

## Legislation to encourage medical innovation – a consultation

### British Medical Association response

#### Executive Summary

This consultation is about proposed primary legislation to liberate doctors from perceived restrictions on their ability to treat patients with innovative treatments under current medical negligence law. The BMA strongly believes that this Bill should not become law and, for the reasons outlined in this response, does not believe that primary legislation which focuses on redefining clinical negligence is the best mechanism to promote or encourage responsible innovation, should there be a need to do so, when other more suitable alternative approaches exist. The draft Bill is therefore unnecessary, risks removing important protections for patients and could encourage reckless practice, with attendant risks for patient safety. Our detailed justification for this position is below.

#### Introduction

The British Medical Association (BMA) is an independent trade union and voluntary professional association which represents doctors and medical students from all branches of medicine all over the UK. With a membership of over 153,000 worldwide, we promote the medical and allied sciences, seek to maintain the honour and interests of the medical profession and promote the achievement of high quality healthcare.

The BMA welcomes the opportunity to respond to the Department of Health consultation on proposed legislation to encourage medical innovation. The BMA believes that the best mechanism through which medical science can advance is through well-regulated research and clinical trials. However, it can still be necessary for doctors to explore non-standard treatments with their patients and innovate outside of a research context. Interventions may not be suitable for full scale clinical trials and not all patients will meet the criteria for enrolment in clinical trials for a new drug or procedure. If there is sufficient justification to believe an untested or unlicensed treatment could be beneficial, doctors should be confident in pursuing these with patients where clinically indicated and in their best interests.

We have no evidence to suggest that the threat of litigation is a barrier to the provision of innovative treatment of this kind and we strongly question the necessity and desirability of introducing statute to clarify or change the law in this area. As no concrete examples of proposals for beneficial treatment being prevented by the threat of litigation have been provided, it is difficult to understand why a change in the law is required and in turn difficult to assess whether the proposed Medical Innovation Bill would be a positive development.

Where it is necessary to pursue innovative treatments and it is not practical to follow a research pathway, doctors are required to act in the best interests of their patient; follow the detailed guidance from the General Medical Council (GMC), particularly on consent; maintain good communication throughout the process; and document their actions fully. It is clear that treatment which is outside of standard practice can be provided in these circumstances and doctors are prepared to explore these options with their patients under the law as it stands. The *Simms vs Simms*<sup>1</sup> judgment itself showed that even risky, innovative treatment, for which there was minimal evidence of effectiveness and which had not been tested on human beings, can be allowed provided it is in the best interests of patients.

The BMA has received anecdotal reports from members that funding requests for innovative treatment are submitted and approved, often on condition that the results will then be distributed, adding to the wider body of medical knowledge.

If the Government's aim is to encourage medical innovation, the BMA believes the focus on negligence is misguided and may send the wrong message to patients. The threat of litigation, alongside other checks on a doctor's conduct like GMC guidance, can act as deterrents to reckless or unsafe practice. Implementing legislation which changes negligence law risks diluting this deterrent effect and the detail of the draft Bill is a concern in this respect. It focuses on the process of decision making rather than the

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<sup>1</sup> *Simms vs Simms; A vs A* [2002] 2 WLR 1465; [2003] 1 All ER 669.

outcome for patients and, in contrast to the current test of medical negligence, places considerable emphasis on individual opinion and subjective analysis, rather than on the validation of a decision from medical peers. Focusing on negligence also fails to acknowledge other barriers to doctors developing and exploring innovative treatments and offering them to their patients, including funding, being allowed the time to undertake the necessary studies, and the various approvals processes.

The BMA believes strongly in the value of innovation in medicine. Whilst the BMA would have concerns if the draft Medical Innovation Bill was to become law, if there was a need identified, we would support the exploration of other initiatives through which responsible, safe and effective innovation can be promoted to doctors. Alternative means through which a culture of innovation could be encouraged may include specific professional guidance, greater expansion of clinical ethics committees or similar support mechanisms, and the creation of registers of novel clinical experience. In the BMA's view, if a need exists and doctors require additional support, these would be better options to explore in the first instance and may achieve the underlying aims of the Bill and incorporate important provisions for public transparency and accountability, without recourse to unnecessary and inflexible primary legislation.

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

***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?***

The BMA is not aware of any evidence which shows that the possibility of litigation deters doctors from pursuing innovative treatments or that uncertainty exists over the circumstances in which a doctor can safely innovate without fear of litigation.

It is worth noting however that even if such evidence is available, this would not necessarily provide justification for the implementation of the draft Bill. If it were the case that the possibility of litigation deterred some doctors from deviating from standard practice, it does not follow that the law is at fault or that all claims to pursue non-standard treatment are equally justified. The law as it stands may, quite rightly, deter doctors from pursuing treatment that would harm their patient without sufficient probability of benefit and would not have the backing of other doctors. The BMA would caution against diluting this protection without good reason. Similarly, it may be the case that some doctors are unclear about how the relevant case law applies to their practice. Again, it does not necessarily follow that the law itself is unclear or needs to be changed. A more appropriate solution would be to provide information and guidance for doctors to improve their understanding and to encourage them to innovate responsibly within the law as it stands.

