avma
action against medical accidents

The charity for patient safety and justice

Briefing on the Access to Medical Treatments (Innovation) Bill

Overview

Action against Medical Accidents (AvMA) is the independent charity for patient safety and justice. We have over 30 years' experience of supporting people affected by medical accidents and partnership work with health professionals, providers, and policy makers to improve patient safety and justice for the injured patient / their family. The Access to Medical Treatments (Innovation) Bill is a private members' Bill brought forward by Chris Heaton- Harris MP. The Bill for the most part simply recreates Lord Saatchi's controversial Medical Innovation Bill which failed to complete its passage through the last parliament. One significant change is that this Bill would introduce a power for the Secretary of State for Health to create a register of innovative treatments. AvMA is not opposed to this part of the Bill, although great care would be needed about how treatments were assessed for inclusion and how the register would be used. We are however gravely concerned about the proposed changes to how the law deals with clinical negligence and the unintended consequences the Bill would have for patient safety. These relate to clauses 3 and 4 of the Bill. This briefing sets out our main concerns and suggests a better informed review of how innovation could genuinely be encouraged and supported.

Summary of our main concerns

We are deeply concerned by this Bill which, although well intended, is fraught with unintended and dangerous consequences.

- We are convinced, as are most medical and legal organisations, that the changes to the law with regard to clinical negligence liability at the centre of the Bill are not needed, and indeed could deprive patients injured by what today would be deemed negligent treatment from accessing the compensation they need and deserve. Existing legal and professional ethics arrangements already allow responsible innovation as was recently evidenced by the treatment of Ebola nurse William Pooley with an unlicensed drug. There is no evidence that clinical negligence litigation is in any way inhibiting responsible innovation. The response from all specialist organisations dealing with clinical negligence to the Department of Health consultation on the Medical Innovation Bill confirms this.
- We agree with the many doctors and doctors' organisations who say that as well as being based on a false premise, the Bill would actually make it harder to provide innovative treatment by creating a confusing, bureaucratic set of rules set in law
- We believe that the Bill threatens patient safety in that it would make it easier for a rogue doctor, such as Dr Ian Patterson who persuaded hundreds of women in the West Midlands to undergo his 'innovative' surgery, to prey on vulnerable patients.
- The Bill may put doctors under pressure from pharmaceutical companies and desperate patients to 'try out' potentially dangerous treatments
- The Bill would leave a patient or family who has lost a loved one as a result of what would today be considered negligent treatment with no remedy under the law
- The Medical Innovation Bill was disingenuously promoted as being about providing a last chance to dying cancer patients and this Bill is also being discussed in the media as if this were the case. In fact, it would apply to absolutely any form of medical treatment, (apart from purely cosmetic treatment).
- There is considerable consensus amongst organisations representing patients, doctors and medico-legal specialists that clauses 3 and 4 of the Bill are unnecessary and dangerous.

A solution where no problem exists

- **The current law on medical negligence does not hinder responsible innovation. This view is shared by leading lawyers, defence organisations and doctors' organisations. For example, in answer to the Department of Health consultation question as to whether people have evidence of this, the NHS Litigation Authority says:**

"We do not. However we are aware of innovation on the part of individual clinicians. For example various types of metal-on-metal hip replacement were invented by particular surgeons and the ideas were then sold to commercial companies for development. Also, we know of cases where drugs are used by NHS clinicians off-licence when doctors consider that their prescription will be beneficial to individual patients."

British Medical Association says:

"We are 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."

- **The law on medical negligence has been clear for over 50 years since Bolam-v-Friern Hospital Management Committee [1957] 1 WLR 582: a doctor is not negligent if he or she acts in accordance with a practice accepted as proper by a responsible body of medical men and women skilled in that art merely because there is a body of opinion that takes a contrary view. So, if 95% of doctors would not give a certain kind of cancer treatment but 5% would, and that 5% represents a reasonable body of opinion, then it is not negligent to give that treatment. Bolitho-v- City &Hackney HA [1998] AC 232 refined the test such that any conduct or decision to treat should be capable of withstanding rational analysis.**
- **The law does not define medical negligence as deviation from standard procedure, as has been claimed, but deviation from responsible or reasonable procedure. There is case law which demonstrates that medical negligence law does not hinder innovative treatment, even treatment previously untested on humans. In Simms-v-Simms [2003] 2WLR 1465 the court considered an application that two persons suffering from variant Creutzfeld Jakob disease should be given innovative treatment which was new and untested on humans. The court decided that the first question was whether the doctors would be acting in accordance with a responsible and competent body of relevant professional opinion as per Bolam, and the court held that there was a responsible body of professional opinion that supported the innovative treatment.**
- **The *Bolam* test is no impediment to innovation, only to irresponsible or unreasonable conduct. Lord Diplock in the House of Lords in the leading case of Sidaway-v-Governors of Bethlem Royal Hospital [1985] AC 871 at 893, said as much:**

"... Members of the public ... would be badly served by the adoption of any legal principle that would confine the doctor to some long-established, well-tried method of treatment [so as to avoid] the risk of being held liable in negligence simply because he tried some more modern treatment... The merit of the Bolam test is that the criterion of the duty of care owed by a doctor to his patient is whether he has acted in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion. There may be a number of different practices which satisfy this criterion at any particular time. These practices are likely to alter with advances in medical knowledge."

- **Properly considered the law already protects a doctor against an allegation of negligence if he innovates responsibly. The Medical Defence Union has publicly stated:**

"The Secretary of State of Health in a written statement introducing the Medical Innovation (no.2) Bill stated that doctors wishing to depart from established procedures and carry out an innovative treatment may be fearful of doing so because of the possibility of a clinical negligence claim. We have seen no evidence to suggest that this is the case ... Our advice is that there should be no consequences providing there are appropriate safeguards in place, the patient full understands what is proposed and why the clinician believes it is in their best interests, and they give their fully informed consent... We are happy to reassure doctors that medical innovation should not leave them open to an increased threat of litigation."

