Department for Health
Legislation to encourage medical innovation

A response by the Association of Personal Injury Lawyers

April 2014

The Association of Personal Injury Lawyers (APIL) is a not-for-profit organisation with a 20-year history of working to help injured people gain access to justice they need and deserve. We have around 4,000 members committed to supporting the association's aims and all of which sign up to APIL's code of conduct and consumer charter. Membership comprises mostly solicitors, along with barristers, legal executives and academics.

APIL has a long history of liaison with other stakeholders, consumer representatives, governments and devolved assemblies across the UK with a view to achieving the association's aims, which are:

- To promote full and just compensation for all types of personal injury;
- To promote and develop expertise in the practice of personal injury law;
- To promote wider redress for personal injury in the legal system;
- To campaign for improvements in personal injury law;
- To promote safety and alert the public to hazards wherever they arise;
- To provide a communication network for members.

Any enquiries in respect of this response should be addressed, in the first instance, to:

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Introduction

APIL agrees wholeheartedly that doctors should be permitted to innovate, and that the law should not be a barrier to advances in medical treatment. The Medical Innovation Bill is not the correct way to achieve this aim. If passed, the Bill may have a number of unintended and potentially dangerous consequences, including:

- The erosion of patient safety, as provided by the current law;
- Allowing the medical profession to undertake untested and potentially dangerous treatments;
- Exposing the medical profession to commercial pressures;
- Exposing the medical profession to needless litigation.

We have fundamental concerns about the misconceptions on which the Bill is based:

- The Medical Innovation Bill is necessary because current law prevents innovation: The current law already allows innovative treatment to be carried out in safe and controlled circumstances.
- The Bill is necessary to address the "culture of defensive medicine*":* The "culture of defensive medicine", if it exists, should be altered by improving guidance and changing the doctors' misperception that they will be sued if they try something other than the standard treatment. The framework for innovative treatment already exists – doctors just need to be signposted to it.

Misconceptions

The current law prevents innovation

This could not be further from the truth; the current law does not prevent innovation. It is simply not the case that deviation from standard procedure is likely to result in a successful medical negligence claim. Under the current law, as set out in *Bolam v Friern Hospital Management Committee*[1]*,* a doctor would only be negligent if no responsible body of fellow practitioners would support their course of action in treatment or management of the patient. Innovation is permitted provided that a responsible body of medical opinion would support it. In *Sidaway v Bethlem Royal Hospital Governors*[2]*,* Lord Diplock made clear that the test in *Bolam* is not about inhibiting advances in medicine: "members of the public who seek medical or surgical aid 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 only, if (the doctor) wanted to be confident that he would not run the risk of being held liable in negligence simply because he tried some more modern treatment (and it failed)... This would encourage "defensive medicine" with a vengeance" He went on "the merit of the *Bolam* test is that the criterion of duty of care owed by a doctor to his patient is whether he 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 these criteria at a particular time".

[1] [1957] 1 WLR 583

[2] [1985] AC 871

As well as satisfying the *Bolam* test, in order to prove negligence there must also be a proven causative link between the doctor's activity and the injury sustained which has resulted in a claim. Under the current law, therefore, it is unlikely that a terminally ill patient would have a successful claim in clinical negligence against a doctor who has carried out innovative treatment for that patient as a "final roll of the dice". Should the treatment go wrong, it would be extremely difficult to prove a causal link between the doctor's decision to pursue the new treatment, and the negative effects on the patient (given that the patient had a very poor prognosis before the treatment began).

Lord Saatchi, one of the main proponents of the Bill, has said that we will get no closer to a cure for cancer until doctors can test new treatments in a controlled way on real patients. The current law already allows for such new treatments to be tested, in a safe and controlled manner. The case of *Simms v Simms*[3] demonstrates this. The "body of responsible and skilled medical opinion" in *Simms* consisted of only three medical experts, and this was enough to satisfy the *Bolam* test, with Lady Butler-Sloss being impressed with the research and evidence demonstrated by those experts. The two claimants in the case suffered from Creutzfeldt-Jakob disease. The parents of the claimants wished for them to receive treatment which was new and so far untested on human beings. Even though the case involved untried treatment and there was no validation of experimental work done in Japan, it was held that the Bolam test ought not to be allowed to inhibit medical progress. Lady Butler-Sloss commented that "if the Bolam test always had to be complied with to its fullest extent, no innovative work would ever be attempted". This case illustrates that far from inhibiting innovation, the Bolam test sets an achievable threshold under which a doctor can safely innovate. There is no need for the "body of responsible and medical opinion" to be hundreds of medical professionals. As long as there is evidence of research, the "body" can consist of as little as three people, maybe fewer.