***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.***

The BMA has significant concerns with the inclusion of clause 1(3) and in particular clause 1(3b).

The Bolam and Bolitho cases, on requiring logically based support from a responsible body of medical opinion, emphasised the importance of gaining independent peer validation of a proposed course of action. In contrast, clause 3(b), in stating that the bill applies where "the proposed treatment does not or would not have such support" arguably allows treatment to be provided not only in circumstances where medical science is "silent" on a proposed treatment but also circumstances where the treatment would be contrary to all medical opinion. For the BMA this opens up the possibility that a patient could be exposed to treatment which is of no clinical value and would have no redress under the Bill, provided a doctor could show they had "ticked the boxes" by considering the processes it sets out.

The "Evidence base" section in the consultation document acknowledges this concern, identifying the "potential inappropriate use of the proposed legislation, if doctors engage in clinically inappropriate or risky behaviour without sufficient justification" but states that this risk is mitigated through the requirement for doctors to meet certain requirements before undertaking innovative treatment, referring

specifically to factors doctors are required to consider under clauses 1(4) and 1(5). As we discuss in more detail below, the BMA is not convinced that these clauses provide sufficient protection to patients. The draft Bill also requires, in clause 1(8b), that doctors must act in the best interests of patients. While the emphasis on this important consideration is welcome, it is not clear how it applies in the context of the Bill. If the reference to “best interests” only requires the doctor to justify that, in her or his own judgement, she or he was acting in a patient’s best interests, then it is not clear that this provides any safeguard for patients and serious concerns about inappropriate treatment being provided under the Bill remain. If this clause is intended to refer to a consideration of what would be objectively in the best interests of a patient, this would arguably require the type of peer review required under Bolam and therefore highlights a potential circularity.

The BMA also questions that the circumstances described in clause 1(3a), where a doctor is unsure that a proposed course of action has or would have the support of a responsible body of medical opinion (and therefore meets the Bolam test), cannot be accommodated under the current law. If a doctor was genuinely uncertain whether a treatment would be supported by other doctors, it would be best practice for the doctor to discuss the issue with colleagues or peers who may have relevant expertise (the need to consult colleagues in this way is specified in the draft Bill). If after these discussions it was evident that even a minority of other colleagues and experts agreed that the proposed course of action was appropriate and in the best interests of the patient, then the doctor would have met the criteria for the Bolam test and, provided the patient gave his or her informed consent, the treatment could go ahead. If consultation with medical colleagues reveals to the doctor that there would be no medical support for a decision to pursue a particular treatment, it would be highly questionable that a doctor should, in the face of this opposition, pursue the treatment. If the Bolam test can be met in this way, by following best practice, it is not clear what additional clarity or reassurance the draft Bill provides in these circumstances.

**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 aim of these clauses is to set out factors which the courts and doctors can consider in assessing whether a decision to “innovate” is responsible and therefore not negligent. As the consultation document states, these factors are based on best practice and are intended to provide safeguards under the draft Bill for patients. There are inherent disadvantages to attempting to codify best practice in this way and it is not clear in this instance that it is possible, desirable or necessary.

For the BMA, best practice should be described in professional guidance. It is our understanding that, where there is no body of medical opinion, a court would currently be expected to refer to what is “reasonable” in the light of all relevant facts and circumstances and, as the consultation document points out in 3.11, could be expected to look to medical best practice to assess whether a doctor has acted negligently. This could include reference to published guidance from medical bodies such as the GMC. Current guidance from the GMC already sets out some of the obligations on doctors which feature in the draft Bill. In *Consent: patients and doctors making decisions together*, for example, the GMC refers to the need to take account of patients’ needs, wishes, priorities and their understanding of the treatment and condition.<sup>2</sup> The guidance also requires doctors to inform their patients whether a proposed treatment constitutes research or is innovative treatment designed specifically for their benefit.<sup>3</sup> In *Good medical practice*, doctors are obligated to provide effective treatments based on the best available evidence and to consult colleagues where appropriate.<sup>4</sup>

As there is existing guidance that doctors are obligated to follow, and to which the courts could refer, the BMA questions the necessity or benefit of duplicating this in statute. Compared to guidance, primary legislation is inflexible and difficult to amend once enacted. It is also unlikely that a Bill of this kind will ever be able to provide sufficient detail or nuance to adequately describe how doctors should approach

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<sup>2</sup> General Medical Council (2008) *Consent: patients and doctors making decisions together*. London: GMC, para 7.

<sup>3</sup> General Medical Council (2008) *ibid.* para 9.

