# Medical Innovation Bill

## Response to the Department of Health Consultation, April 2014

**Kingsley Napley LLP are a firm of solicitors. We have a team that specialises in clinical negligence, acting exclusively for Claimants. We have a wide range of experience stretching back over 20 years.**

Two of our team attended the consultation event for Lord Saatchi's Medical Innovations bill at the Department of Health on 10 April. Having engaged in the lively discussion, we are pleased to also put our response in writing.

The premise of the bill is that the threat of clinical negligence litigation is a barrier to medical innovation. The bill aims to encourage responsible innovation by providing that, in particular circumstances, it is not negligent for a doctor to depart from the standard medical treatment provided that the decision to do so is taken responsibly and the patient consents.

The bill does not define innovation. For the purposes of this response we understand that innovation means a treatment, or a decision not to treat, which deviates from the standard or established practice.

Before we address the 9 specific questions raised in the consultation document we would like to highlight that, in our experience, a clinical negligence claim does not demonise the responsible doctor or team of healthcare professionals. Very few clinical negligence cases end in a civil trial, and, in a civil case, there is no "guilty" verdict or prison sentence. Claims are rarely, if ever, a career ending event for medical professionals and, with an appropriate cultural shift towards shared responsibility for errors, which are then learned from in a supportive environment, clinical negligence claims should be viewed as a learning opportunity leading to training and development within the NHS.

We are sympathetic to the aims of the bill. Too many people find themselves in the desperate situation of wanting to try anything to survive a terminal illness. However, we do not think that this bill is the answer to finding a cure for cancer, or for any other terminal or life altering disease.

1. ***Do you have experience or evidence to suggest that the possibility of litigation sometimes deters doctors from innovation?***

In our experience, doctors are not deterred from innovation by the possibility of litigation. Blaming the external factor of the law may, we accept, at times provided a convenient "hook" for a clinician to explain to a desperate patient or their family that the end of the road for rational treatment options has been reached. This is an appropriate deterrent and permits a clear message to be given to the patient or their family.

Current case law provides protection to doctors for any treatment they give which would be supported by a responsible body of medical opinion.

The law has evolved from two cases, *Bolam v Friern Hospital Management (1957) 1 WLR 582* and *Bolitho v City and Hackney Health Authority (1998) AC 232.* As it stands, the case law is clear and straightforward and has allowed and supported significant medical innovations over the last 50 years, whilst protecting patients from reckless experimentation.

The consultation paper refers to the number of clinical negligence claims increasing. This does not indicate that doctors are under pressure to practise defensive medicine, nor does it follow that if doctors are under such a pressure that they are dissuaded from attempting innovative treatments.

Looked at another way, the increase in claims can be seen as evidence that the NHS is struggling to provide standard treatments to an acceptable standard. The question of whether the NHS could provide innovative treatment safely therefore arises. Perhaps, instead of focusing on innovation, the NHS should focus on avoiding avoidable mistakes.

Jeremy Hunt writes in his ministerial statement accompanying the consultation document that "we must create a climate where clinical pioneers have the freedom to make breakthroughs in treatment." Little research seems to have been done on what, other than a perceived fear of litigation, might be preventing breakthroughs, whether this is the cost of research trials or the time available to practising doctors to participate in discussions with their peers, in the UK and worldwide, about improvements in current practices.

There were no doctors, or representatives of leading doctors unions, such as the Medical Defence Union or Medical Protection Society present at the consultation event. We believe that more evidence is needed to confirm that fear of litigation is frustrating innovation.

If it is established that a fear of litigation is frustrating medical innovation then it would seem that the solution would be to train doctors on the current law and provide clear guidance on safe innovation rather than introduce legislation which has the potential to create further confusion.

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

Our experience is that there is not a lack of clarity or certainty about the circumstances in which a doctor can safely innovate. For example, many patients within the NHS safely participate in clinical trials every day.

Our concern is that if this bill becomes law there will be confusion and lack of certainty which will mean that doctors are less inclined to innovate.

Furthermore, in our view this legislation will open the door to satellite litigation. We can envisage there being two patients being treated at the same Hospital, but by different doctors. One patient is offered innovative treatment, the other the standard treatment. If the second patient believes that the innovative treatment would offer them a better chance of survival then it is likely that they will do everything they can to obtain it. Arguably, concerns about satellite litigation would add to the confusion and discourage doctors from offering innovative treatment, or prevent it being sanctioned (see below).

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

In our opinion, Clause 1(3) is too widely drafted, creating a mavericks charter which would allow doctors to freely experiment on vulnerable patients provided that the patient consents. Arguably, a desperate patient will consent to any treatment on offer. We are concerned that the legislation does not require an ethical check or balance by an independent body to verify the patient's consent.

Clause 1(3) sets out the circumstances where a doctor can depart from the existing range of accepted medical treatment for *a condition*. This *condition* could range from an infected toenail to a terminal cancer diagnosis. The publicity surrounding the bill focuses on finding a cure for cancer, but the failure of the bill to restrict sanctioned innovation to situations in which the standard treatment has not worked, leaves all patients vulnerable to experimentation.

Furthermore, at paragraph 3.6 of the consultation document, the protection offered by the bill covers both the doctor's decision and what the doctor does as a direct result of the decision, but not how the decision is put into effect. This is confusing.

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

Clauses 1(4) – (5) leave too much to the individual doctor's discretion or opinion. Again, this does not protect the patient from a maverick doctor intent on experimenting on his or her patient.

