Response form

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Are you responding as an individual or on behalf of an organisation? Individual
If as an individual, are you responding as:
a) a doctor?
b) a patient?
c) a lawyer?
d) other? X
f you are responding on behalf of an organisation, please give the name of the organisation and say who it represents:

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?

I have long experience as chairman, president or a board member of a number of national healthcare and bioethics charities. It is true that some crass laws inhibit good innovation. It is also the case that litigation is a serious threat to medicine. While it sometimes results in compensation to provide vital care for those disabled by medical mistakes all too often its principal success is in diverting resources from health care to lawyers.

However, this Bill almost wholly misses the point.

It is stuck in a nineteenth century concept of medical practice before ideas of evidence-based or even socialised medicine had taken hold. Innovation is so poorly defined in the Bill that it would open the door to all sorts of misconduct. Indeed, under the guise of innovation it would entrench old-fashioned malpractice and quackery.

In any case there is no need for this Bill. It is a hammer to crack a non-existent nut. Worse, to use a colloquialism, it could encourage nuts – whacky, foolish and even unscrupulous practitioners - which, where patient safety is concerned, would be scandalous

Presently, where an individual clinician steps outside established protocols, he or she does not have any special dispensations. Nor are any needed. There is usually ample room for innovation WITHIN established protocols (although there are exceptions – see Question 4). The larger problem has been that too many clinicians have taken whimsical approaches to treatment in which best evidence has been trumped by supposition, outdated teaching or personal experience.

Innovation in medicine is hugely important but also has its dangers. It is not to be trifled with, and its history is littered with examples of terrible damage done by treatments which did not have adequate scientific evidence for safety and efficacy. It is usually best undertaken collaboratively and with ethical and scientific oversight.

All off-label prescribing and all unconventional treatments should be regarded as part of a therapeutic trial and the onus should be on the lead clinician to ensure that (a) he/she has consulted widely with knowledgeable colleagues (unless in an emergency where collaboration is impractical); (b) there is real informed patient or guardian consent; and (c) the “trial” (since this is what innovative treatment amounts to) should be registered and its results should be made available to others.*

*The All Trials Campaign is successfully ensuring that pharmaceutical companies should publish full details of experimental treatments, and the same persuasive public interest logic should apply to surgeons and physicians.

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?

As I say, the threat of litigation is a major problem in medicine and a huge drain on the NHS (mostly because the disproportionate cost of contesting the actions).

But not because of innovation.

Litigation is almost invariably the result of a diagnosis that has allegedly been missed, or of claims that a treatment has negligently failed or backfired.

Uncertainty is a routine part of medical reality and existing law has proved flexible enough to allow practitioners to make difficult, sometimes life or death decisions, within existing guidelines. Even when novel treatments have been tried *in extremis* I am not aware of a single instance which has resulted in litigation so long as professional and ethical guidelines have been followed – notably collaboration with colleagues and explicit and informed patient consent.

I myself have helped authorise innovative treatments (for example as a member of the Gene Therapy Advisory Committee) and to fund experiments on humans (for example, as a member of the UK Stem Cell Foundation). Neither I nor colleagues have ever been deterred from good practice by concerns about improper litigation.

There is no need for this Bill.

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. Frankly this is an outrageous clause that risks returning us to the age of pre-enlightenment.

If it is “unclear whether the medical treatment that the doctor proposes to carry out has, or would have, the support of a responsible body of medical opinion” then of course the patient must have recourse to law if things go wrong.

It is hard to conceive of a circumstance in which a doctor would go against the responsible concerns of his or her colleagues without recognising that such a course of action is open to both professional and legal challenge.

Medicine should not be Wild West buccaneering. It is a science built on the careful accretion of knowledge, and a profession that, in managing uncertainty, seeks to default to conventional methods except in properly authorised trials.

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?

I can only imagine that those in favour of this Bill have not thought through the consequences, while others might be keen to take us back to a pre-scientific age.

Clause 1(4) requires that there must be "plausible reasons why the proposed treatment might be effective". This might be sensible if it required "*scientifically* plausible reasons", but, to quacks, faith healers, fools and conmen almost anything is plausible, including meridians, spirits, water memory and laying on of hands.

In any case, plausible theories can be, and have often proved to be, spectacularly and fatally misleading. Laying babies to sleep on their stomachs (so they don't ingest vomit) was a plausible idea that resulted in thousands of cot deaths. Dozens of other half-baked ideas - applying albumen on burns or steroids for brain injury - have taught how persuasively dangerous credible ideas can be.

