

Response form

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Are you responding as an individual or on behalf of an organisation? An organisation
if as an individual, are you responding as:
a) a doctor?
b) a patient?
c) a lawyer?
d) other?
If you are responding on behalf of an organisation, please give the name of the organisation and say who it represents: HealthWatch – charity 1003392 which supports evidence based health care, established in 1991. www.healthwatch-uk.org

The questions posed in the consultation paper are as follows:

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

Our members comprise a variety of specialisms and professions, with a substantial representation of medical and paramedical practitioners, and individuals involved in health care research. We consider that opportunities for innovation already exist within the established processes of drug discovery and development. We are not aware of any cases where fear of litigation has inhibited innovation.

Question 2: 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?

No. Doctors currently are expected under the terms of their registration to follow evidence based clinical practice. Evidence is not defined proscriptively, in that the best available evidence for a treatment may not always be from randomised controlled trials (the so-called 'gold standard'). Doctors prescribing a treatment must always be prepared to defend their decisions on the basis of a risk versus benefit evaluation. We consider that these mechanisms provide adequate clarity to enable doctors to try new treatments. By introducing yet more new legislation that there might be a real danger of confusion which would inhibit good care and responsible innovation.

Question 3: 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.

No. Clause 1 (3) is extremely badly worded. Medical opinion is not the issue, but medical evidence is. The question is whether the proposed treatment has any objective evidence or plausible science based mechanisms that it might be effective.

Question 4: 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 responsible? 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?

Again this section erroneously focuses on medical opinion. Whereas all doctors have opinions, all opinions are not equally valid - these must always be underpinned by evidence. When medicines are in early development, evidence is necessarily scant, but it is not absent. A responsible decision therefore must be one which takes into account the available evidence. A decision based only on opinion, or even on personal experience, would be irresponsible.

However, it is possible that the word 'opinion' is used in the legal sense. When the courts ask for expert opinion, they expect it to be underpinned by evidence. Therefore, if the Bill allows a doctor to depart from the body of medical opinion, it effectively allows them to ignore evidence. That would be reprehensible.

Clause 5(d) does not mention informed consent. Requests by the patient must be within the context of an adequate understanding by the patient of the risks and likely lack of benefits of an untested or unproven treatment. Any decision made without such informed consent would be unethical. Whereas clause 8(a) appears to reinforce the existing need for consent, clause 5(d) conflicts with that by not basing consent on the need to convey to the patient the current status of evidence for the proposed treatment.

Clauses 1(4)-(5) are likely to cause a great deal of confusion, as they cross-refer and create circular references. In summary, these clauses are unclear and violate basic principles of medical ethics.

These clauses imply detailed record keeping, such that the entire process is open to audit. Assuming that such a process exists, clauses 7(b) and (c) expose highly vulnerable patients to significant risks. The Bill seems to assume that all 'innovation' will take place within the National Health Service. However there is a large private sector in health care in which 'alternative' treatments abound. Such practices can seem very attractive to desperate patients, but at least they are subject to GMC regulation. For example Dr Philip Jack is currently before the Medical Practitioners Tribunal Service for giving a cancer patient ozone therapy, which has no evidence for effectiveness. Similarly Dr Julian Kenyon is under MPTS investigation for administering Sono Photo Dynamic Therapy. However, the Bill is so loosely worded that private practitioners could easily assemble a multidisciplinary team of like-minded people and a 'responsible

officer' to rubber-stamp unhelpful and even bizarre or dangerous treatments.

Worse still, the notes to the Bill recognise that self-employed doctors may not have a responsible officer so could do more or less as they please.

Alternative practitioners are often sincere, though some (including qualified doctors) are charlatans. In either case this Bill would make it much more difficult to regulate those who exploit vulnerable patients.

Question 6: If the draft Bill becomes law, do you have any views on the best way to communicate its existence to doctors?

No. The Bill should not become law. But if it does, all responsible bodies should tell doctors to ignore it. The GMC and other institutions including the Royal Colleges will continue to require evidence-based medicine, and those who depart from good practice will risk sanctions or be struck off.

Question 7: To reinforce the Bill, are there other things that need to happen to encourage responsible innovation?

Other measures are already in place, and developing. The MHRA announced on 14th March 2014 the Early Access to Medicines Scheme, which will enable seriously ill patients to access innovative medicines as soon as initial clinical trials are completed.