Relying on the individual doctor to base their decisions on *plausible reasons why the proposed treatment might be effective* or to identify *the relative risks that are…associated with the proposed treatment* when the proposed treatment may not be supported by a responsible body of medical opinion does not provide effective protection for patients.

The legislation around research studies already protects patients well. Including treatment offered as part of research studies within this bill would create confusion and uncertainty, which is exactly what this bill aims to avoid.

5. ***Do you have any comments on the processes set out in clause 1(6) – (7)? Are there any provisions that should be reversed, changed or added? If so, why?***

Clause 1(6) is too vague to offer patients any real protection. Although amended, clause 1(7) is ill thought out and Multi-Disciplinary Teams (MDT) are not equipped to act as rigorous gatekeepers of medical innovation. There is no proposal for how innovation will be safeguarded when the patient does not have MDT involvement, or in respect of a private doctor.

It is not clear how a doctor's process would be shown to be accountable or transparent, although the consultation document explains that accountable *is intended to ensure that the doctor's decision involves internal professional accountability, such as creating an audit trail which could be examined by other doctors.* This is confusing, given that the current case law (see above) determines negligence on the basis of a responsible body of medical opinion.

We understand from the consultation event that at clause (7) *may* will become *must* in relation to Multi-Disciplinary team approval.

We have concerns that the MDT meeting would be the wrong place to consider innovative treatment. The MDT will reflect the prevailing culture of an organisation. Therefore, the impact of MDTs is potentially inconsistent. For example, MDT meetings did not prevent the well established failings at Stafford Hospital. Nor did MDT review prevent Mr Ian Patterson offering chest saving mastectomies at the Heart of England NHS Foundation Trust. Experience has shown that we cannot rely on them being rigorously objective.

In addition, the vast majority of MDTs are already overstretched and under resourced. All of those attending a MDT meeting will have busy patient lists and it cannot be envisaged that they will have time to consider or research the potential benefits of proposed innovative treatment which may be well outside their usual area of practice. Thus, they will not have the level of necessary knowledge to act as the gatekeepers of innovative treatment. Innovative treatment might therefore be frustrated, or worse, permitted when it should be refused.

During the consultation, Lord Saatchi referred to the Effective Multi Disciplinary Team Working paper, published in 2010. Although this paper sets out laudable aims, our experience, and that of our clients, suggests that many trusts have some way to go before every MDT is as excellent at these guidelines provide.

If doctors are risk averse in offering innovative treatment then it is likely that an MDT would also to be risk adverse. Perhaps, given the wide range of knowledge and specialisms within an MDT, many members would feel ill-qualified to comment on innovative treatment that is outside their field of expertise and refuse to sanction it on this basis alone.

The use of an MDT as gatekeeper, rather than an ethics committee, means that knowledge about potential innovative treatments would be kept at a local level. We know that the NHS does not have well established communication processes and that this is something it is trying to address. As such, we would have serious concerns about how successes and failures of innovative treatment would be communicated at national, or even international level.

6. ***If the draft bill becomes law, do you have any views on the best way to communicate its existence to doctors?***

If doctors are reluctant to innovate because they are afraid of litigation then further training regarding the legal tests for negligence is needed. Detailed advice on how and when this bill applies will also need to be given on the introduction of the bill and regularly thereafter.

7. ***To reinforce the bill, are there other things that need to happen to encourage responsible innovation?***

Our experience is that the NHS does not have well established channels of communication. Our concern is that innovative treatments are, or would be taking place without the results being reported. In general, there should be a requirement to report all innovative treatment and the results, both good and bad so that the results of innovative treatment taking place elsewhere can properly be discussed with the patient.

The AllTrials campaign highlights the need for the results of clinical trials to be shared and published, regardless of whether the results are positive or negative. Both NICE and the NHS Health Research Authority are signatories to this petition, but the consultation does not address how positive and negative experiences of innovation will be reported.

There is a serious danger that the better informed patient will be able to demand innovative treatment, or threaten satellite litigation which, because of limited time and financial resources will lead to them securing treatment. Less informed patients will be left with fewer opportunities to undergo innovative treatment. The consultation document rightly identifies this risk but does not address how it would be managed.

As the consultation document identifies, there is a possibility that funding for innovative treatment will not be made available by NHS commissioners. Therefore, it seems that clinical time could be taken up with investigating innovative treatment, proposing it to an MDT, an MDT considering and sanctioning it, not to mention patient's hopes being raised at every stage, only for the commissioner to refuse to pay for it.

8. ***Do you have any comments and suggestions for inclusion in the draft impact assessment and equality analysis?***

In the Summary: Analysis and Evidence Policy Option 1 the potential of costs savings for the NHS for the innovative "holding back" of treatment are identified. The reasoning behind this is flawed. As the law is currently, if standard treatment is unlikely to work then patients should be advised of this. This Bill adds nothing to the current law therefore no savings will be made.

We cannot think of any claims in which we have represented successful claimants that would be unsuccessful if brought once this bill became legislation. Therefore, we do not think that this bill will reduce the number or cost of clinical negligence claims. On the contrary, we have identified the potential for satellite litigation which would increase legal costs.

More consideration needs to be given to whether or not a patient with no other alternative can really consent to innovative treatment. There is a real and serious danger that desperate individuals will agree to anything that offers them hope.

**9. *Should the draft bill become law?***

For all of the reasons discussed, the draft bill should not become law.

Final Note: Recent news that NICE have rejected the use of Kadcyla, a breast cancer drug, on cost grounds rather underscores the potential risks of doctors attempting expensive innovative treatments when, as it stands, the NHS cannot afford drugs that are proven to have some benefit and could be used to ameliorate the lives of existing cancer suffers.