This is not to deny that at least in one sense doctors do routinely have to "responsibly innovate": in fact clinicians frequently provide treatments which are not officially endorsed. Oncologists may use last-ditch efforts (such as non-approved use of drugs) to save a patient even where there is considerable risk of failure or even of causing harm. A more common example is with pregnancy where most drugs are off-label because medical trials have specifically excluded pregnant women. Even so, there is no reason to absolve a doctor of responsibility if he or she experiments on patients in a manner which might be held to be negligent or reckless.

A more useful Bill would require the systematic notification of off-label treatments and formal collection of evidence of individual outcomes so that patterns can be identified, thereby giving warning of adverse events and notice of efficacy and safety. We all contribute to the NHS and each individual treatment is, in effect, a natural experiment. It is an unforgivable waste of knowledge and resource that currently the collection of data is so haphazard, whether in hospitals or from GP practices.

Responsible innovation in medicine can rarely be piecemeal because of the difficulties of controlling against chance and bias. What appears to be a cure in one individual, or an undesirable aftermath, might be a natural outcome. And bias is quite as contaminating as coincidence. Any number of studies show how powerfully all of us are inclined to unconscious preconceptions (this is one reason why placebos can be so effective). There is also the challenge of human variability, so that what seems to work for one patient may not work for others.

This is why freelance "innovation" on real patients is unlikely to be ethical, except in the most extreme cases, and is unlikely to advance medical knowledge. We must not promote a culture of amateurism.

Question 5: 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?

These clauses are redundant in all but appallingly bad medical practices.

Naturally, where unconventional treatments are proposed the patient should be explicitly warned of risks and of likely failure; but a physician or surgeon should ALWAYS discuss a proposed treatment with the patient and give the patient reasons for carrying out a treatment. This goes to the heart of medicine and has nothing uniquely to do with innovation.

Any but routine treatments should ALWAYS be made in consultation with colleagues where practicable, and often with a multidisciplinary team (for example, with pharmacists if unconventional off-label use of drugs is proposed).

A doctor should also be expected to notify responsible colleagues of any unusual treatments. This is basic professionalism and should not be relied upon to excuse a physician who has acted incompetently or recklessly. Anything different would put practitioners in conflict with GMC good medical practice and, *in extremis*, could rightly have them struck off the medical register.

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

Yes. Tell them they might just as well not have bothered to go to medical school because parliament has decided that they can be held to be acting “responsibly” if they make things up as they go along.

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

Nothing should be done to reinforce the Bill; only to prevent its passage into law. It will NOT encourage responsible innovation. It may very well provoke irresponsible and dangerous medical practice.

The colonisation of medicine by lawyers has to be resisted, but this is not the way to do it.

Real breakthroughs in medicine come from persistent research, not unscientific trial and error on individual patients. In fact anecdotal evidence of success has often led medicine astray.

In any case, arguably the most pressing need for innovation in healthcare is to encourage more efficient ways of working so that precious resources are used more effectively. For example, there is a pressing need to shift health spending from vastly expensive hospitals to more innovative smaller units and to better social and primary care, but doctors who understand the logic have nonetheless frequently been in the forefront of Luddite and self-interested campaigns which whip up public anxiety and make hospital closures seem retrograde rather than innovative.

If we wish to encourage responsible innovation we should promote anything which helps us all to ration our finite and precious health resources more wisely.

The last thing we should encourage is arbitrary try-outs even within conventional medicine, let alone with so-called “alternative” treatments which, because many lay people find them intuitively attractive, risk additional burdens to health budgets without any improvement in morbidity or mortality.

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

No, other than that if legislators are so imprudent as to pass this Bill into law it would have its most forceful impact on the sick, the elderly and other vulnerable people who will face an elevated risk of being treated as guinea pigs by rogue physicians.

There are substantial inequalities in medicine, such as in access to timely, convenient, caring and high quality medical treatment or to research that does not sideline children, pregnant women, co-morbidity and other factors. But these inequalities will not be meaningfully reduced, and may be worsened, if clinicians are encouraged to make *ad hoc* decisions based on personal judgement rather than collective wisdom, ethical supervision and peer reviewed research.

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. It may be well intentioned but it is naïve. And it does nothing to stem the real and pressing problems either of lack of innovation or of excessive litigation in healthcare.

It is a Charlatan’s Charter. The media may well call it such

We also welcome any other comments you wish to make.