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Innovation in medicine through degeneration in law? A critical perspective on the Medical Innovation Bill

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Abstract
The current debate surrounding the Medical Innovation Bill purports to be aimed at improving the normative framework to the extent that innovation is more likely. A closer look at the mechanisms of the proposed legislation and a more detailed assessment of the reasons given for initiating the legislative process in this instance reveal that the Bill seem to rest on a significant misunderstanding of the current law of medical negligence. This article analyses the provisions of the Bill, puts them into the wider context of medical negligence and critically reviews the utility of the proposed legislation.

Keywords
Medical Innovation Bill, medical negligence, litigation, patient protection

Introduction

Any change in societal circumstances that increases the likelihood of innovation in medicine, whilst at the same time giving proper regard to the protection of patients, is to be welcomed and supported wholeheartedly. If the current law gives rise to a reticence on the part of doctors to perform appropriate interventions for fear of facing litigation, this

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needs to be addressed without delay. The Medical Innovation Bill (the Bill) has set its sights on doing so by improving the law to the extent that doctors are able to go outside what is established medical practice without fear of incurring liability. Its proponents argue that this is wholly necessary in order to provide impetus for innovation. However, we do not believe this to be the case and argue that the Bill does no such thing, adds nothing to the law which is not already adequately regulated by existing medical negligence jurisprudence and fails to take into account the safeguards of patient interests painstakingly developed in nearly 60 years of case law.

The Bill was introduced to the House of Commons by Michael Ellis MP and to the House of Lords by Lord (Maurice) Saatchi. It is for this reason, and because Lord Saatchi has been a very vocal and public proponent of his Bill, that it is often referred to as the 'Saatchi Bill'. The Bill's sponsors, the Secretary of State for Health Jeremy Hunt among them, assert that the current system of liability in medicine represents a barrier to medical innovation.[1] The Bill is intended to clarify the law to the extent that innovative treatment options can be deployed without fear of being penalized for going outside the envelope of acceptable medical treatment. These assertions make it necessary for the Bill's proponents to demonstrate that (a) the current system of medical negligence is inefficient and represents an inappropriate deterrent to medical innovation, (b) the Bill appropriately addresses these deficiencies in the law and adds to the law in a desirable fashion and (c) the Bill does not inappropriately or disproportionately cause detriment to other legitimate interests (most notably patients' interests). We consider each in turn.

Is the current system inefficient?

The NHS Litigation Authority reports 10,129 claims in the year 2012/2013, up 10.8% from the previous reporting period. Less than 1% of these claims required litigation, and approximately 40% of claims were considered (by the NHS Litigation Authority) to be entirely without merit.[2] Where errors happen in medicine, an efficient system providing redress for patients who have suffered a detriment is entirely appropriate. As a secondary concern, this system should also provide adequate protection and indemnification of the acting professionals in order to ensure that medical care can be provided without fear of exposing oneself to undue liability. This latter point is not to be underestimated; in order to encourage bright individuals to enter into the profession and provide a service that is extremely socially desirable, it needs to be clear that they can do so without unduly exaggerated risks of liability.

It is worth noting that the discussion about the current law's capacity to encourage or discourage innovative medical treatment is quite similar to that in the context of defensive medicine. A breach of duty in relation to medical treatment constitutes an act or

1. Jeremy Hunt, Written Ministerial Statement on the Medical Innovation (No. 2) Bill. HC Deb, 22 November 2013, cols 65WS–66WS.
2. NHS Litigation Authority, Annual Report and Accounts 2012-2013. Available at: http://www.nhsla.com/aboutus/Documents/NHS%20LA%20Annual%20Report%20and%20Accounts%202012-13.pdf (accessed 26 April 2014).

omission that no reasonable doctor would countenance.[3] This is known as the '*Bolam* test' as the principle was outlined in the case of *Bolam v. Friern Hospital Management*.[4] In that case, Justice McNair stated that a doctor did not breach her duty if her act or omission conformed to a 'reasonable body of medical opinion'.[5] Medical conduct would thus be judged in relation to whether other doctors might have done the same thing in the circumstances and expert evidence as to this professional validation was key. In the case of *Bolitho v. City and Hackney Health Authority*, the House of Lords added the proviso that the courts could reject medical evidence only in the 'rare case[s]' where it was 'unable to withstand logical analysis'.[6] It should be noted that this 'logical analysis' goes far beyond mere preference or dislike of the evidence and essentially means that there must be such a failure of the logic employed that the practice was obviously (even to a layman) nonsensical. We mention this legal detail because this is the current system explicitly declared to inhibit innovation by the consultation document.