A further case demonstrating that *Bolam* is not intended to inhibit medical innovation is *Khoo James v Gunapathy*[4], a case from the Singapore Court of Appeal. Here, the doctor had recommended that the patient undergo knife radio-surgery, which was a relatively unproven and innovative procedure at the time. It was held at the appeal that the court had no business vilifying the acts of medical practitioners. Only if the doctor had failed to consider the patient's scan and completely ignored the evidence before him would he have fallen foul of the *Bolam* test. This case demonstrates the high threshold that is required in order for there to be a successful claim in clinical negligence. The doctor will only be subject to a claim in clinical negligence if he does something that no other medical practitioner in his situation would do.

Further proof that the current law does not inhibit innovation can be demonstrated by the numerous innovative treatments that have been made available since the Bolam test was developed in 1957. Lumpectomies have been carried out since the mid-1970s, and HIV combination therapy has been used to treat those living with HIV since the early 1990s. We are unaware of any cases that have been brought as a result of these "innovative" treatments. Innovative treatments continue to be developed today, for example, Botox has been used as a treatment for an over-active bladder. Recently, doctors at Liverpool Women's Hospital carried out keyhole surgery on a woman who was 11 weeks pregnant and

[3] [2002] EWHC
[4] [2002] 1 SLRC (R) 1024

had been diagnosed with cervical cancer. This was the first time this procedure has been carried out on a woman as far along in her pregnancy as this. The standard procedure for such cases has been the immediate termination of the pregnancy, followed by a hysterectomy. The doctors deviated from the standard procedure, removing the tumours and lymph nodes, and the woman successfully gave birth to a baby girl. It is simply not true that the current law requires strict adherence to "standard procedure".

Despite the evidence above to the contrary, it appears that many doctors harbour the misconception that they will be sued if they attempt innovation. This is apparent from the comments on the "Saatchi Bill" blog. One supporter of the Bill stated "when discussing the benefits/disbenefits of certain treatments with my GP, he pointed out that if he did not follow the "guidelines", and something went wrong, he could be open to a legal suit." This is incorrect – the doctor would only be open to a legal suit if he did something which no other medical professional would do in his situation. Addressing this misconception is an issue for guidance and education, and not a change in the law.

An increasingly litigious culture puts pressure on doctors to practise defensive medicine

Whilst it cannot be disputed that the number of clinical negligence claims has increased over the past five years (as demonstrated by figure A), we believe that this is unrelated to any issues surrounding medical innovation. The number of claims has risen because the number of adverse incidents has risen – this is a separate issue to "innovative treatment". The consultation document does not provide any evidence to show the number of claims made as a result of medical innovation has increased, or even if such claims exist. We fail to see the link between increasing claims and "innovative treatment". Indeed, the Medical Defence Union has stated that they have seen no evidence to suggest that doctors are fearful of departing from established practice because of the possibility of a clinical negligence claim. The MDU has said that legal and ethical requirements do not prevent a barrier to innovation so long as doctors follow procedure. There are many factors that affect innovation – such as lack of funding and resources – and efforts should be made to address these.

Simply showing that medical negligence claims have increased does not prove that doctors do not innovate. If this is the case, though, clear and accessible guidance to give doctors the confidence to innovate within the current law is the way forward, not legislation.

Confusion as to what the Bill would achieve

Some proponents of the Bill appear to be confused as to what the Bill would achieve in practice. Some have spoken out in support of the Bill, referring to delayed diagnosis of cancer, and a refusal of doctors to operate on a tumour until it is too late. This is a separate issue to innovation, and one which would not be resolved in any way by the Bill being brought into force.

General comments on the Bill

The Bill is unnecessary

Litigation is not a barrier to medical innovation under the current law – therefore the Bill is unnecessary. A change of culture may be needed, but the law is already there to be utilised-

as case law proves. Clearer guidance should be given to doctors to alter the perception that deviation from the standard treatment will result in a legal suit.