Lack of protection of patients

- **The Bill provides a defence - doctors will not be negligent in relation to any treatment currently regarded at common law as negligent, if they take the decision to treat "responsibly". Whilst the purpose of the Bill is a laudable one - to promote responsible medical innovation - the unintentional effect of the Bill is to deprive patients who are harmed[1] by doctors**

1 A patient is entitled to redress for negligence only if they have suffered harm as a result of the alleged negligence.

of a right of redress, even when the doctor has acted in a way that no other doctor would support. It is the rationale behind the Bill that doctors who would currently be regarded as negligent, should no longer be held liable.

- **AvMA is concerned that patients are afforded proper protection from irresponsible or negligent doctors. Regrettably the Bill does not provide adequate protection and could actually encourage unsafe practice and lead to further tragedies and scandals such as that involving Dr Ian Patterson, amongst others.**
- The provisions at under clause 3 are intended to offer some protection to patients. However, they do not actually "require" that the ultimate decision should be rational or reasonable. The decision is left to the individual doctor, provided they manage to obtain the patient's consent and "consulted" one other doctor even if the treating doctor refuses to accept the advice they are given. Axiomatically, a decision may be "taken responsibly" even if it is a decision which would not be supported by any responsible body of medical opinion. So, it can be seen that a "responsible decision" under the Bill is not the same as a responsible decision under the common law. The Bill dilutes the protection currently afforded to patients.
- The Bill does re-state the existing requirement that patients' consent is obtained. However, AvMA is concerned that patients who may agree to treatment which is beyond the bounds of what is considered acceptable by all responsible bodies of medical opinion, are precisely those who require particular protection. The desperate patient who will try anything to be "cured" or for a short extension to their life, for example, may be the most vulnerable to exploitation. However, patients with non life-threatening conditions can also be equally desperate and vulnerable to accepting the recommendation of a treatment which is unsafe. A doctor selling vitamin X from his private practice may very well be able to show that he took his decision to treat "responsibly" whilst providing treatment which no other doctor would support.
- There is a danger that an individual doctor's decision with regard to 'innovative' treatments could be affected by other influences. For example, there could be a financial interest / conflict of interest for the doctor themselves to be motivated to put forward a particular treatment. The pharmaceutical industry and others may certainly try to influence doctors to exercise their freedom that this Bill would provide to step outside the normal systems designed to protect the safety of patients, to push their particular product.

The Bill would have no positive effect on innovation

- **There is no evidence that the law of clinical negligence is a significant restriction on the freedom of doctors to try new treatments. Yet, changing the law so that treatment decisions which would currently be deemed negligent is the only way in which this Bill seeks to encourage or support responsible innovation.**
- Most obviously, substantial funding is required to research, develop and instigate new treatments. Often, whether as a result of determinations by NICE or otherwise, funding is not available for doctors to allow access to new treatments to all patients. The Bill has nothing to say on ensuring funding is available.
- All doctors are regulated by the General Medical Council. Most will be subject to employment contracts which stipulate adherence to protocols or ethics committee guidance and directives. The Medicines and Healthcare Products Regulatory Agency (MHRA) regulates the provision of new medicines and medical devices. The Bill has nothing to say about these controls on the freedom of doctors to innovate.
- The Bill is directed to individual doctor/patient relationships. It has nothing to say about funding, laboratory research, drug development, professional regulation, the MHRA or the requirements for large scale and peer reviewed studies.

There are better ways of encouraging and supporting innovation

- In addition to the concerns AvMA and others have about clauses 3 and 4 of this Bill, it is also premature. The Government has asked Sir Hugh Taylor to conduct the Innovative Medicines and Medtech Review, and this is yet to report. Moreover, there could be a more in depth review of the issues which this Bill simply takes for granted – such as whether and to what extent clinical negligence litigation has any bearing on

access to medical treatments. A review by the Health Select Committee for example could look at this and consider any other real barriers to innovation and make recommendations.

- In particular urgent attention is needed to making funding available for research and for the actual funding of innovative treatment. For example, the Cancer Drugs Fund, which has provided access to drugs which are not routinely available in the NHS to some 74,000 patients, is under threat.
- Another area that could be usefully be reviewed is the process and speed of approving new treatments by NICE and the MHRA.
- If primary legislation is needed to promote and support medical innovation it should be informed by all of these reviews.
- It is vital that such important and contentious changes enjoy consensus amongst patients, doctors and lawyers who specialise in medico-legal matters. Responses to consultation on the Medical Innovation Bill revealed unprecedented consensus amongst organisations representing doctors, patients and specialist medico-legal organisations, that the changes re-created in clauses 3 and 4 of this Bill are both unnecessary and dangerous. See the joint letter from the Patients Association, National Voices and AvMA criticising the Bill here: http://www.thetimes.co.uk/tto/opinion/letters/article4362099.ece

See various organisations' position statements on the Medical Innovation Bill here: http://www.stopthesaatchibill.co.uk/what-do-doctors-lawyers-and-medical-charities- say/

The changes proposed in clauses 3 and 4 would apply in England and Wales. However when it considered the same proposals as part of the Medical Innovation Bill, Welsh Assembly Government unanimously disapproved of them: http://gov.wales/about/cabinet/cabinetstatements/2015/medicalinnovation/?lang=en

AvMA briefing for 2nd Reading
House of Commons
16th October 2015

Action against Medical Accidents

Freedman House
Christopher Wren Yard
117 High Street
Croydon CR0 1QG

020 8688 9555

www.avma.org.uk

www.facebook.com/AvMAuk

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