But, as we note below, we do not believe this to be the case. A doctor who, under the current system, fails to act, in the sense that she shirks the responsibility to undertake a diagnostic or therapeutic measure, does not avoid liability but rather invites an action in negligence. Her duty, currently, is to provide no more (but also no less) than appropriate diagnosis and treatment. Innovative, even entirely experimental, therapeutic options can in many circumstances be appropriate in this very sense, on the condition that the patient's interests are safeguarded. This was illustrated very persuasively in the case of *Simms v. Simms* – a case referred to in the Bill's consultation document, and the briefing note that accompanies the latest version of the Bill.[7] In *Simms*, declarations were sought that it was lawful to treat two incompetent patients who were suffering from variant Creutzfeld–Jakob disease with a pioneering intervention that had been shown to prevent the formation of abnormal prion proteins in mice. In the absence of an alternative treatment being available and given the evidence that there were possible benefits to be expected from the pioneering treatment, the court held that it was in the patients' best interests to receive such treatment. Indeed, Dame Elizabeth Butler-Sloss, P spelt out the Court's attitude to the current law of medical negligence in relation to medical innovation:

> The '*Bolam* test' ought not to be allowed to inhibit medical progress. And it is clear that if one waited for the '*Bolam* test' to be complied with to its fullest extent, no innovative work

3. N. Hoppe and J. Miola, *Medical Law and Medical Ethics* (Cambridge: Cambridge University Press, 2014), at p. 48 *et seq*.
4. *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582.
5. *'Bolam v. Friern Hospital'* at para 587.
6. *Bolitho v. City and Hackney Health Authority* [1998] AC 232, at paras 241–242.
7. *Simms v. Simms and another* [2003] 1 Fam 83, cited in Department of Health, *Legislation to Encourage Medical Innovation: A Consultation* (DoH, 2014) at para 2.4 and the briefing note to latest version of the Bill: *Medical Innovation Bill, Session 2014-15, Briefing Note.* Available at: http://medicalinnovationbill.co.uk/wp-content/uploads/2014/05/Medical-Innovation-Bill-Briefing-Note-10th-June-2014.pdf (last accessed 13 June 2014), at para 40.

> such as the use of penicillin or performing heart transplant surgery would ever be attempted.[8]

This quote was relied upon in the consultation document as evidence of *Bolam*'s capacity to discourage innovation. However, it is a lamentably incomplete analysis of what the court meant and did in *Simms*, and it is disappointing that it was included in both the consultation document and the briefing note without context. This is amply demonstrated by the fact that in that case the judge nevertheless authorized the treatment – with *Bolam* thus providing no impediment whatsoever. Indeed, the quote can be taken to mean that the correct *Bolam* interpretation includes significant consideration of avoiding detriment to innovation. *Simms* could be decided in this way because the judge was able to find other medical practitioners who stated that they *might* have acted in the same way in the circumstances, thus lending weight to the views of the treatment team (we shall return to the theme of peer validation below). It should be noted that on this point we entirely share the views of Sir Robert Francis QC, who chaired the inquiry into the events at Mid Staffordshire Hospitals, in his response to the consultation.[9] The courts are thus evidently not only not ignorant of the delicate balance between providing redress to harmed patients and encouraging innovation in medicine they are also quite ready to tip the balance in favour of innovation where this is clearly appropriate. The new Bill therefore seems to be attempting to fix a problem that does not exist.[10] If the current state of affairs did indeed discourage doctors from deploying innovative medical treatments in appropriate circumstances for fear of incurring liability, we would in fact have more instances of medical negligence rather than less; a persistent failure to act arguably represents negligence in all cases, whereas acting in an experimental/innovative context only represents *potential* negligence in cases where actual harm is the result, that is, in significantly less than all of the cases.

If the Bill's thrust is to be preserved before the background we have outlined above, its logic must be reduced from its current assertion that *the current law of medical negligence is a discouragement to medical innovation* to *the law's current focus on protecting patients is a discouragement to medical innovation*. The result of this change would

8. *Simms*, above '*Simms v. Simms'*, at para 48.
9. Response of Robert Francis QC to Legislation to Encourage Medical Innovation – A Consultation. Available at: http://www.serjeantsinn.com/ImageLibrary/Medical%20Innovation%20Bill.pdf (accessed 6 May 2014), at paras 3–5.
10. This, moreover, is a view shared by the Medical Defence Union (MDU), who stated that, 'We have no experience or evidence to suggest there is or that our members believe there is a lack of clarity or certainty about the circumstances in which they can innovate without fear of litigation', in *MDU Response to the Consultation on the Medical Innovation Bill*. Available at: http://www.themdu.com/media/Files/MDU/Publications/Consultation%20responses/MDU%20response%20to%20consultation%20on%20Medical%20Innovation%20Bill.pdf (accessed 9 September 2014). It is shared by many other bodies, including the General Medical Council and British Medical Association. Available at: http://www.stopthesaatchibill.co.uk/what-do-doctors-lawyers-and-medical-charities-say/ (accessed 9 September 2014).