A change of culture should also involve addressing other issues that may be halting innovation at present. These include a lack of funding and resources for research into rarer illnesses.

The law to allow for innovation is already there; what is required is clearer guidance and greater funding for research. If the approval of a senior panel or MDT is required, as the Bill indicates, this mirrors the Bolam test, which is the current law.

The Bill would erode protection for the patient

The Bill would erode the necessary protection that is currently available to patients undergoing treatment. This protection prevents maverick doctors taking advantage of vulnerable patients, by exposing them to untested and potentially dangerous treatments.

As demonstrated above, doctors are permitted to innovate in safe, controlled circumstances. If the current law were changed to allow for the Bill, a rogue doctor would be able to carry out a procedure for which they had no backing from colleagues or evidential support (provided for by clause 1(3) of the Bill). All that they would have to do was show that they had followed the procedure outlined in clauses 1(4) and 1(5) which, as detailed below, is inadequate.

Proponents have said that the Bill would allow the dying patient a final chance at treatment. If the Bill became law, however, a doctor would be able to test a radical and untested treatment on a person who is not dying, but who may have a long term illness which, although not life threatening, affects their quality of life. This treatment, unsupported by research or other doctors, could lead to a further deterioration of that person's quality of life, or even be fatal. The doctor would be permitted under the Bill to carry out the treatment and so the patient would be denied redress for their injuries. The Bill would have far wider reaching consequences than simply offering a dying person a "final roll of the dice" – it would allow the doctor to "play God" with no consequences.

We are also concerned that some drug companies may see the changed law as an opportunity to put pressure on doctors to push certain untested drugs onto their patients. Because of the requirements of the current law, there must be research to support a doctor's decision to give a patient new drugs. Thresholds are in place to ensure that patients are only given drugs that are safe. The Bill would remove these thresholds, and drug companies may exploit this, paying doctors to push their untested drugs onto desperate and vulnerable patients. If the patient is injured as a result of the untested treatment, they would not be able to bring a clinical negligence claim. This claim would be vital in covering the patient's costs as a result of the injury, such as adaptations to the home, loss of earnings through not being able to attend work. The only possible method of redress would be for the patient to pursue a product liability claim against the multi-national drug company, which would be extremely difficult and costly to pursue – with little chance of success.

A further risk to patients is that doctors who may wish to make a name for themselves and further their career by "discovering a cure" could embark on dangerous and experimental

procedures without any consequences. Terminally ill people would be particularly vulnerable to exploitation in this way.

The Bill would expose the doctor to further clinical negligence claims

The clauses in the Bill could even leave doctors more exposed to clinical negligence claims than is currently the case. If something should go wrong during an innovative treatment, the patient may seek to sue the doctor and could easily argue that the doctor has not complied fully with the requirements in the Bill. There is a danger in trying to be too precise when defining the law. Because the Bill sets out the exact requirements that must be complied with, a doctor could leave themselves vulnerable to legal challenge should the treatment go wrong, with the patient able to say that the doctor has failed to fully comply with one of the factors on the list.

Questions

As an association representing those injured as a result of negligence, we only answer those questions within the remit of personal injury law.

Q2) Do you have experience or evidence to suggest that there is currently a lack of clarity and certainty about the circumstances in which a doctor can safely innovate without fear of litigation?

We believe that it is precisely the *lack* of certainty and definition which protects doctors under the current law, and allows them to innovate. If attempts are made to define the law and enshrine it in statute, it is more likely that something will be left out of the definition – eroding protection for the patient. On the other hand, over-definition may also cause further problems for doctors trying to innovate. Doctors will be at risk of a clinical negligence claim against them if they are deemed by the patient not to have complied fully with list of factors contained within the statute. Trying to define what is and is not negligent for each branch of medicine will cause problems, and leave loopholes open to exploitation.

The current test is that someone is acting negligently where they are adopting something that no medical practitioner of their standing would adopt. This works well because of its broad application, allowing for flexibility and providing room for innovation. As is evident from the cases above, medical innovation is not inhibited under the current law. It is the doctors' perception of the current law that must be changed, and this can only occur through guidance.

Q3) Do you agree with the circumstances in which the Bill applies, as outlined in clause 1(3)? If not, please identify any changes you suggest, and give your reasons for them.

