

MEDICAL INNOVATION BILL

1. Introduction

The questions the Academy asked itself in considering the Bill were:

- Do we support the purpose and intention 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

2. Purpose

The Academy applauds the intentions of the promoters of the Medical Innovation Bill. The stated purpose of the Bill to encourage responsible innovation in medical treatment, and accordingly to deter reckless irresponsible innovation are aims which medical Royal Colleges would wholeheartedly support and welcome.

We believe there are barriers to effective innovation. These are primarily the very considerable bureaucratic hurdles involved in establishing and approving proper clinical trials and research; lack of time and space for innovation in health organisations; sufficient funding for effective clinical trials; and lack attention and effort to spread and adoption of innovation.

We do not feel there is evidence that the fear or threat of litigation is a barrier to innovation for doctors. Medical defence organisations state 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.

3. Will the Bill achieve its stated purpose?

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 are good examples. However, in these cases legislation is effective through *prohibition* rather than *promotion*. Legal sanction would seem more effective as a tool to drive compliance rather than to promote behaviour change.

The barriers identified above will be overcome by streamlining current processes and a culture shift within NHS organisations. We are not, therefore, persuaded that legislation is going to be effective in promoting the change required to encourage medical innovation.

4. Will the Bill have unintended adverse consequences?

This remains our most serious concern. Our response to the Department of Health consultation (available at <http://bit.ly/1iYwyC1>) was very clear that it is essential for the protection of patients that irresponsible clinicians are prevented from undertaking practices that are not in patients' best interests and could cause short and long term damage.

The Academy recognises that the Bill has been amended by its sponsors from that originally presented and believes the changes are welcome. However the concern that doctors could push ahead with innovations without the support and endorsement

of clinical colleagues to the potential detriment of patients remains a real anxiety. Currently there is an active requirement to show support from clinical colleagues. The Bill seeks only “consultation” with colleagues. Peers need to assure themselves that the Bill will not therefore give protection to cowboy doctors who follow the required consultation process but then ignore their colleagues’ advice.

We are also concerned that the Bill could inadvertently undermine the undertaking of or participation in proper clinical trials. 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.

Further to this we believe there should be 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

The Academy’s Patient Group has also urged that, whilst the Bill does say that all consents required by law are obtained, there should be explicit reference to having informed patient consent and ensuring best practice in relation to vulnerable adults and children.

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. Conclusion

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.

We have, however, 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.

AoMRC
June 2014