be tantamount to suggesting that patients' rights ought to be renegotiated for the benefit of accelerating innovation. In order to preemptively dispel any misunderstanding of our position, we ought to make it very clear that we believe that this is a discussion that can be had. The proposal of a derogation from the protection of patients for the benefit of medical innovation is a wholly legitimate debate. If, however, we define the parameters for efficiency of the current system as *primarily* appropriately providing redress to wronged patients, whilst, *secondarily*, at the same time ensuring that those providing the care are protected against unmeritorious claims, and, only *tertiarily*, providing an environment in which innovation can prosper, there seems currently to be very little wrong with it.

Does the bill appropriately address the purported deficiencies?

The Bill's regulatory intent seems to rest on a misunderstanding of how current medical negligence jurisprudence works in practice. A correct application of *Bolam* means that a defendant doctor would merely have to show that there is a reasonable body of medical opinion that *might* have done as she did rather than establishing that others do as she does. The italicized word is important – it means that rather than having to find a body of opinion that *has* acted as the doctor did, it instead requires that the defendant finds other doctors who, in the same circumstances, *may hypothetically* have made the same decision – such as in *Simms*. A doctor taking a calculated risk to innovate in the face of imperfect existing choices would, if thinking clearly and being correct in her analysis, surely find support within the profession for the proposed course of action – thus meeting the requirements of the law. If she cannot find such support then we would argue that it is not just proper but most appropriate that the court asks a very pertinent question 'why is there no support for this course of action?' Indeed, if the doctor cannot find *any* peers who might have acted as she did, she might very well be a misunderstood genius. This is a risk the law needs to take because more often than not she will instead simply be dangerously wrong.

Unfortunately, what the Bill proposes is a reclassification of the definition of reasonableness from peer opinion to the subjective feelings of the defendant, and this is, in our view, completely inappropriate for that very reason. The law of negligence has long used the filter of expert evidence by the peers of professionals to help the courts determine whether the defendant's actions were reasonable and thus defensible. As things stand, the Bill is somewhat unclear regarding where it stands on this spectrum. Indeed, as the Department of Health's consultation document makes clear, the Bill 'is intended to avoid litigation',[11] and the view that it intends to support the *responsible* subjective judgement of individual doctors is supported by the Bill's section 1(2), which states that:

> [i]t is not negligent for a doctor to decide to depart from the existing range of accepted treatments for a condition if the decision is taken in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters.

11. Department of Health, *Legislation to Encourage Medical Innovation: A Consultation*, '*Simms v. Simms*' at para 3.13.

At first sight, this appears to be sensible. However, it should be noted that section 1(2) is here providing a blanket immunity from negligence to doctors who act within the ambit of the Bill.

A critical issue, then, is how we know whether the decision was 'accountable, transparent and allowing full consideration of all matters'. Section 1(3) provides list of factors that the doctor will have to take into account in order to meet this criterion of responsibility. The doctor must:

(a) obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment, 10
(b) 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),
(c) obtain any consents required by law to the carrying out of the proposed treatment, 15
(d) 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 20 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

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

We do not support this section, which we find too lax. It will be noted that the section itself does not require agreement or consent from these parties, only a 'consideration' of their views and notification of the responsible officer (who, if disobeyed, may take disciplinary action but still leaves the patient without legal recourse or compensation). It should be noted that the legal advice contained in Annex C of the briefing note suggests that whilst there is no duty to follow the advice, given as part of the consultation, the duty to consult is a serious one that must be taken with an open mind.[12] So how do we interpret section 1(3)? If it allows a court to second guess the doctor's decision if, after consultation, the doctor proceeds where others would not, then the raison d'être of the Bill is lost, as the doctor would have either complied with *Bolam* anyway or not be covered by the Bill.

On the assumption that the Bill intends for the test of responsibility to be determined using something like *Bolam*, it appears (at best) that the Bill adopts a type of circular logic; peer validation is not required if the doctor's decision to innovate is responsible, but whether the decision is responsible will depend on whether it is validated by the doctor's peers in their capacity as expert witnesses. This might be an indication of either poor draughtsmanship or poor understanding of the law.

12. *Medical Innovation Bill, Session 2014-15, Briefing Note*, '*Simms v. Simms'* at para 24.