We do not agree with the circumstances in which the Bill applies. It is stated at paragraph 3.2 of the consultation that the Bill aims to provide clarity, and at paragraph 3.5 that the Bill is not intended to replace the *Bolam* test. Clause 1(3) of the Bill goes far wider than this stated aim, by providing (in contradiction to the *Bolam* test) that the doctor would be permitted to proceed with treatment if the proposed treatment does not, or would not, have support from a responsible body of medical opinion. This would have dangerous consequences, and would mean that if a doctor did not satisfy the well-established and effective Bolam test,

injuring the patient as a result, that patient would not be entitled to claim compensation, and that doctor would not be held accountable. The Bill is drafted in such a way that a doctor would be permitted to carry out treatment that under the current law would be negligent. This is unacceptable and could have extremely dangerous consequences for vulnerable people.

If the Bill were to go ahead, a vital element would be that the existing law should remain - that this Bill is simply a refinement or clarification of the existing law.

Q4) Do you have any comments on the matters listed in clause 1(4)-(5) on which the doctor's decision must be based for it to be reasonable? Are there any that should be removed, or changed, or added, and if so why? For example, should the Bill explicitly indicate that the other treatments mentioned in 1(5)(a)-(c) include treatments offered as part of research studies?

We do not agree that clauses 1(4) and (5) make the current law clearer. We believe that the clauses instead change the current law, and give a free pass to doctors who may wish to carry out untested and potentially dangerous treatments without proper research and support. Instead of requiring the doctor to act in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion, the single doctor can go off on a frolic of his own – unsupported by anyone else.

Clause 1(4)

Whilst it has been suggested by proponents of the Bill that "a panel of senior doctors" would have to approve the innovative treatment, it is clear from the proposed draft Bill that there is no such safeguard. Clause 1(4) refers to the single "doctor's opinion", and "doctor's consideration of the matters". Any decisions will therefore proceed on the subjective opinion of a single doctor. Clause 1(4) also fails to provide a suitably high threshold that the doctor must reach before being permitted to innovate. All he must do is think of "plausible reasons why the treatment might be effective". The doctor can carry out treatment that he or she has had no support for, but he or she themselves think might be effective. There is no requirement that they have to provide evidence of research to back up why they think it may be effective. A particularly radical doctor, embarking on untested and unsupported treatment, would not be brought to account if they injure a patient as a result of their folly.

We are also concerned that the "catch-all" clause "any other matter that appears to the doctor to be appropriate to take into account in order to reach a clinical judgment" is heavily subjective, and does not provide an adequate safeguard.

Clause 1(5)

We are unsure how the doctor would be able to satisfy the criteria in clause 1(5) if there had been no previous research on this treatment for humans. They will not be aware of the relative risks, likely success rates or likely consequences of proposed treatments if it has not been properly researched or trialled. To take the case study example in the consultation document, Box A states that Dr A has found a new treatment that has not been tested in clinical trials and does not know if other doctors would support her use of the treatment. If the treatment had not yet been tested in trials, how can the doctor arrive at likely success rates, and relative risks? We also question the requirement to "take into account the opinions

of colleagues". These colleagues do not have to be fellow medical practitioners, therefore this does not provide an adequate safeguard.

Further, clause 1(5) omits to mention a number of considerations that we feel must be taken into account as part of a sensible decision on whether or not to innovate. There is no mention of scientific studies or international research. It is not even necessary to take into account the qualifications of the doctor to assess the situation in the first place. We are concerned that this may open patients up to exploitation and untested treatment from doctors who are not even specialist in the field in which they are "innovating". There is nothing within the Bill to prevent a doctor who specialises in knee surgery on implementing one of their innovative treatments concerning brain surgery on a vulnerable patient who may agree to such treatment because they have "nothing left to lose". The criteria in clause 1(5) fail to recognise the increasingly complex specialisms in the medical profession.

Q5) Do you have any comments on the process set out in clause 1(6)-(7)? Are there any provisions that should be removed, changed or added – and if so, why?

