Access to Medical Treatments (Innovation) Bill
House of Lords, Third Reading
Tuesday 22\textsuperscript{nd} March

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 170,000, 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.

Key points
- The Bill seeks to ‘promote access to innovative treatments’ by establishing a ‘database of innovative medical treatments’, and enabling access to that information for ‘specified persons’.
- We welcome the removal at Report stage in the Commons of previous clauses 3 and 4 on medical negligence, which would have created an unnecessary and problematic additional legal framework for doctors.
- In principle, a database or similar means of recording innovative practice and disseminating information and evidence about treatments is a measure which is worthwhile exploring as a means of encouraging and supporting innovation.
- However, we have concerns about the Bill’s intention to legislate for a database without first identifying the purposes of the database and ascertaining whether it would meet those agreed purposes. We acknowledge the Government’s commitment to further clarify and refine the purpose, design and stewardship of the database “following the Bill’s enactment”, if it were to become law.\textsuperscript{3} However, we believe that these points, and other concerns about patient safety and quality assurance, should be considered and consulted on before any decision is taken to establish a database.

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, therefore, welcome the ongoing debate on how best to encourage medical innovation, but have been unconvinced that the Bill has met this objective.

The BMA believes that other measures should be adopted to facilitate medical research and innovation in the NHS. These include breaking down bureaucratic barriers to clinical trials and research in NHS organisations; ensuring that all doctors have time in their contracts to undertake research and innovation, and are rewarded for that activity; and ensuring that doctors and other healthcare professionals have the skills needed to carry out medical research.
What would be recorded in the database and how?
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 their results. In the absence of a formal consultation process it has not been made clear precisely what would be recorded in the database, how and by whom. Furthermore, it may be appropriate to ascertain whether other bodies, such as the Health Research Authority (HRA), National Institute for Health and Care Excellence (NICE), and National Institute for Health Research (NIHR) would be involved in any such database.

Definitions
Innovation, in this Bill, is defined very broadly as “medical treatment for a condition that involves a departure from the existing range of accepted medical treatments for the condition”. During parliamentary debates on the Bill, the scope of ‘medical treatments’ was amended to include off-label drugs, unlicensed drugs and those currently in clinical trials; the only type of treatment that is explicitly excluded is that which is carried out solely for cosmetic purposes. As such, the extent of the treatments doctors would be expected to record in the database is not clear, nor the level of detail. Without a clear and precise definition of what constitutes an innovative treatment it would be difficult for doctors to identify when a particular treatment should be recorded in any proposed database (and what further information should be recorded), and, therefore, comply with any potential duty to record treatments (as suggested by the Government at the Lords’ Second Reading).

Point for clarification: what would constitute an ‘accepted medical treatment’, and who would be responsible for deciding what is to be recorded in the database?

Function of the database
It is unclear whether the database would:

- hold information about individual instances of ‘innovative treatments’ passed to the HSCIC through coding in patients’ notes, as stated in the Bill’s explanatory notes;
- and/or, serve as a resource that brought together, ‘at the click of a mouse’, all existing evidence of off-label or unlicensed treatments and information about drugs which are in trials, as was suggested by the Government in the Commons. Mr Heaton-Harris MP has also said that he hoped the database “will provide clarity through the vast web of registries, information and data that already exist and help clinicians find evidence for innovative treatments simply and quickly”.

Point for clarification: what would be the scope of the information recorded, and what would the recording mechanism entail? Why is primary legislation needed to fulfil this purpose?

How would the data be quality assured?
Very little detail has been provided regarding how records included in the proposed database would be quality assured or subjected to scrutiny and comment by suitably qualified peers. Without this rigour the value of the data would be limited as the inclusion of instances of innovative practice in a database may give the impression that they are approved or have been given some form of endorsement for use again, which could represent a serious risk to patient safety.

Point for clarification: how would the HSCIC’s quality-control mechanism work? Would this include peer review of the recorded information?

How would patient confidentiality be protected?
Lord Prior has said that an independent committee would be established to make sure that the database did not breach patient confidentiality, but no information has been provided as to how this would work.
• Lord Prior has said that access rights, “to start with”, would be restricted to doctors but we have not received adequate reassurance of a robust governance framework. This must, for example, exclude companies that might wish to target patients or access the database for other commercial purposes.

• It is not clear whether information recorded in the database would include any patient identifiable data (or data which might enable identification).

• If it is not possible to anonymise the data – either in the entire database, or in some subgroups, such as those with rare diseases – then this raises concerns about patient confidentiality, which requires much wider consideration and clarification about compliance with data protection law.

• Further information is required about the process for obtaining and recording patient consent or dissent for holding and transferring data.

Point for clarification: would recorded information include any data that could identify a patient? If so, how would the process for consent be managed, and how would the database be restricted to prevent companies using the tool for commercial gains?

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References