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

A major negative impact is the increased difficulty of regulating private sector 'alternative' practitioners, who already exploit desperate and hence vulnerable patients. This is not mentioned in the impact assessment. This could create a greater demand for 'alternative' treatments within the NHS, which will divert resources from evidence based practice. We wish to be clear – we are a charity which supports "treatments that work". We support the proper testing of all therapies. Patients should always be offered compassionate care, and be offered choices, where valid choices exist. We do not support whims, biases or the use of dangerous treatments presented as 'innovations' when they are not.

Question 9: Overall, should the draft Bill become law?

Yes / Yes with modifications outlined in response to questions 3-5 / Yes with other modifications (please specify) /No

No. The Bill addresses a problem which does not exist and thus creates more difficulties than it intends.

We also welcome any other comments you wish to make.

This consultation does not appear delete to be neutral. It fails to pose many of the challenging questions about potential risks to patients. HealthWatch does not support the Bill, and will not provide responses aimed at making the Bill easier to become law.

The Bill's website at Tumblr states:

“Under the Department of Health-backed scheme, any severely ill patient with a life-threatening or debilitating condition will be able to get new drugs that have been proved to be safe but are still in development”.

This shows how poorly drug development is understood by those backing the Bill. There is no such thing as ‘proved (sic) to be safe’. Safety is a relative assessment, and the earlier the drug is in development the less is known about safety. If the Bill means that the drug has successfully completed phase 1 trials, then only basic safety will have been demonstrated. If there is no evidence in humans of efficacy, then the drug will not have completed phase 2a trials (proof of concept). Patients should not be told that the drug is safe if it has only completed very small early phase trials.

The term ‘innovation’ has not been properly defined in the Bill. The present definition is based simply on a departure from established practice and from current medical opinion. Opinion is the worst basis for a clinical decision. The standard should be that of evidence, and that will be the best available evidence to date. It may not always come from randomised controlled trials (RCTs), but in general the greater the doubt about a proposed intervention the greater the need for RCT evidence. Even drugs in early development will have some evidence, from pre-clinical and phase 1 studies. At present, the Bill would allow treatment with untested drugs if a multidisciplinary team can be assembled to agree to it.

Currently, innovative treatments can be used, but only in clinical trials. This is because trials are the means by which we obtain good evidence. If such treatments are offered outside clinical trials, we will stop collecting evidence, so other patients cannot benefit.

At the House of Lords launch for the Bill, the Department of Health spokesman stated that any requirement to record outcomes from ‘innovative medicine’ was deliberately kept out of the text. This was because it was thought to be a deterrent to trying unusual interventions. It is very hard to see how any successes emerging from such treatments might be propagated to other patients in need. Doctors will not need to keep meticulous records as is the case for clinical trials, and there is no requirement that any records they do keep are subject to quality assurance, and are published. The value of any genuine innovation will therefore be lost. Medicine will revert to the pre-20th century paradigm, where treatment decisions were based on recommendations from other doctors, and not on objective evidence. When legislators come to consider this Bill they should be aware that they might open the flood gates to quackery. It is hard to discipline clinicians who make outlandish claims and our members have experienced many occasions where complaints to the GMC have foundered and patients are still put at risk.

We have given two examples in this response where the GMC is taking action, but there are very many more where complaints have been brushed off. In another case a registered doctor has been advised by the Advertising Standards Authority to remove false claims from their website, and now invites patients to telephone for verbal advice which the ASA will not allow in writing. The GMC still refuses to take any action. Such a doctor may well be able, should the Bill become law, to make a case for ‘innovative’ treatment and escape even ASA regulation. The ASA is a voluntary code and

several cases remain unresolved because traders refuse to remove false claims. Doctors in private practice will be encouraged to resist even more if they think they have a legal defence via this Bill. Similarly the GMC might be discouraged from pursuing cases if they assess the chance of success to be lower because of a defence being mounted via this Bill.

In the USA, there is the notorious case of Dr Stanislaw Burzynski who for well over 30 years has falsely claimed to be able to treat seriously ill cancer patients, charging them enormous amounts of money. He has exploited loopholes in US drug regulation, but has never produced any robust evidence to support his claims. Such a case has not arisen in the UK because it would be illegal, but this Bill clearly would make such abuses more likely.

In reality, this Bill addresses a problem which barely exists, and in any case is being addressed by measures such as the Early Access to Medicines Scheme. But most importantly, it exposes highly vulnerable patients to exploitation by 'alternative' medical practitioners. It will add nothing to patient benefit, and should not become law.