Response form

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Are you responding as an individual or on behalf of 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:

This response is from the Royal College of Psychiatrists Faculty of Academic Psychiatry and the Special Committee of Psychopharmacology.

The Royal College of Psychiatrists is the professional medical body responsible for supporting psychiatrists throughout their careers, from training through to retirement, and in setting and raising standards of psychiatry in the United Kingdom.

The College aims to improve the outcomes of people with mental illness, and the mental health of individuals, their families and communities. In order to achieve this, the College sets standards and promotes excellence in psychiatry; leads, represents and supports psychiatrists; improves the scientific understanding of mental illness; works with and advocates for patients, carers and their organisations. Nationally and internationally, the College has a vital role in representing the expertise of the psychiatric profession to governments and other agencies.
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?**

Evidence-based medicine is at the heart of clinical practice. However, non-evidence based medicine is not uncommonly required, and as the consultation paper suggests, innovation also has its place in day-to-day clinical medicine. All doctors should be aware of the practices and legalities of off-label prescribing. In psychiatry the absence of evidence from RCTs and from studies with sufficient rigour, such as those involving controlled conditions, randomisation and blinding, is generally countered by extensive clinical experience and expertise supporting a treatment.

Nevertheless, in the last few years management of risk has increased such that doctors may not be able to be as innovative as they wish. NICE demands a certain level of evidence, which may be lacking. By contrast, guidelines for a range of psychiatric disorders from the British Association for Psychopharmacology are built on a range of evidence, including clinical expertise. A likely unintended consequence of NICE is that some provider organisations appear to regard them as a protocol, with the result that if NICE does not recommend a treatment or approach, a doctor will find it hard if not impossible to deliver it. We suggest that fear of litigation is at the heart of this caution. Of course, this may result in a potentially successful treatment or approach not being given. Indeed, introducing a licensed treatment may also incur significant ‘paperwork’ to gain approval to use and this can take many months.

**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?**

Our experience is that there is variability within Trusts and provider organisations as well as between doctors about innovation without fear of litigation – or even prescribing ‘off-licence’, as is commonly done.

**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.**

The definition of ‘doctor’ requires consideration since currently ‘doctor’ means ANY registered doctor, specialist or not, and therefore the way is open for any doctor who might be wholly unqualified to determine whether the conditions of subsection (3)
apply.

This goes some way beyond the Bolam test for medical negligence (Bolam v Friern Hospital Management Committee [1957] 1 WLR 582), where the test is that a ‘medical man’ needs to act in conformity with a ‘responsible body of medical opinion,’ in other words, NOT in the manner of 1 (3) (a) and (b) of the Bill.

Concerning “or would have the support of a responsible body of medical opinion” – it would be helpful to clarify who might constitute such a responsible body.

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?

The use of ‘relative risk’ requires reconsideration and clarification. ‘Relative risk’ carries very specific scientific meaning with respect to the background comparator in a statistical test. An alternative should be used, clearly specifying what is meant by ‘risk’ and ‘relative’ to what.

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?

7(a) is very important – it is impossible to proceed without doing this.

7 (b) appears reasonable. However, if a doctor was thinking about doing something unorthodox, a multi-disciplinary team (MDT) with a range of expertise which is likely to include non-medical and non-nursing staff may not necessarily be aware of all the knowledge and also be risk-averse. Therefore, what would happen if the MDT declines the innovation? Would it not be better to ask other medical colleagues in the field rather than the MDT? It is important for the MDT to understand why the approach is being taken, however it would not be appropriate to have one member with insufficient knowledge blocking the innovation.

7(c) It is not clear what the purpose might be of giving ‘notification’ to his or her responsible officer ‘(if any)’. What power would the responsible officer have? We are not clear what the GMC would say about that. It leaves doctors without a responsible officer in a difficult / different position – what should they do or what should be expected of them?

Local governance structures will be important here, yet the Bill makes no explicit reference to these. For example, for medicines, the Medicines Management Committee approval is critical. Doctors are also likely to ask their defence
organisation, and these are not mentioned here. These should be reflected in 7c and include the wording ‘relevant advisory bodies in their local governance structure’.

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

We suggest that the General Medical Council and Royal Colleges possibly via the Academy of Medical Royal Colleges, could be asked to disseminate knowledge – preferably electronically.

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

Publicly registering clinical trials allows anyone to access what trials are going on worldwide. Whilst not wanting to add to ‘paperwork’, a register that is available to other doctors would allow sharing of knowledge about a potential innovation and this would be beneficial. Some form of publication about the outcome would also be valuable.

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

We suggest you include whether or not a research study has been developed, based on the experience of doctor(s) and patient(s) and outcomes from the innovation.

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

We also welcome any other comments you wish to make.

Yes, with modifications outlined in response to questions 3-5, and with the other modifications we propose below:

Regarding (8) Nothing in this section permits a doctor—
(a) to provide treatment without consent that is otherwise required by law, or
(b) to carry out treatment for the purposes of research or for any purpose other than the patient’s best interests.

We suggest that this requires clarification. Research should be covered by research
protocols and regulatory approvals (e.g. from Research Ethics Committees, the Medicines and Healthcare Regulatory Agency [MHRA], the Research and Development Consultative Committee).

It should be clear, and specifically pointed out, that this Bill does not apply to the conduct of research that has been sanctioned by research ethics committees and is following an agreed protocol.

There is nothing about how the innovative approach will be evaluated and that it is beholden on doctors to evaluate their work appropriately. It is even more important when undertaking such work covered in this Bill. It is also not clear how other individuals will know about innovative work being undertaken.

We support a legal framework to enable doctors to be innovative and to work in areas where there is a lack of evidence-based medicine or significant clinical expertise or experience, whilst providing safeguards against irresponsible and arbitrary prescribing or delivery of other treatment approaches.