Medical Innovation Bill
Royal College of Physicians’ response to Department of Health consultation
April 2014

About the Royal College of Physicians

The Royal College of Physicians of London (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We harness the skills, knowledge and leadership of physicians in setting challenging standards and encouraging positive change based on sound evidence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing around 30,000 fellows and members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare. Our membership is drawn from over 30 medical specialties and our primary interest is in building a health system that delivers high quality care for all patients.

Overview of the RCP’s response

The stated purposes of the Bill are to both encourage responsible innovation in medical treatment while preventing irresponsible innovation, but we are concerned that as currently drafted it may not achieve these aims.

The RCP strongly supports the aims of the Bill, and welcomes the debate and discussion around innovation that has occurred as part of the proposed Bill. We want to ensure that suitable safeguards are in place, both for the clinician and patient. The RCP already encourages innovation in healthcare, and supports our members and fellows in making responsible decisions and protecting vulnerable patients from harm. We welcome the opportunity to work with the Department of Health and the Bill’s sponsors to identify and take forward actions that will promote and support responsible innovation. A summary of the key points contained in our response is below.

Summary of RCP’s recommendations

1. **Mandatory reporting.** The RCP is concerned that any legislation might be seen as allowing experimentation or quackery. Innovative treatments must be centrally recorded, reported and be publicly accessible; this must include both positive and negative results, and information about small scale treatments and patient experience. A clear strategy for achieving this must be developed if there is to be true innovation. The strategy must address patient confidentiality, accessibility, thresholds for reporting, and practicalities, such as the method of hosting the database and reporting results.

2. **Peer review.** There must be more robust safeguards in place to prevent doctors from innovating inappropriately. These should include:
   - stronger requirements for robust peer and ethical review before commencing treatment
   - stronger assurances for patients, carers and families
   - continued and active support for referral into larger NHS clinical trials.
3. **Safeguards and promotion of innovation.** We support the statutory best practice checklist as a safeguard against irresponsible innovation. This could be supplemented by guidance designed to emphasise the benefits and mechanisms supporting innovation.

4. **Communication.** There must be a clear strategy for bringing any new legislation into operation, and ensuring its requirements are communicated to and understood by the profession and the public.

5. **Removing existing barriers to innovation.** The RCP encourages the Department of Health to analyse the evidence for the size of the central problem, and review whether or not the Bill will achieve its stated aims of creating an environment that enables innovation and discourages irresponsible innovation. The RCP recommends that alternative routes to achieving these shared aims should be explored, such as opportunities to remove existing barriers to innovation, or improving and streamlining the funding and approval processes.

### Encouraging innovation

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

The RCP agrees with the principle of removing legal ambiguity if it exists and reducing risks to doctors’ practice that have arisen as a result of case law. The RCP does not have significant evidence (anecdotal or through case examples) from our members and fellows, nor we understand do two medical protection organisations, that litigation or potential litigation is a substantial or primary deterrent to clinicians’ use of innovative treatment.

However, the RCP is aware of other barriers to innovation. For example:

- the protracted processes involved in establishing clinical trials within timescales that are competitive internationally and attract investment from the pharmaceutical industry
- complex bureaucracy and delays in gaining approval for new treatments and devices and securing funding for their use can take a substantial amount of time and money and involve negotiation with multiple agencies
- localised decision-making at trust and Clinical Commissioning Group-level can prevent uptake of new and expensive treatments
- new ‘personalised’ medicine technologies may need a new approach to trials and testing of treatments
- ethics committee consideration and broad large-scale randomised trials may now take too long to be of benefit to many patients.

**RCP recommendations:**

- The RCP encourages the Department of Health to analyse the evidence for the central problem proposed, and review whether or not the Bill will achieve its stated aims of creating an environment that enables innovation.
The RCP recommends that alternative routes to achieving these aims are explored, such as opportunities to remove existing barriers to innovation or improving and streamlining funding and approval processes. The RCP encourages the government actively to support the extension of existing opportunities to promote the delivery of, and access to, innovative treatments, devices and technologies.