The alternative is to interpret the Bill as *not* requiring *Bolam* and for the word 'reasonable' to be superfluous and the individual doctor's judgement to be sufficient justification for the innovative treatment. In this scenario, we would thus have to interpret the Bill as providing a blanket defence where the doctor's subjective opinion is that the innovation would meet the criteria – and it would thus be perilous legislation. This is because it would simply no longer matter that the doctor might be entirely misguided either about the comparative risks and benefits of each option or about the actual efficacy of the innovative treatment. In such a scenario, the patient will be sacrificed as forseeable and preventable collateral damage in a quest for innovation. This would not be so bad if the Bill only applied to cases where the existing treatments, for example, would not save the life of the patient or offered no cure. However, the Bill makes no such limitation, at least in explicit form. Sadly, this latter interpretation is the most likely, given that the Bill's stated aim of allowing legality to be determined *before* treatment necessarily precludes a court using *Bolitho* to examine decisions that seem poor in retrospect.[13]

Does the bill disproportionately affect others' interests?

Resting entirely on the defendant's notion of what is reasonable and what is not has a significant impact on the patient's ability to adequately consent to the innovative treatment. Section 1(3)(d) of the Bill suggests that there still ought to be consent as otherwise required by law. The ethical justifiability of treatments (and with it the quality of consent obtained) rests to a significant extent on an appropriate risk/benefit analysis. Where the defendant has erroneously or recklessly decided that there is no (or negligible) risk involved in the proposed innovative treatment, the information given to the patient will be flawed to the extent that the validity of the consent can very well be questioned. The Bill also makes a policy guidance statement to doctors in that it manifests a political will to encourage viewing experimental interventions as legitimate treatment options. Making it explicitly easier for medical professionals to provide experimental treatments thus raises a legitimate conflict of interest issue. Many medical professionals in large teaching hospitals will be clinicians as well as researchers. An increased impetus for the mixing of these two roles may give rise to ulterior motivations in recruiting patients from the clinical context into a research context. Again, whilst this is not per se an indefensible state of affairs, the Bill and the consultation remain silent on this aspect. In essence, the Bill is so concerned with decreasing a perceived liability risk to clinicians that the legitimate interests of patients seem to take the back seat entirely. It is striking that this aspect is ignored entirely, though one might argue that the metamorphosis of consent from a protection of individual autonomy into nothing more than a flak jacket against doctors' liability is simply coherently continued and developed with this Bill.

Concluding thoughts

The proponents of the Bill are correct in suggesting that innovation in medicine is part and parcel of taking risks and going beyond what is established practice. It is also correct to assume that this will in nearly all cases that reach litigation stages to have been to the

13. *Medical Innovation Bill, Session 2014-15, Briefing Note*, '*Simms v. Simms*' at para 4.

detriment of a patient – a price society may have to be willing to pay to ensure that innovation takes place at a pace that is commensurate with the interests of the many. Nonetheless, we have to be mindful of having the debate about appropriate regulation in the context of accurate facts. The discussion in relation to the Bill is generally had on the premise that under the current legal regime, any doctor who leaves the well-trodden path of medical options exposes herself to liability. This is wrong. Any doctor who stands still and does not leave the path where it ends, to the detriment of the patient, has already exposed herself to an action in negligence. Indeed, the consultation paper itself outlines (at para 1.2) that medical innovation has moved at an impressive pace in this country, for example, children born in 1912 had a life expectancy of 53 years for males and 56 years for females. By 2012, this had risen to 79 and 83. The paper calls for moves to *continue* this progress. It provides no evidence that innovation *is* being stifled by the law and thus potentially seeks to correct a problem that does not exist. It certainly does not meet any standard of proof in showing that there is a problem that ought to be addressed. Indeed, as we note above, even the Medical Defence Union (MDU), in its own response to the consultation, argues that there is no evidence that innovation is currently being stifled, nor that the law is unclear. It suggests that the Bill might *itself* deter innovation rather than facilitate it.[14]

Our principal concern lies in the notion that this support for innovation comes at the price of sacrificing safeguards protecting patients. The courts have traditionally used peer support (or the lack of it) as a key driver regarding the reasonableness of medical decision-making, and the Bill potentially discarding this mechanism may well result in the undue protection of maverick doctors who have made foreseeable errors in analysing the benefits of attempting an innovative treatment. In other words, despite there being scant direct evidence of genius being held back, patient safety is being put at risk in order to stop potential litigation against those who misjudge. As we have shown, if a doctor's proposed innovative treatment cannot garner the support of her colleagues, we ought properly to ask 'why not?' We would also hope and expect that a court would do so. The law as it is already allows proper scrutiny whilst maintaining as much flexibility as possible. We feel that this proposed legislation limits its power to continue to do this and indeed compromises patient safety in order to promote innovation and all of that is to be regretted. As such, and in common with representative groups such as the British Medical Association, General Medical Council and MDU, we cannot and do not support the Bill in its present form. Given the lack of any evidence that it is needed at all, we do not think that we will be able to support it in any form that lessens protection for patients.

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14. *MDU Response to the Consultation on the Medical Innovation Bill* – see '*MDU Response'*.