Parliamentary brief
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BMA

Access to Medical Treatments (Innovation) Bill
Second reading
Friday 16 October

About the BMA

The British Medical Association (BMA) is a voluntary professional association and an independent trade union which represents doctors and medical students from all branches of medicine all over the UK. With a membership of over 154,000, 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.

Executive Summary

- **The BMA believes this Bill is unnecessary. In particular, the sections of the Bill which focus on negligence and "responsible innovation" are counterproductive and are not based on any felt need from the medical profession.**

- **We have concerns that the Bill seeks to establish a database to record innovative treatments without first exploring the need for such a measure or considering the risks or benefits this entails. We also seek further clarification on how such a database will operate in practice.**

- **We are not aware of any evidence to suggest that the threat of litigation inhibits innovation or that confusion exists amongst doctors over the circumstances under which they can deviate from standard practice.**

- **Common law currently allows doctors to deviate from standard practice and provides protection for patients and doctors. Recent legislative proposals add nothing of value to the current law – rather, they increase bureaucracy and could create confusion, which may have implications for patient safety.**

- **If there is a need for additional support for doctors, this should be achieved through professional guidance capable of responding to changing circumstances rather than statute.**

Introduction

Innovation – the identification of new treatments and the development of new procedures - is at the heart of what it means to be a doctor. We believe that the best mechanism to advance medical science is through well-regulated research and clinical trials. However, it can still be necessary and beneficial for doctors to explore non-standard treatments with their patients and innovate outside of a research context. 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 therefore welcome the sentiments behind the ongoing debate around encouraging medical innovation but do not believe that this legislation will achieve this.

The Bill is made up of two components – one enables the creation of a database of innovative medical treatments, and the other is a legislative pathway for doctors to 'innovate' by departing from the existing range of medical treatments. The stated aim of the Bill is improving access to innovative medical treatments.

We have concerns about the creation of a database for innovative treatments and the safeguards it will have. There are no plans for the information and innovative treatments to be quality assessed or peer reviewed. The inclusion of events on a database may give the impression that they are approved or have been given some form of endorsement for use again. This may lead to the inappropriate use of a treatment. Further it is not clear what safeguards will be in place ensure that all patient data is anonymised.

We oppose the creation of a legislative pathway for doctors to 'innovate' by departing from the existing range of medical treatments. The current law allows doctors to innovate and successfully defend a claim of negligence provided they can show their actions were supported by a reasonable body of medical opinion (the 'Bolam Test'[1]) and are logical (The Bolitho Test'[2]). Doctors should act in the patient's best interests, follow General Medical Council (GMC) guidance, particularly on consent, and document their actions fully. This provides adequate protection to doctors and patients.

Establishing a database of innovative treatments

Clause 2 of the Bill would enable the Secretary of State to direct the Health and Social Care Information Centre (HSCIC) to establish and maintain a database of innovative treatments and results. We believe it is important for the findings from individual instances of innovative practice to be disseminated to other doctors and researchers. Where it exists, information of this kind, whether positive or negative, has the potential to help generate an evidence-base to inform future research studies, be used by other doctors in making decisions with patients about potential treatment options, and show that others are innovating in these areas.

We believe there may be merit in exploring whether there is a need for a database, or similar, to record information and the benefits and risks this might entail. However, we question the need for a Bill to enable the establishment a database of this kind before these discussions have taken place. If there is a need to establish a database, and we are not convinced there is, it is not clear that this would require primary legislation.

Whilst the Bill provides very little details of how the database would work in practice, we have some initial concerns.

We would like to seek clarity on what information would be included in a database and whether it could include any identifiable data (or data which might enable identification). It is our understanding from discussions with the sponsor of the Bill that it has been acknowledged that it may not be possible to guarantee full patient anonymity. This raises a number of concerns about patient confidentiality on which the BMA requires assurance. In particular, we require clarity on the access arrangements to the information and confirmation that its use would be restricted to doctors and researchers for medical innovation within a robust governance framework which must, for example, exclude companies which might wish to target patients for commercial reasons.

We also seek clarity on whether there would be any obligation on a doctor to provide information to the database. The Bill sponsor has indicated that would be up to the Secretary of State for Health to decide on this.

