

National Assembly for Wales / Cynulliad Cenedlaethol Cymru
[Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol](#)

[Legislative Consent Memorandum: Medical Innovation Bill / Memorandwm](#)
[Cydsyniad Deddfwriaethol: Y Bil Arloesi Meddygol](#)

Evidence from Royal College of Radiologists – MIB 01 / Tystiolaeth gan Coleg Brenhinol y Radiolegwyr – MIB 01

The Royal College of Radiologists

Response to:

Department of Health Consultation – *Legislation to encourage medical innovation*

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

No, we have no evidence that doctors are deterred from innovation by fear of litigation.

- 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?**

Individual doctors sometimes seek clarification about the circumstances in which they can safely innovate. Our advice is that when doubt exists, they should seek guidance from the relevant medical defence organisation.

- 3. Do you agree with the circumstances in which the Bill applies, as outlined in clause 1(3)?**

If the doctor considers that the proposed treatment would not have the support of a responsible body of medical opinion, as outlined in clause 1(3), and would therefore not satisfy the Bolam test if challenged in court, then the overwhelming likelihood is that the treatment will not be of value and there is a significant risk that it may be harmful.

- 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?**

No comments.

- 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?**

If the decision to offer an innovative treatment has been made within a multi-disciplinary team, as in 1 (7) (c), then it is highly likely that it would satisfy the Bolam test if challenged in court, therefore making this Bill unnecessary.

We are unclear about the reference in the draft to "the doctor's responsible officer (if any)". If this refers to the role defined under revalidation structures, then clearly any doctor practising in the UK and requiring a licence to practise should also have a responsible officer. There is concern therefore, that the intent of the Bill is that those in independent practice would have greater flexibility and opportunity for innovation. This could have perverse effects as there might be fewer checks and balances to ensure that innovation is appropriate, safe and potentially effective.

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

No comments.

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

- An improved system of registration of innovative treatments, together with recording of outcome data, would be extremely valuable and would support responsible innovation.
- Securing funding is also one of the biggest obstacles to innovation at present.

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

We are very concerned that there could be serious unintended consequences of the proposed legislation. Existing governance mechanisms protect patients from inappropriate experimentation and protect doctors from pressure to innovate in ways which are potentially detrimental to their patients. Patients who are not satisfied with the response of a particular doctor to a proposed innovative treatment may seek a second opinion. Relaxation of these governance mechanisms, which this Bill proposes, risks exposing vulnerable and desperate patients to false hope, futile and potentially harmful (and expensive) treatments.

9. Overall, should the draft Bill become law?

In our view the draft Bill should not become law.

Fundamentally, we do not believe this legislation is needed. We do not feel that doctors are constrained as regards innovation and we believe that the current structures provide the appropriate checks and balances.