

MEDICAL INNOVATION BILL

1. Introduction

The Academy of Medical Royal Colleges (the Academy) speaks on standards of care and medical education across the UK. By bringing together the expertise of all the medical Royal Colleges in the UK it drives improvement in health and patient care through education, training and quality standards. We welcome the opportunity to comment on the proposed Medical Innovation Bill which has been the subject of considerable discussion amongst medical Royal Colleges and consultation by the Academy.

The Academy applauds the intentions of the promoters of the Medical Innovation Bill. The stated purpose of the Bill is to encourage responsible innovation in medical treatment, and accordingly to deter innovation which is not responsible. Those are aims which medical Royal Colleges would wholeheartedly support and welcome.

The questions that medical Royal Colleges have asked themselves in considering this Bill (or any intended legislation) are:

- Do we support the purposes of the Bill?
- Are we persuaded that the Bill will achieve its stated purposes?
- Are we assured that the Bill will have no unintended adverse consequences?

Whilst supporting the Bill's stated intent, the Academy and medical Royal Colleges are not persuaded that the Bill will achieve its stated purposes and we are concerned that it could have unintended adverse consequences.

2. Promoting Innovation

We have not seen any evidence that suggests litigation or the possibility of litigation is deterring clinicians from innovative practice and, anecdotally, that is not the experience of members.

Medical Royal Colleges recognise that legislation can play its part in forcing or reinforcing behaviour change that brings health benefits. Legislation on the wearing of seat belts or smoking in public places would be good examples. However, we believe that in these cases legislation is effective through *prohibition* rather than *promotion*. Legal sanction or financial penalty drives compliance rather than promotes behaviour change.

Therefore we are not convinced that legislation is going to be effective in promoting the culture change required to encourage medical innovation.

We believe that access to funding and the current complex and bureaucratic arrangements for agreeing trials and research play a far more significant role in inhibiting innovation and would welcome any improvements that can be made to current processes.

3. Deterring irresponsible innovation

Colleges are quite clear that innovation cannot be unconstrained. It is essential for the protection of patients that irresponsible clinicians are prevented from undertaking practices that are not in the patients best interests and could cause short and long term damage. Simply obtaining patient consent does not negate this requirement.

We welcome the fact that the Bill makes clear the need for responsible innovation and is explicit in setting out tests for what would be responsible and reasonable decisions.

However, there are serious concerns that the provisions in the Bill, which in effect obviate the Bolam judgement principle of having to seek support from peers gives undue weight to the unmediated judgement of an individual clinician. This could easily lead to innovation that is not responsible or in the best interests of patients.

We are therefore concerned that the Bill will not actually deter innovation which is irresponsible and may indeed have the opposite effect.

4. Unintended Consequences

We are concerned that the Bill could inadvertently undermine the undertaking of proper clinical trials. Clinical trials provide a large scale evidence based assessment of the success and effectiveness of a product or procedure. As importantly they should provide evidence of risks and ineffectiveness. If individual clinicians feel that the Bill offers them the opportunity of by-passing the need for clinical trials on a regular basis we believe that there will be adverse consequences. If innovation is to be of general benefit it has ultimately to be a collective and not an individual activity. We recognise the role of individuals in promoting innovation but do not want to see innovation remain on an individual level.

A further concern has been expressed that informed consent, which can be difficult enough when a body of evidence has accumulated following clinical trials, becomes much more difficult when there is little evidence to support innovation.

Whilst we are sure it is not the intention, it is important that there is no inconsistency between this Bill and the other new proposed legislation on ill-treatment and wilful neglect. The doctor whose actions are sanctioned by the Medical Innovation Bill in giving innovative therapy in the absence of strong evidence must not run the risk of falling foul of the Bill designed to prevent ill-treatment.

Finally, there is an opportunity cost. If doctors devote time, drugs or operating time to patients where there is no consensus on likely benefits, those doctors, drugs and operating theatres will not be available to those who might more clearly benefit from them.

5. Specific Questions

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

No.

Whilst there has clearly been a significant increase in clinical negligence claims and cases our expectation is that these relate to standard or common procedures. We would be surprised if the claims relate to innovative procedures. It would be helpful if the NHS Litigation Authority could provide a breakdown of the type of claims received and identify, if possible, the proportion relating to innovation.

The advice of the Medical Defence Union (MDU) is that doctors should not fear the consequences of innovating providing there are appropriate safeguards in place and proper patient consent. They do not believe doctors are currently prevented from pushing the boundaries of innovation. The MDU states that they do not know of any cases of doctors being sued for innovative practice nor do they have any experience or hard evidence of the threat of litigation deterring doctors from 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?

