

the Nightingale Collaboration

Response to the Department of Health's consultation:

Medical Innovation Bill

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Challenging misleading healthcare claims

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Introduction

We welcome the opportunity to respond to your consultation on the Medical Innovation Bill.

In general, we found the consultation document confusing, poorly written and biased and this has not helped tease out the various issues involved.

Additionally, we are aware that the Bill is in the progress of being amended as a result of consultation responses already received. This makes it very difficult to respond to the substantive issues.

Because of this and because our response does not fit well with the questions posed in the consultation document, we are responding to these issues below.

About the Nightingale Collaboration

The Nightingale Collaboration is a consumer pressure group set up by Dr Simon Singh primarily to challenge misleading claims in the promotion of healthcare therapies to the public.

For further information on our activities and details of our successes, please see our website at: www.nightingale-collaboration.org.

No evidence of need

We find the consultation document not persuasive of the need for the Bill, with frequent *non sequitur* arguments and unevidenced suppositions.

For example, paragraph 1.2 talks about medical innovation over the last century leading to great strides in life expectancy. However, it then goes on to imply that future progress will be impeded if the law is not changed. We find this a *non sequitur* and an argument from emotion; no evidence is provided to substantiate this claim.

Similarly, charts are given (Figures A and B) that show the number and cost of clinical negligence claims in the past few years. However, it is not clear that these data correlate with issues of refusals to innovate, never mind demonstrating any causal link.

As such, we can only assume these were chosen for maximum visual impact and not to provide clarity in demonstrating a need for the Bill.

However, the Bill, at 1 (1), states:

The purpose of this section is to encourage responsible innovation in medical treatment (and accordingly to deter innovation which is not responsible).

We find that the consultation document provides no evidence that the encouragement to innovate that the Bill seeks is necessary; or that the current legal climate is hampering responsible innovation; or that the measures it seeks to introduce would achieve that aim.

We note that many others share our view and have already expressed that view.

Opposition

We note that the Medical Defence Union, which helps 50% of UK doctors with complaints and claims, has said it sees no need for new legislation:

[Current] Legal and ethical requirements don't present a barrier to such innovation so long as doctors can show they acted with reasonable care, had good reason to depart from established or standard practice and the patient has consented to the treatment proposed.¹

Professor Michael Baum FRCS, ChM, MD (hc), FRCR (hc), Professor emeritus of surgery at Kings College London, the Royal Marsden Hospital and University College London and Past President of the British Oncology Association has stated:

I believe therefore that I am well qualified to pass an opinion on the Saatchi Bill. I categorically state that in over 40 years first hand experience at the “coal face” on innovative research governed according to the highest ethical principles, *I have never once experienced any obstacle that could even indirectly be linked to fear of litigation.*²

Similarly, Nigel Poole QC, who specialises in clinical negligence and personal injury law, also believes the Bill is unnecessary.³

We are aware of similar views expressed by doctors, researchers and lawyers and we are confident that many will make their views known to you through their responses.

In terms of the current climate for innovation, we note the views of Cancer Research UK:

It's worth pointing out that here in the UK, there are many things already in place to encourage innovation. For example, early stage clinical trials provide the best way in which patients can be recruited to test new treatments – many trials of brand new agents are run through our national network of Experimental Cancer Medicine Centres. There are also flexible mechanisms in place that enable doctors to get access to treatments that aren't widely available on the NHS.⁴

However, if there is a problem with the perception of doctors that if they were to innovate they run a very real risk that they will be sued, then that might be an issue that should be addressed — and addressed by better education and training, not by a Bill that is, however well-intentioned, creates more problems than it seeks to resolve and that reduces the protection for vulnerable patients.

Bolam

The consultation refers to the *Bolam* and *Bolitho* tests and these were mentioned by Lord Saatchi in his discussion hosted by Dr Ranj Singh.⁵

In that discussion, Saatchi summarised the Bill saying that its effect would be to move the Bolam test out of the courts after the fact to become a test to be passed before treatment is given:

The doctor has to pass a very high test. ... So the doctor has to pass the Bolam test. Instead of worrying whether he will or won't later, he can pass the Bolam test in advance. You see that gives certainty to the doctor.

We believe this is an accurate summary of the intent of the Bill but we find this very worrying.

Currently, a doctor challenged in the courts or tribunal for providing a treatment would be judged on the ability to meet the Bolam and Bolitho criteria. However, to do this, both sides can call their own experts and cross examine in open court allowing the court to establish a full, fair, open and proper view as to whether a treatment does indeed pass those tests. Doing this provides a well-established means of protecting both doctor and patients.

