Amending the Medical Innovation Bill

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*J.P.I.L. 251 In a follow up to his previous article on the Saatchi Bill, Nigel Poole QC considers the current batch of proposed amendments to the proposed fourth version of the Bill.

Amendments to the Medical Innovation Bill proposed by Lord Saatchi will create a new test for the liability of doctors. First the court will consider, as now, whether a doctor’s treatment was in accordance with a responsible body of medical opinion. If so, then the doctor is not negligent. If not, the court will have to examine how the doctor made the decision to treat. Will new rules on consultation create clarity or cause confusion?

The Medical Innovation Bill is Lord Saatchi’s private member’s Bill. He believes that clinical negligence law is the main obstacle to medical innovation and intends to change the law to relieve innovative doctors of the fear of litigation. The Bill does not define innovation but does define treatment as including management and “inaction”. It therefore applies to all treatment decisions, whether innovative or not, and whether they are decisions to withhold treatment or to give treatment. Its importance is evident.

By the time this is published, but not at the time of writing, the Medical Innovation Bill (No.4) will have passed through the committee stage in the House of Lords. Lord Saatchi has proposed a series of amendments which have been drafted after consultation with the Department of Health. It can be presumed, therefore, that they have the government’s backing. They re-write the Bill’s procedural requirements with which doctors who would otherwise be negligent must comply in order to avoid a negligence claim.

**Lord Saatchi’s amendments**

Clause 1(2) of the draft Consolidated Bill provides that:

"It is not negligent for a doctor to depart from the existing range of accepted medical treatments for a condition if the decision to do so is taken responsibly."

Clause 1(3) sets out the new provisions for determining whether a decision has been taken "responsibly".

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(3) "for the purposes of taking a responsible decision to depart from the existing range of accepted medical treatments for a condition, the doctor must in particular—

(a) obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment,"
take full account of the views obtained under paragraph (a) (and do so in a way in which any responsible doctor would be expected to take account of such views),

obtain any consents required by law to the carrying out of the proposed treatment,

consider—

(i) any opinions or requests expressed by or in relation to the patient,

(ii) the risks and benefits that are, or can reasonably be expected to be, associated with the proposed treatment, the treatments that fall within the existing range of accepted medical treatments for the condition, and not carrying out any of those treatments, and

(iii) any other matter that it is necessary for the doctor to consider in order to reach a clinical judgement, and

take such other steps as are necessary to secure that the decision is made in a way which is accountable and transparent.''

An appropriately qualified doctor is defined by cl.1(4) as one who has "appropriate expertise and experience in dealing with patients with the condition in question".

A choice not to meet the Bolam test

Sensitive to objections that this will re-write the common law, the amendments include a new clause:

"Effect on Existing Law"

(1) Nothing in section 1 affects any rule of the common law to the effect that a departure from the existing range of accepted medical treatments for a condition
is not negligent if supported by a responsible body of medical opinion.

(2) Accordingly—

(a) where a doctor departs from the existing range of accepted medical treatments for a condition, it is for the doctor to decide whether to do so in accordance with section 1 or in reliance on any rule of the common law referred to in subsection (1);

(b) a departure from the existing range of accepted medical treatments for a condition is not negligent merely because the decision to depart from that range of treatments was taken otherwise than in accordance with section 1."

The new cl.2(1) is a partial statement of the common law. It does not fully reflect the Bolitho test of whether the view of a responsible body of medical opinion is rational or logical. More obviously it does not refer to the common law rule that a departure from accepted treatments is negligent if not supported by any responsible body of medical opinion. That rule is affected.

Section 2(2)(a) envisages doctors making conscious decisions to act in a way which no responsible body of medical opinion would support but instead to rely on cl.1 of the Bill. Whether this is a realistic approach to the way treatment decisions are made or not, it at least has the merit of recognising that the Bill is directed at changing the existing law in relation to doctors whose treatment does not have such support. At present those doctors are negligent. Under the Bill they may "choose" to comply with cl.1(3) and thereby avoid liability in negligence when their patients suffer harm.

The requirements for consultation

It is important therefore that doctors, their employers, patients and the courts will be clear as to whether in any particular case a doctor has acted in accordance with cl.1(3). Lack of clarity will be liable to cause confusion and may even hinder the deployment of innovative treatments.

Unfortunately cl.1(3) is far from clear. In assessing whether there has been compliance a number of questions would arise including:

• What constitutes “appropriate experience and expertise in dealing with patients with the condition in question”? If innovative treatment of an aggressive prostate cancer is being considered, is it sufficient for the other doctor to be an oncologist, or must they be an oncologist specialising in prostate cancer? What if he or she were a urological registrar who has dealt with patients with prostate cancer, or a histopathologist?