Preventing irresponsible 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?

Current professional standards and guidelines (for example from GMC and NICE) give clinicians a clear framework for responsible action and should deter unprofessional and irresponsible action. In addition, departure from standard practice is not prevented in law and there should not be a fear of litigation provided that:

- appropriate safeguards are in place
- the patient fully understands the risks and benefits of what is proposed and why the clinician considers it in the patient’s best interests
- and the patient gives informed consent.

It is important for clinicians to have the freedom to innovate within limits that are based on best practice, and that the profession is encouraged to think laterally and creatively within a supportive culture and environment for innovative (and safe) practice. But, there could be unintended consequences of the Bill with the opposite effect to that intended. For example, encouraging experimentation without sufficient and appropriate peer review and evidence based decision-making, or potentially breaching professional guidelines and regulatory standards.

Questions 3, 4 & 5: Circumstances where the Bill applies; and the process and basis for decision making

The UK has an established medical research framework to support medical innovation, which though imperfect, is among the best in the world. Improvements that have been made in research regulation in recent years may be set back if this legislation inadvertently separates ‘medical research’ from ‘medical innovation’.

Obtaining proper consent from patients is crucial. Beyond this, it is also necessary to protect vulnerable patients who may have received a devastating diagnosis or have exhausted standard treatment options. We support the safeguards proposed in the Bill, including a statutory best practice checklist as a tool to assist in identifying and discouraging irresponsible innovation. In addition, however, the Bill needs stronger

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1 For example, the EU Clinical Trials Directive and the UK Medicines for Humans Use (Clinical Trials) Regulations could be clarified; highlighting the flexibility that is possible and proportionate regulation can be achieved.
2 For example, by working more closely with industry to encourage well-designed and monitored ‘compassionate access’ programmes (with treatment and outcome databases) for new drugs that are not yet approved by NICE, and novel surgical procedures; confirming the long-term future of the Cancer Drugs Fund and similar mechanisms for other clinical indications which could become a source of funding for innovative treatments.
explicit assurances for patients, carers and families that they will not be at greater risk from changes to legislation that may enable irresponsible and unsupported experimentation in the name of innovation.

The Bill appears to water-down the requirement for robust peer review and so could have the unintended effect of enabling a clinician to take action based primarily on their own judgement. It is essential that irresponsible clinicians are able to be identified and prevented from carrying out treatment that may harm patients and is not in patients' best interests. We are concerned that as the Bill stands it may not sufficiently prevent doctors from innovating inappropriately.

We support the consultation’s additional question which reinforces the necessity for clinicians to demonstrate that the case for innovation has been discussed with clinical colleagues and that feedback from colleagues in the multidisciplinary clinical team and ethics committee has been taken into account.

We strongly support clinician involvement in and patient referral into larger NHS clinical trials and are concerned that this could be put at risk by the Bill focusing on innovation by individual clinicians.

RCP’s recommendations:
- We support the statutory best practice checklist as a safeguard against irresponsible innovation. This could be supplemented by guidance designed to emphasise the benefits and mechanisms supporting innovation.
- There must be more robust safeguards in place to prevent doctors from innovating inappropriately. This includes:
  - stronger requirements for robust peer and ethical review before commencing treatment
  - stronger assurances for patients, carers and families
  - continued and active support for referral into larger NHS clinical trials.

Recording, reporting and disseminating information about innovative treatment

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

Any legislative change and its potential impact on clinical practice will not be self-evident. It will therefore be essential that it is accompanied by a well-developed multi-agency communications plan if it is to deliver on its intent. In developing such a plan consideration should be given to potential resource costs for other organisations, such as professional bodies.

Question 7: Are there other things that need to happen to encourage responsible innovation?

