasons why a treatment might be effective, as set out in (4a), where the proposed treatment would not have the support of a responsible body of medical opinion (as described in 3a). If a treatment is plausible, this would – by default – be recognised by others in the profession.

Essentially clause 1(3), when put together with clauses 1(4) and 1(5), indicates that a doctor is to be protected from a negligence claim as long as he can claim a genuine belief that there are plausible reasons for thinking that a treatment would be effective and has considered the factors set out in clause 1(5) – even if his belief is unreasonable and his analysis of the relevant factors is of poor quality and below what would generally be expected of a clinician in his position.

**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?**

The points covered in Clause 1(4a) and (5a-d) are sensible factors to consider within the context of appropriate innovation. These factors can, however, be considered by doctors within the existing legal framework. In addition, as indicated in response to question 3, while these are sensible factors to consider the Bill contains no requirement for the doctor's analysis of the factors, or the conclusions he draws from consideration of them, to be reasonable or of an appropriate standard.
Clause 1(5e) puts patients at risk as it allows a doctor to disregard any other doctor's opinion. This other opinion could be extremely well-informed, but be disregarded if the opinion does not 'appear to the doctor to be appropriate to take into account'. This is potentially very dangerous and provides no safeguards to the patient.

**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 as set out is clear, and reflects the process that would be expected – and possible – **within the current legal framework**.

It is unclear, however, how point (7b) about making a decision within a multi-disciplinary team, sits alongside previous clauses that do not require input or approval from any other colleagues?

While it may be thought that the requirements for transparency mitigate risks to patients from doctors pursuing innovation inappropriately, we do not consider that transparency alone is sufficient protection. It places too great an onus on the patient to object and to identify themselves deficiencies in the doctor's reasoning.

**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 would need to be communicated primarily via the GMC, as the regulatory body, and by the Medical Defence Societies.

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

There are activities that can – and should – happen **within the existing legal framework** to encourage responsible innovation. Support for the areas indicated below would be very welcome, within the existing legislation, to facilitate responsible innovation:

- Mechanisms for appropriate data collection, such as registries, and more support to facilitate the development of clinical trials
- Development of an appropriate consent form by the GMC
• An online resource providing advice on potential new treatments to support doctors in finding potential new treatments, and to facilitate sharing of information and support.

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

No further suggestions.

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

Legislation is matter for Government, but the consultation document presents a weak case in favour of it. NICE would recommend that further research into doctors’ attitudes to treatments with no or inadequate evidence of safety or effectiveness should be undertaken before proceeding further.

In any event, the draft Bill has been very helpful in stimulating discussion in this area, and support (as indicated above) to facilitate innovation within the existing legal framework would be extremely welcome.