Innovative treatment is defined in the Bill as that which "involves a departure from the existing range of accepted medical treatments for the condition". This is very broad. There is no indication that the information on innovative treatments will be quality assessed or peer reviewed. The inclusion of events on a database may give the impression that they are approved or have been given some form of endorsement for use again. The inclusion of such treatments on the database may therefore undermine its utility and where inappropriate treatments are recorded and used this could represent a risk to patient safety.

The threat of litigation as a barrier to innovation

One of the reasons given for requiring primary legislation to encourage doctors to innovate responsibly is that doctors do not currently do so out of fear of litigation. Clause 3 sets out in legislation that a doctor may lawfully divert from standard practice providing certain conditions have been met.

The BMA is not aware of any evidence that the threat of litigation prevents doctors from innovating (and therefore there is no evidence that new legislation will have a positive effect) or that there is confusion or a lack of clarity in the current law. Other bodies that also had no evidence of this include: the Medical Defence Union[3], the National Institute for Clinical and Health Excellence[4] and the medical Royal Colleges[5] alongside notable individuals such as Sir Robert Francis QC.[6]

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. It is worth noting that 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. If confusion or concerns did exist regarding the current law and how it would be applied, the appropriate and most effective means of addressing is through guidance not primary legislation.

We strongly question the necessity and desirability of introducing statute to clarify or change the law in this area. We are also unconvinced that uncertainty exists over the circumstances in which a doctor can safely innovate without fear of litigation.

Current avenues for innovation outside a research pathway

Where it is necessary to pursue innovative treatments and it is not practical to follow a research pathway, doctors are already required to:

- Act in the best interests of their patient
- Follow the detailed guidance from the GMC, particularly on consent
- Maintain good communication throughout the process
- Document 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 *Bolam*[7] and *Bolitho*[8] cases require a doctor to show that their decision has logically based support from a responsible body of medical opinion to successfully defend a claim of negligence – taking into account an objective assessment of what is reasonable in all facts and circumstances.[9] The BMA has no evidence to suggest that this legal test represents a barrier to innovation. Recent case law has shown that the courts have not held a decision to provide

innovative therapy to be negligent provided the doctors have weighed up the available options and the decision could be reasonably and rationally supported.[10] The *Simms vs Simms*[11] judgment 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.

Common law allows for doctors to deviate from standard procedure where a course of action would have logical support from a responsible body of medical opinion.

Responsible innovation and negligence

The explanatory notes to the Bill states that it "seeks to offer clarity for doctors in advance of offering innovative treatment about the steps that they need to take to demonstrate that the decision to innovate was taken responsibly". The Bill therefore aims to codify best practice and legislate for the exercise of judgement with respect to innovative treatment. For the BMA, best practice should be defined in professional guidance. Primary legislation is a crude tool to do this, inflexible and difficult to amend once enacted.

The Bill, mirroring the common law test in *Bolam,* includes a requirement for doctors to seek the views of one or more appropriately qualified doctors with a view to ascertaining whether it would have the support of a responsible body of medical opinion. As the Bill is not intended to affect the common law defence of negligence, the BMA would question the merit of duplicating this in statute. Furthermore the common law also requires, as per the judgment in *Bolitho*, that the decision to provide treatment is logically defensible. This is absent from the Bill as drafted and therefore represents a weaker form of protection for patients than that described in the common law.
We believe this section of the Bill risks creating unnecessary confusion over the circumstances under which doctors are able to pursue "innovative" treatments. This would not only be counter-productive to the Bill's aim of encouraging innovation but could also have implications for patient safety.

If a need to clarify the current law or provide additional best practice advice is identified, this should be done through professional guidelines, rather than statute.

For further information, please contact:

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References

[1] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582
[2] *Bolitho v. City and Hackney Health Authority* [1997] 4 All ER 771
[3] Medical Defence Union, Response to consultation on Medical Innovation Bill
[4] Department of Health, Report on the consultation on the Medical Innovation Bill: summary of responses and next steps, p13
[5] Department of Health, Report on the consultation on the Medical Innovation Bill: summary of responses and next steps, p12
[6] Sir Robert Francis QC, Comments on the Medical Innovation Bill
[7] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582
[8] *Bolitho v. City and Hackney Health Authority* [1997] 4 All ER 771
[9] See also: *Hunter vs Hanley* [1955] SC 200
[10] Duffy v Lanarkshire Health Board 1998 SCLR 1142, 1999 SLT 906, OH
[11] *Simms vs Simms; A vs A* [2002] 2 WLR 1465; [2003] 1 All ER 669.