<sup>4</sup> General Medical Council (2012) *Good Medical Practice*. London: GMC, para 16.

decision making, particularly in the challenging circumstances to which the draft Bill applies, so as to provide any real protection for patients or support for doctors. If a need to clarify or provide additional best practice advice is identified, this should be done through professional guidelines rather than statute.

The BMA also has specific concerns with the detail of clauses 1(4) and 1(5). It is not clear what weight, if any, a doctor needs to give to the factors listed in these clauses. The wording in the Bill also places significant emphasis on a doctor's individual viewpoint. For example, clause 1(4a) states that a responsible decision is one which is based on the doctor's own opinion that "there are plausible reasons why the proposed treatment might be effective". Plausibility, without any reference to a research or evidence base, or sound reasoning from first principles, is a weak criterion by which to judge a medical intervention, particularly one which may involve significant risk to a patient. This could allow doctors to justify a decision to pursue a treatment based on reasoning which was not scientifically or logically robust. Similarly, clause 1(5e) requires doctors to consider the "opinions or requests expressed by colleagues whose opinions appear to the doctor to be appropriate to take into account". The BMA has a number of concerns with this clause. As it only requires a doctor to "consider" such views it raises the possibility that he or she could ignore the views of colleagues who might vehemently disagree that the proposed course of action was justified. It also allows doctors to consult whomever they believe to be appropriate, which could in reality just be colleagues who agree with their viewpoint, arguably making the process redundant and offering no protection to patients. As footnote 9 in the consultation document acknowledges, there is no requirement that these colleagues are medical colleagues. This could mean that a doctor could ask any colleague for their opinion, irrespective of their training, impartiality or relationship with the doctor, and meet this requirement in the Bill. Other sub-clauses in this section, which reference the consideration of the likely success rates of different treatments and the likely consequences of carrying out a proposed treatment compared to another or no treatment, specify that the decisions made must be in the "doctor's reasonable judgment", but what is "reasonable" in this context is not defined in the Bill.

***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?***

Clause 1(6) states that decisions regarding treatment must be made in accordance with a process which is accountable, transparent and allows a full consideration of relevant factors. The consultation document explains further that the reference to "accountable" in the clause "is intended to ensure that the doctor's decision involves internal professional accountability, such as creating an audit trail that could be examined by other doctors". Whilst the BMA agrees with these statements, they would apply to all clinical decisions, not just those that involve innovative treatment. Given that these considerations, along with the key factors covered in 1(7), are covered by more detailed best practice guidelines published elsewhere it is not clear what the purpose or benefit is of including them in legislation of this kind.

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

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

The BMA does not believe that the draft Bill should become law. If a need to encourage innovation has been identified, there are other, non-statutory, approaches which can be explored to support doctors in pursuing innovative treatment with their patients.

Exposing patients to innovative treatments is likely to engage a greater range of ethical and legal issues and concerns than pursuing standard treatments. Unlike in a research context, where protocols for testing new interventions are assessed by research ethics committees and the conduct of trials is strictly regulated, often the decision to pursue experimental or unproven treatment may be down to the professional judgement of an individual clinician or clinical team. It may be the case that support and guidance is required in making this decision or advice on any potential legal and ethical implications it may have. Some hospital trusts have clinical ethics committees which may perform similar functions to this at present, although the role of these committees is not standardised and their constitution and

functions can vary nationwide. Ensuring doctors have access to this type of support service could help doctors in making decisions on treatments which deviate from standard practice should they require it.

A key issue which neither the consultation document nor the draft Bill addresses is the importance of disseminating the findings from individual instances of innovative practice to other doctors and researchers. The Nuffield Council on Bioethics, in its inquiry into the ethical and practical issues associated with the use of novel neurotechnologies, recommended that professional bodies work together to establish “registers of clinical experience” to capture and publically disseminate the learning from single-patient interventions and small scale studies.<sup>5</sup> Although this recommendation was specific to the innovative or experimental use of neurotechnology, this option may be worth exploring for other types of intervention. Such registers could play a dual role. Recording the experiences of doctors and patients, any side effects experienced and the success or otherwise of the intervention, could be used to generate an evidence-base to inform future research studies. Making this information publically available would also allow other doctors to use the evidence-base in making decisions for their own patients and show that others are innovating in these areas.

Finally, there may be other practical barriers in the organisational, educational and economic context in which doctors make decisions that may inhibit the pursuit of innovative treatment and would need to be addressed to help ensure innovation is an integral part of medical practice. Issues include workforce capacity, the quality of facilities available in different organisations and, crucially, the availability of funding for such treatments.

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

The BMA has no comments to make on these documents.

***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**

The BMA strongly believes that the draft Bill should not become law and, for the reasons outlined in this response, does not believe that primary legislation which focuses on redefining clinical negligence is the best mechanism to promote or encourage responsible innovation.

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<sup>5</sup> Nuffield Council on Bioethics (2013) *Novel Neurotechnologies: intervening in the brain*. London: NCB, p.113-114.