3 Email received 24/04/14: ‘1. To enhance the safeguards in the Bill we would be interested in views on whether the Medical Innovation Bill should only apply when the case has been discussed with clinical colleagues and their recommendations taken into account. The idea of this would be to give doctors greater confidence in advance that they had acted responsibly and thus not negligently. 2. Is the most appropriate approach for doing this (considering issues such as timeliness and the need to not add levels of bureaucracy) to use Multi-Disciplinary Teams (MDTs) to secure this input?’

4 For example, mandating that clinicians must discuss the proposed treatment with the chair of the local committee, and, if time allows, the full committee.
Innovation relies on a culture of knowledge sharing and a collaborative environment that stimulates ongoing improvement.

For innovation to add to the knowledge base and not become an isolated experiment by a lone clinician, all treatments must be recorded; and the results must be reported, accessible and disseminated. Reporting should offer a transparent and accessible record of considerations, decisions - including seeking other opinions and the involvement of patients in decision-making - and treatment. It will be crucial that the dissemination of both positive and negative results is mandatory, structured and widespread.

Collating information about small scale innovative treatments and patient experience, and having a process for audit of decision-making, will be help drive improvement. This will enable clinicians and researchers to learn from even small-scale interventions, and provide information for patients.

The lack of a clear strategy for collating and reporting raises additional questions about patient consent and confidentiality. The privacy, transparency and dissemination issues were not developed in the draft Bill to avoid over-complication. However, these are crucial aligned issues. It is essential that the Department of Health develops a reporting strategy and process to support the Bill that robustly explores and addresses:

- the protection of patient data
- how data will be used to advance medical innovation
- the threshold of intervention before ‘requiring’ or ‘recommending’ submission to a database of innovative treatment
- where and how such a ‘database’ would be hosted.

RCP’s recommendations:

- New treatments must be recorded, reported and be publicly accessible and disseminated. There must be dissemination of both positive and negative results. This should include information about small scale innovative treatments and patient experience. Consideration should also be given to developing a process for the audit of decision-making.
- A clear strategy for collating and reporting must be developed. This will need to address issues around patient confidentiality, accessibility, thresholds for reporting, and practicalities such as hosting the database and publishing results.
- There must be a clear strategy for bringing any new legislation into operation, and ensuring that its requirements are communicated to the profession.

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

- **Commissioning decisions:** As the draft impact assessment indicates, commissioning decisions are crucial in enabling innovative treatment, in addition to decisions of individual doctors. Taking action to address funding and access barriers is also possible without new primary legislation.
- **Negligence claims:** While the consultation and impact analysis make reference to the cost of clinical negligence claims and theorises that these may reduce as a result of ‘less ambiguity over

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5 The Systematic Anti-Cancer Therapy (SACT) data set, managed by the National Cancer Information Network provides a potential model wherein all treatments for malignant disease are mandated to be recorded electronically and uploaded monthly to a national database which is available for audit and which informs organisations and individual practitioners of variance from benchmark activities for any specific treatment indication.
when it is appropriate to try out an innovative treatment’, we encourage the Department of Health to carry out a more detailed analysis of NHS Litigation Authority statistics to confirm what percentage of claims and awards were for errors in standard practice or in non-standard practice.

- **Equity of access:** We consider that there is more of a risk of exacerbating health inequalities than is reflected in the Impact Assessment. Limited health resources need to be strategically managed in a way that benefits the greatest number of people across the country. The draft Bill and accompanying impact assessment should provide more explicit assurance about how it will ensure innovative treatment is made accessible to all potential patients, and not inadvertently prioritise those patients and carers who most stridently advocate for treatment and can self-fund where necessary (for example to travel to different areas and pay for additional innovative interventions carried out by individual clinicians).

- **Innovative treatment of children:** While there are fewer clinical trials involving children than adults, it is inaccurate to state that clinical trials are rarely conducted on children and that the Bill would somehow redress this.

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

In our consultation response we have highlighted our support for responsible innovation and outlined our recommendations for additional consideration as part of any new primary legislation or alternative methods that may more directly tackle barriers to innovative treatment, devices and technologies. Prior to the Bill becoming law we would want to see these points answered and included before we could offer our support.

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