13 October 2015

Royal College of Surgeons

Parliamentary Briefing

Access to Medical Treatments (Innovation) Bill

House of Commons, Second Reading Briefing

The Royal College of Surgeons (RCS) recognises the good intentions behind the Access to Medical Treatments (Innovation) Bill. However, we have significant reservations about this Bill.

At best it will confuse doctors about the law on medical negligence. At worst it risks harming vulnerable patients and has the potential to change the legal standing of the doctor-patient relationship.

We unequivocally oppose this Bill, especially clause 3. Detailed comments on individual clauses from the Bill are listed below.

Clause 2: Database of innovative treatments

Surgeons in England have been the first in the world to publish their individual outcomes from surgery. We support this level of transparency in all areas of surgery including research and innovation. The College expects all researchers conducting trials, including those we directly support, to register the trial in a publicly accessible database.

However, we do not see the need for a new database of innovative treatments in surgery. A number of audits in surgery already exist and it is unclear what different data this additional database would cover. It would be helpful for the Government to clarify what data it envisages collecting under this Bill. It would also be necessary to explain what 'innovative treatments' are as opposed to research.

The present wording of clause 2 simply provides the Secretary of State with the power to establish a database of innovative medical treatments without being prescriptive. Indeed, there is no requirement on the Secretary of State to proceed to establish one. We wish to make the following points about this clause:

- It is unnecessary. We believe the Secretary of State already has the power to establish a non-statutory database of innovative treatments without legislation.
- The clause is limited to 'medical treatments carried out by doctors'. Why? There may be merit in improving

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the transparency of innovations outside of those used by doctors – e.g. in physiotherapy or the use of osteopathy for some types of pain.

- Why should the database be limited to England? Many existing audits cover one or more devolved nations and limiting its scope to England would reduce its relevance to doctors inside and outside the UK.
- Until there is clarity about what data might be captured, it is unclear whether the Health and Social Care Information Centre would be the best host for such a database. For example, doctors may have greater confidence in a database managed by a clinical society if the data is limited to a particular area of medicine.

Clause 3: Responsible innovation

At present there is no evidence that doctors are deterred from innovating due to the threat of legal action. It is unclear why new laws are required in this area when the present Bolam test is regarded as adequate. Medical defence bodies (such as the Medical Protection Society and the Medical Defence Union) are also unconvinced of the need for additional legislation.

While there may be merit in clarifying to clinicians what steps they need to take to ensure compliance with the existing law, this could be achieved through clearer guidance rather than through legislation.

We have a number of concerns about the present wording of this clause:

- The present wording is not significantly different to Lord Saatchi's medical innovation bill. This was widely opposed by medical royal colleges, patient charities, and research organisations.
- Subclause (2)(a) requires a doctor to obtain the views of one or more doctors (with experience of patients with the condition in question) 'with a view to ascertaining whether the treatment would have the support of a responsible body of medical opinion'. This relies on someone's interpretation of a responsible body (such as a specialist medical body), as opposed to seeking a view from a responsible body directly. Rather than clarify the law on medical negligence, this risks confusing it. This sub-clause could also provide post-hoc justification for an unethical treatment from a doctor asserting s/he sought the view of one other doctor.
- The wording of the Bill confers the decision-making power on the doctor rather than the patient. There is a risk it misunderstands the doctor-patient relationship. According to Nigel Poole Q.C.[1], a prominent barrister on medical negligence, a recent court ruling confirmed 'The doctor's role is to provide the patient with material information on which they can make an

[1] http://nigelpooleqc.blogspot.co.uk/2015/06/when-facts-change.html

informed decision about treatment. It is not the doctor's "decision" to provide treatment (save in certain circumstances[…]), it is the patient's decision to elect and consent to undergo a certain treatment'.

- Similarly, the emphasis in the Bill is on proving the doctor's *decision* was responsible. Courts are not asked to deal with whether a patient's treatment has been negligent.

We are absolutely committed to improving access to innovations and we are delighted that Chris Heaton-Harris MP has shown an interest in this area. However, we have significant reservations about this Bill.

The Government's consultation on the Accelerated Access Review recently closed and this is likely to prove a more productive route for identifying ways to encourage innovation.

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