This Bill removes all these very necessary patient safeguards.

It seeks to replace the scrutiny of that court with a potentially brief and possibly cursory discussion with a doctor's colleagues on a Multi-Disciplinary Team (MDT). It is our understanding that the members of that team will not all have the same qualifications, expertise and abilities as the doctor requesting the 'innovative' treatment. Additionally, they may have no prior knowledge of that treatment.

It is likely, because of the time criticality of the situation, that a decision might have to be made swiftly, particularly if, say, a new drug had to be manufactured or obtained before it could be administered.

We do not believe this can ever be in the best interests of patients — we believe that far greater scrutiny is required as a necessary patient, and doctor, safeguard.

Having said that, we are aware of some criticisms of the current situation where the process of granting permission to a doctor to try a new treatment may be too cumbersome. We feel that is a different issue, outside of this consultation, and one that may be best improved by looking at those issues separately. We do feel that this would be a far better area to investigate in terms of encouraging innovation whilst maintaining the necessary patient safeguards.

Additional concerns

We also have concerns about the following:

1. The MDT may or may not have the skills, training, knowledge or experience to judge whether a proposed new 'innovative' treatment meets the requirements that there are plausible reasons why it might be effective and what the risks might be reasonably expected to be.
2. The MDT may or may not have the independence necessary to judge whether a proposed treatment is in the best interests of the patient.

3. The Bill is silent on how any potential conflicts of interest should be handled to ensure they cannot affect such a decision.
4. We acknowledge that most doctors would only provide treatments responsibly. However, there is no general agreement that there would be a consensus for some of the more unorthodox treatments. We are aware that some who advocate non-mainstream cancer treatments (eg vitamin C injections, mistletoe therapy, dietary supplements, homeopathy, detoxification) are GMC-registered doctors. We do not believe the Bill recognises this fact nor does it protect vulnerable patients from such treatments.
5. There is currently no requirement to properly record details of the treatment, how a decision was arrived at, any conflict of interests, outcomes, etc other than that which would be recorded normally in the patient's notes. We believe this means that any knowledge gained about benefit and harms will be lost and no lessons learned for future doctors and patients.

Amending the Bill

We are aware that there are intentions that the Bill be amended to counter some of the objections that have so far been voiced. We do not believe that the Bill is capable of being amended in such a way as to raise the protection of patients to an acceptable level. Also, given that we are not aware of any need for the Bill in the first place, it is unlikely we could support an amended Bill.

Without the main assumption of the Bill — that doctors are unwilling to innovate because of fears of litigation — being substantiated, the whole Bill disintegrates.

Summary

However well-intentioned the Bill might be, it is thoroughly misguided and we believe it will simply encourage irresponsible 'innovation' to the detriment and harm of vulnerable patients.

We do not believe that these failings can be corrected by amending the Bill.

But we must come back to the original premise of the Bill: that the current legal climate stifles innovation. Until this can be substantiated with good evidence, taking the Bill forward cannot, in our opinion, be justified.

We owe it to patients to base all treatments on the best evidence available, and this is what all medical staff strive to do daily.

We similarly owe it to patients to base all laws governing those treatments also on the best available evidence.

We therefore urge that decisions on this Bill are not made on emotion, anecdotes or unevicenced grounds.

The Bill should not become law.

References

- ¹ “The MDU - MDU Reassures Doctors They Are Free to Push Medical Boundaries,” February 27, 2014, <http://www.themdu.com/press-centre/press-releases/mdu-reassures-doctors-they-are-free-to-push-medical-boundaries>.
- ² Nigel Poole Q.C, “Learned Friend: Guest Post by Professor Michael Baum,” April 24, 2014, <http://nigelpooleqc.blogspot.co.uk/2014/04/guest-post-by-professor-michael-baum.html>.
- ³ Nigel Poole Q.C, “Learned Friend: Opposing the Saatchi Bill,” April 23, 2014, <http://nigelpooleqc.blogspot.co.uk/2014/04/opposing-saatchi-bill.html>.
- ⁴ “Public Consultation on the Medical Innovation Bill,” *Cancer Research UK - Science Blog*, March 11, 2104, <http://scienceblog.cancerresearchuk.org/2014/03/11/public-consultation-on-the-medical-innovation-bill/>.
- ⁵ “Medical Innovation Bill Hangout - Hosted by Dr Ranj - Google+,” *Google+*, April 22, 2014, <https://plus.google.com/u/0/events/c80kqapi0048lilguoc1idq0934>.