Clauses 1(6) and 1(7) are not adequate safeguards. There have been numerous references by proponents of the Bill to a legal requirement within the Bill that a doctor would have to get the approval of a panel of senior doctors for any innovative treatment, and that this is a higher legal barrier than the current law. This requirement is in fact, not included in the Bill. Indeed, if it did introduce a higher legal barrier than the current law, thus surely making it more difficult to innovate than at present, the whole premise of the Bill would be a nonsense. S 1(7) states that it *may* be taken into account whether the decision has been made by a multi-disciplinary team, or whether the doctor has given notification in advance to the doctor's responsible officer. The explanatory notes of the Bill explain that the requirements in s 1(7) *may* be taken into account (and not must be taken into account) because a Multi-Disciplinary Team may not exist for all diseases, and therefore the doctor would be unable to consult. If a MDT does not exist for the disease and treatment at hand, the doctor would be able to proceed unapproved. If approval of a panel of senior doctors is sought and obtained, then this would be likely to satisfy the Bolam test anyway (in *Simms v Simms,* only three experts in agreement was enough to satisfy the Bolam test).

Q8) Do you have any comments and suggestions for inclusion in the draft impact assessment and equality analysis?

The impact assessment does not address many of our above concerns. There is no mention of the particular vulnerability of those with terminal illnesses being open to exploitation by a doctor who may want to make a name for themselves. The Bill's list of factors to be taken into account would lead to satellite litigation and may expose the doctor to further clinical negligence claims than is currently the case. The impact assessment does cite "increased litigation" as a bar to innovation but fails to provide any hard evidence to support this.

Q9) Overall, should the draft Bill become law?

We do not believe that the draft Bill should become law. We understand the importance of allowing doctors to attempt new and innovative treatments. The best way to ensure that this happens, however, is for the doctors to be fully aware of their responsibilities and to be given guidance on how they are permitted to innovate under the current law.

Addendum

APIL is aware that the Medical Innovation Bill has been redrafted since the launch of the Department of Health consultation. We cannot comment fully on the revised draft Bill, as it has not been made available to us. It is important that the revised version of the Bill is made available, and is subject to further separate consultation. The government's consultation principles, as of October 2013, state that sufficient information should be made available to stakeholders to enable them to make informed comments. Failing to provide an up-to-date draft of the Bill will severely hinder the quality and relevance of feedback that is given by consultees. In the meantime, our preliminary thoughts on the revised Bill are outlined below.

We understand that in the revised version of the Medical Innovation Bill, there will be an explicit requirement that the doctor must obtain the approval of a Multi-Disciplinary Team (MDT) before being permitted to innovate. We have a number of concerns with this requirement:

A Bill requiring the approval of an MDT would reflect the existing law, so the Bill is unnecessary. Any doctor who has obtained such approval would already have done enough to satisfy the *Bolam* test (in *Simms v Simms,* the approval of 3 experts was enough to satisfy the threshold). Some may argue that this requirement in the Bill would clarify the current law. We suggest that GMC guidance could clarify the law in the same way, but would be cheaper to implement, and could easily be adapted to suit changing circumstances.

There are not MDTs for all illnesses and conditions. The law will remain unclear where a doctor would like to innovate in an area where there is not an MDT. This may even reduce innovation, as doctors may be put off innovating where there is not an MDT, as they will be unsure if they are complying with the law or not. If guidance on innovation is issued instead, doctors would not be limited to seeking the approval of an MDT if they wished to innovate. They would instead be given clear information on how to comply with the *Bolam* test, which may include, but would not be limited to, seeking the approval of an MDT.

MDTs may not always be a suitable safeguard. MDT resources are often stretched, and it is likely that if a doctor presents their innovative idea at an MDT, there may not be adequate time to dedicate to discussion of that idea. MDTs may be an ideal way to gain expert approval, but sometimes they may not be a suitable option. The standard and quality of MDTs throughout the country is inconsistent - the innovating doctor should not be forced to seek MDT approval as their only safeguard. If clear guidance was issued instead of the Bill, the doctor could use their own judgement to decide how best to obtain approval of a recognised body of medical opinion. A number of options may be open to them to help them satisfy the *Bolam* test.

MDTs by nature may not provide the doctor with sufficient knowledgeable support. Multi-disciplinary teams are by nature, multi-disciplinary. There may be experts and specialists within the MDT, but there is no requirement that these senior medical professionals are specialist in the area in which the doctor is innovating. These people may not have the same knowledge and understanding in that particular area of treatment, so may not be best placed to support (or refuse to support) the proposed innovative treatment. Again, if clear guidance is issued in place of the Bill, the doctor could use their own judgement to decide how best to obtain the approval of a recognised body of medical opinion. This may include, but would not be limited to, discussion with an MDT.

- Ends -

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