• Was the other doctor expert and experienced not only in the condition but in the mode of treatment proposed? Would it comply with the Bill to consult an oncologist about a new surgical technique, or a surgeon about a new form of chemotherapy?
• Were the other doctor’s views sought in relation to the particular patient or generally in relation to the proposed treatment—were they giving generic or specific views?

• What information did the other doctor have? Was that information put in writing? Did he have sight of the full medical records? Had he examined the patient?

• Did the other doctor discuss the case and options with the patient?

• Did the other doctor support or oppose the proposed treatment decision? Did they give their opinion in writing or orally?

• Was the other doctor’s opinion rational?

• Was the other doctor’s opinion one which would be supported by any responsible body of medical opinion, or would not be supported? Ought the treating doctor to have known whether the other’s views were those of a responsible body of doctors or otherwise?

• What published research or data did the treating doctor and the consulted doctor rely upon?

• Was the other doctor wholly independent of the treating doctor? Is he or she in the same hospital team or at the same private clinic?

• Did the other doctor have any financial or professional interest in the decision to treat the patient in the way proposed?

• Was the other doctor in a position of authority over the treating doctor or vice versa?

• Was the treating doctor more or less experienced and expert in the condition being treated, than the other doctor?

• What was the time between the other doctor giving his views and the treatment being given, and what happened of relevance in that time? Having regard to the patient’s condition, was there time to consult further or in more depth?
Was it, or ought it to have been, evident that the views of experts in more than one field should have been taken into account (e.g. surgery, oncology and radiology)? The Bill only requires one other doctor to be consulted, but could a doctor reasonably take into account the views of only one doctor when other specialist opinions are relevant?

Were the other doctor’s views communicated to the patient before the patient’s consent was obtained? Did informed consent involve telling the patient about the other doctor’s views?

If the other doctor’s views were against giving the treatment but the treatment was nevertheless given, what reasons did the treating doctor have for not accepting the other’s advice, and were those reasons rational and justified?

Would any responsible body of doctors have so treated the patient having taken into account the views of the other doctor?

What other steps were necessary to take to secure that the decision to treat was transparent and accountable?

It might be said that it would be easier for a doctor to be satisfied that he is acting in accordance with a responsible body of opinion than to be satisfied that he has complied with the requirements of cl.1(3) of this Bill. Worryingly for the promoters of the Bill, it might be easier for a doctor simply not to try any new treatment than to seek to comply with cl.1(3). Certainly, any NHS trust worried about being sued if a doctor failed to comply with cl.1(3) would have to develop some quite sophisticated protocols or rules to ensure compliance.

**Responsible innovation**

Lord Saatchi’s Bill has certainly provoked a debate about medical innovation. Many believe that the debate would be better focused on issues such as the conduct and funding of research and the regulation of new treatments.

Responsible innovation should be based on a relationship of trust between doctor and patient. Whatever the nature of a patient’s condition, he or she would surely want to know that their doctor is providing treatment which has a rational justification. And which patient wants to know that their doctor has actually chosen to act in a way which no responsible body of doctors would support: cl.2(2)(a)?

Responsible innovation involves introducing new treatments in a controlled way where information gained is useful for further development, is recorded and shared. This Bill is directed at the individual doctor who is not acting as part of a team of responsible doctors. It includes no requirements to record, publish or share information about the treatments given. Lord Winston and Lord Turnberg have proposed amendments seeking to introduce such requirements. They, along with Lord Pannick, have also tabled an amendment which would require that doctors departing from the existing range of accepted treatments shall act reasonably and proportionately. That looks rather like an attempt to preserve something similar to the *Bolam* test. It will be interesting to see who will be prepared to oppose an amendment requiring all doctors to act reasonably.

One view is that any amendments to this Bill are attempts to cure the incurable. The Bill is fundamentally flawed—the British Medical Association, NHS Litigation Authority, Academy of Medical Sciences, Medical Defence Union, Medical Protection Society and many other bodies have said that
they do not recognise the premise of the Bill that clinical negligence litigation is a barrier to medical innovation. Patient safety and medical innovation are not necessarily opposing forces, but where they are in tension, the Bolam / Bolitho test of negligence holds a flexible and practical balance. Lord Saatchi’s attempts to change and codify the doctor-patient relationship are proving to be fraught with difficulty.

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