Individual doctors may or may not be clear about the circumstances in which a doctor can safely innovate without fear of litigation and there will without doubt be many who are not. However, the organisations for whom they are likely to turn to for advice, particularly the medical defence organisations in such cases, can certainly provide that clarity.

The issue is probably less about the complexity of the legal position and more about the level of awareness. It has to be said, therefore, that it seems unlikely that passing a further piece of legislation with its own set of rules will in itself ensure that individual doctors are any clearer than they would have been before.

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. We have significant concerns.

We understand that because of timing considerations there may be occasions when it is unclear if a proposed innovative treatment yet has the support of a responsible body of medical opinion (Clause 1.3.a). Having that support must, however, be the intention.

Therefore to state that the Bill should apply when the proposed treatment explicitly “does not or would not have such support” (Clause 1.3.b) is a matter of considerable concern. Promoting innovation that unequivocally does not have the support of responsible medical opinion would seem to be entirely flawed, is unlikely to be of value and gives a real risk of inappropriate innovation that may be harmful.

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 list of matters in Clause 1.5 a doctor should consider to ensure that their decision is deemed to be responsible seems broadly sensible.

We are concerned about the implications of the wording of Clause 1.5. (e). Saying that the doctor should consider “opinions expressed by colleagues whose opinions *appear* to the doctor to be appropriate to take into account” suggests that the doctor has the option to ignore opinions which do not seem to him/her to be appropriate. It seems to give licence to be selective in the opinions which the doctor seeks and ignore views which do not accord with the doctors own opinion. If this is what is actually intended we do believe it is completely inappropriate. If this is not the case we believe the intention needs to be clarified and the wording amended.

In relation to the last question it is important that comparisons include treatment being offered as part of research studies. Not to include them would provide an incomplete picture of the relative risks, benefits and consequences.

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?

We fully support the proposal that the process for making a responsible decision must be accountable and transparent. It is important that the process allows full consideration all the relevant matters not only by the doctor themselves but also by other clinicians. To this end it is essential that that as suggested in paragraph 3.13 of the consultation document that there is a clear audit trail.

Further to this we believe that Clause 7 should include an explicit requirement for the results of an innovation to be properly recorded with the outcomes made available to clinical colleagues for scrutiny and learning. Without recording and dissemination a new treatment or procedure practised by an individual clinician becomes an experiment rather than an innovation. The Academy believes that this is an essential requirement.

We are unclear how the issue of making the decision with a multi-disciplinary team in Clause 1.7.b fits with the earlier permissions for innovation without the support of a responsible body of medical opinion. If the decision to offer an innovative treatment has been made within a multi-disciplinary team then it is likely that it would satisfy the Bolam test if challenged in court, therefore making this Bill unnecessary.

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

There would be roles for the GMC as the profession regulator, medical Royal Colleges as the professional bodies for doctors’, the BMA and the medical defence organisations in explaining the implications of the legislation to doctors. Employers will obviously have a responsibility to ensure that innovation is carried out in line with the legislation and ensure that their staff are aware of their obligations.

However, doctors do not expect to have extensive or detailed knowledge of legislation. We do not believe that this Bill so simplifies the current legislative position as to make it self-evident to doctors.

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

As stated earlier we are not convinced that legislation will necessarily encourage innovation. With or without this Bill there are various ways to encourage and promote innovation. These include:

- Removing or streamlining the very considerable bureaucratic barriers involved in establishing and approving proper clinical trials and research
- Supporting an innovative culture within NHS organisations which gives the clinicians the time and space for innovation
- Ensuring the funding for effective clinical trials
- Devoting real attention and effort to spread and adoption of innovation.

We have welcomed the debate that the proposed Bill has engendered and would be very keen to work with the Department of Health and the Bill's sponsors on identifying actions that, we believe, may actually have a more significant impact in promoting our shared desire for greater responsible innovation than a new piece of primary legislation.

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

No

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

Individual medical Royal Colleges will have their own views but the overall general opinion of the Academy is that we do not believe the Bill should become law.

If the Government chooses to proceed with the Bill we believe it is essential that the modifications outlined in our response are included.

6. Conclusion and next steps

As set out in this response, medical Royal Colleges do not believe that this proposed legislation is necessary and, indeed, may have unintended adverse consequences.

However, the Academy and medical Royal Colleges are very supportive of promoting innovation and would be pleased to join with the Department of Health and the sponsors of the Bill to discuss ways to most effectively promote and disseminate innovation in the NHS for the benefit of patients.

AoMRC
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