Briefing on the Medical Innovation Bill
House of Lords Committee Stage – 24 October 2014

Patients need access to innovative, safe and effective treatments in a timely manner, and we therefore support the intention behind the Medical Innovation Bill. However, we have concerns over whether the Bill as drafted achieves its aims, and we question the necessity and practicality of further legislation as a means of encouraging innovation.

A summary of our key outstanding concerns over the bill, and our comments on relevant amendments, are set out below.

Overall comments

- Even with the safeguards provided in the Bill, and in the amendments, we are concerned that the Bill risks subverting the frameworks currently in place to preserve patient safety. There may be unintended consequences for patients who could be at risk when receiving treatments for which the evidence base is not fully established, including treatments which could prove ineffective or harmful.
- We are not aware of significant recorded evidence that doctors are being deterred from medical innovation due to the fear of litigation, which is the main premise of the Bill. We believe there is a need for better evidence to establish the main barriers to the development and utilisation of innovative medical treatments, and to clarify the best way to address this issue. We are also concerned that the Bill could introduce a degree of ambiguity to the law governing clinical negligence, potentially placing doctors at risk of further litigation.
- We believe the best way to assess the efficacy and safety of treatments is through robust research studies with appropriate clinical monitoring and collection of data and other evidence, on a rigorous statistical basis and with appropriate ethical approval(s). We support amendments to strengthen these provisions. It is not currently clear how the Bill would be enacted to allow the monitoring, assessment and follow up of innovative treatments, and to ensure that it does not conflict with existing law or regulation.
- We are also concerned that the Bill may discourage patients and their clinicians from participating in clinical trials by encouraging the provision of novel treatments on an ad hoc basis, leading to a failure to develop the robust evidence of efficacy necessary to support wider adoption of innovations in the NHS .

- While we support the aims of the Bill in seeking to encourage medical innovation, we believe there are other important barriers to medical innovation that the Bill does not address. These include the cost of innovative products and budgetary constraints, the complexity of the current regulatory system which can make it time-consuming and expensive to set up clinical trials, and the lack of financial incentives, clinical engagement and training for the development, adoption and diffusion of innovative approaches and treatments. Other important barriers are set out in the Association of Medical Research Charities' (AMRC) document *Our vision for research in the NHS*.[1] Without addressing these barriers we are concerned that the Bill will not achieve its overall aim.

Comments on key issues and amendments:
(amendment numbers refer to the Marshalled List)

1. Data collection (support amendments 15 & 19)

We are concerned that the Bill does not make provisions for follow-up or data collection. This is a key aspect of innovation since new interventions require an evidence base to demonstrate safety and efficacy and to ensure effective uptake in practice. Such an evidence base is dependent on data collected from a broad range of patients, on a rigorous statistical basis and with structured follow-up information. We are also concerned that a lack of data collection or follow-up could lead to some practitioners continuing to provide untested and ineffective (or potentially harmful) treatments to numerous patients.

We therefore support the principle of amendments 15 & 19 to require the process and outcomes of responsible decision-making outlined in the Bill to be recorded in a patient's medical record (in line with guidance issued by the Medicines and Healthcare Products Regulatory Agency on off-label use of medicines) and in a public record within six months of the treatment ending. This will provide additional oversight by recording decisions to innovate and their outcomes, and will provide evidence of how the legislation is being used and implemented. However, we would welcome further clarification on how such a public record would be situated and constituted, how it would operate, and how it would cohere with existing legislation and guidance governing data collection and handling.

2. Code of practice and existing regulation (support amendments 31 & 32)

We have concerns regarding how the Bill, if implemented, would interact with existing law governing medical negligence. There is a danger it could introduce greater ambiguity that potentially could place doctors at greater risk of litigation, contrary to the aims of the Bill.

We support amendment 31, which allows the Secretary of State to issue one or more codes of practice in connection with the provisions set out within the Bill. However, we would welcome further clarity on how compliance with such codes of practice would be monitored and enforced, while not introducing unnecessary administrative burdens.

We also have concerns over how the Bill will interact with existing legislation and regulation governing clinical trials and research more broadly. We support the principle behind amendment 32, which makes explicit that nothing in the Bill, if implemented, will conflict with or obstruct existing legislation or regulation governing clinical trials in research. As noted

[1] AMRC (2013), Our vision for research in the NHS. http://www.amrc.org.uk/publications/our-vision-research-nhs

above, research is integral to innovation; we believe the best way to assess the efficacy and safety of treatments is through robust research studies, and so it is crucial that nothing in the Bill or its implementation should conflict with or impede the practice and governance of clinical trials, and of clinical research more broadly. However, this amendment as currently drafted does not provide sufficient clarity as to how the Bill, if enacted, will interact with broader legislation and regulation governing clinical trials, and so further clarification and guidance on what it means in practice will be necessary if the Bill is passed.

3. Requirements for doctors in undertaking innovative treatments (support amendments 7 & 12)

We have concerns that the Bill risks subverting the appropriate frameworks currently in place to preserve patient safety. There may be unintended consequences for patients who could be at risk of receiving treatments for which the evidence base is not well established, including treatments which could prove ineffective or even harmful.

We support amendments which seek to clarify and strengthen requirements for doctors deciding whether to pursue an innovative line of treatment. In particular, we support the principle of the requirement within amendment 7, that a doctor must consult with at least one other doctor who has expertise in the relevant condition and is independent from him, and from any other doctors or organisations with responsibility for the care and treatment of the patient. The requirement for independent expertise is important to improve oversight of decisions and strengthen protection for patients, though we would welcome further clarification on how this would work in practice.

Amendment 7 introduces a requirement that doctors must have formed an 'honest and responsible opinion' that there is a prospect that the innovative treatment is more effective than the accepted treatment. However, such a requirement would be difficult to apply in the case of treatments where the efficacy is not fully known, and introduces a subjective element relating to the integrity of decisions taken. Further clarification and guidance on this issue will be required if this amendment is accepted.

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