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Legislation to encourage medical innovation in healthcare

Proposed UK legislation aims to clarify when medical innovation is responsible in order to reduce the risk of clinical negligence claims. In its response, the PHG Foundation argues the Bill should not be enacted in its current form.

Genomics has enabled a more detailed approach to diagnostics and the development and delivery of new and innovative treatments that are more precisely tailored to individual patients, and treatments are becoming increasingly personalised.

The PHG Foundation is broadly supportive of approaches that encourage medical innovation that lower or remove barriers to innovative care (diagnosis and treatment) that provide benefit to patients. We strongly support the view that doctors should be able to innovate in the best interests of their patients. We believe that approaches to innovative care should be evidence-based, proportionate, and effective. As such, on the strength of the proposals set out in the consultation and associated documents, we do not support the current Bill, but do support efforts to improve access to innovative, effective, and safe care for patients and also recognise the difficulties inherent in attempting to provide such access.

If the draft Bill does become law, we recommend that additional systems are put in place to a) help ensure that the benefits of innovative medical care are realised for patients generally and b) mitigate the possibility of negative and unintended effects of the Bill.

Insufficient evidence

We accept that one of the reasons for holding a consultation is to develop an appropriate evidence base to support the introduction of the Bill, but we are of the view that within the consultation and associated documents,

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insufficient evidence is provided. More evidence is needed about the number of relevant negligence claims and whether the effect of such claims is to actually inhibit the provision of innovative care.

1. Although the increasing number of negligence claims made against the NHS is a significant concern, it is not made clear in the consultation what proportion of those claims are made in the context of innovative care
2. Paragraph 2.1 of the consultation notes that “Some argue that our increasingly litigious culture puts pressure on doctors to practise defensive medicine”. But no description is provided regarding the extent to which this is the case or how it might influence the provision of innovative care; or how its influence compares to that of other structural conditions, such as commissioning guidelines. Work by Kessler, Summerton, and Graham has found that medical liability systems in the USA, UK and Australia are important factors in the practise of defensive medicine, but they drew no explicit conclusions as to the effect of the current systems on the provision of innovative care¹. Questions 1 and 2 do ask for evidence about these points, but the draft Bill seems to be based on the idea that doctors are already deterred from acting.

Case law

There is also little evidence shown that the current common law framework is insufficient to protect doctors from claims of negligence when they try innovative treatments in the best interests of their patients. The consultation states: “A doctor who is not confident of being able to satisfy the Bolam test may feel obliged to follow standard treatment” (consultation paragraph 2.8). But the law does not always require doctors to follow standard treatment to avoid claims of medical negligence.

The consultation document does make clear that the draft Bill is not intended to replace the Bolam test, notes Bolitho, and briefly mentions the famous exhortation in *Simms vs Simms* by Lady Butler Sloss about the dangers of using Bolam to inhibit medical progress.

However, the effect of *Simms v Simms*, *De Freitas v O’Brien**, and *Hunter v Hanley*** are not explored, although between them (as well as Bolam and Bolitho) there is considerable scope for doctors to provide innovative treatment without fear of being found guilty of negligence.

The cases are dealt with in detail in the standard text by Mason and Laurie². Broadly, the cases provide some scope for doctors to act in innovative ways when there is limited evidence relating to how to proceed.

- *Simms v Simms* provides some defence for doctors that use highly experimental treatments in ‘last chance’ cases where there are no alternatives, no evidence that more harm will be done, and that evidence does not exclude the possibility of some benefit accruing

- In *Hunter v Hanley*, Mason and Laurie note Lord Clyde's view that even "a substantial deviation from normal practice may be warranted by the particular circumstances". *Hunter v Hanley* was accepted in *Bolam*, in this respect
- *De Freitas v O'Brien* offers some "comfort to the so-called 'super-specialist' who may... undertake procedures which others might regard as being inappropriate or even too risky"². In that case the defendant, a spinal surgeon, successfully defended himself from a claim of negligence by reference to the views of a pool of sub-specialists numbering only 11 people in the whole country

It is also worth noting that, as mentioned above, medical care is becoming increasingly personalised (in the physiological sense). As this phenomenon progresses, reliance on an evidence base for possible innovative options will become increasingly difficult, as the options proposed may be suitable only for the particular patient in question. Attempting to rely on a relevant body of medical opinion regarding the provision of a particular treatment may become impossible. Rather, the focus must be on the evidence base associated with the process by which a treatment option is determined, rather than the treatment itself. If the draft Bill becomes law, the nature and implications of the process of determining the appropriate treatment should be addressed explicitly.

Possible impacts of the draft Bill

It is unclear what effect the draft Bill might have on current systems. For example:

1. Unforeseen impact: while clearly not the intent of the draft Bill, there is a risk of increased bureaucracy – requirements and criteria can develop into checklists, and audit trails may become an unnecessary burden. Concerns have been raised that the draft Bill might actually provide its own unintentional disincentive to innovate if it formalises current arrangements for offering "*patients potentially innovative treatment before very long clinical trials have [been] done*"³. The draft Bill might disincentivise innovation by setting out yet more criteria to which doctors must adhere to avoid negligence claims⁴

If the draft Bill does become law, we recommend a full review to avoid accidental development of two parallel systems.

To avoid these possibilities, if the draft Bill does become law, we recommend a full review to avoid accidental development of two parallel systems, as well as an exploration of what checks and balances might be needed to ensure that the requirements stipulated do not develop into a burdensome bureaucracy. Although necessary for avoiding potentially negative repercussions of the draft Bill, the cost and time of performing such a review should be taken into account when debating its implementation.

Increased use of innovative care for individual patients will only improve outcomes for patients more widely if the process is to some extent formalised. For this to be achieved each instance of medical innovation would need to be documented and aggregated.

Obligations of the physician and restrictions on available care: the criteria set out in clause 1(5) frame responsibility in terms of the best interests of an individual patient. But doctors are also under other obligations. For example, doctors in the NHS have to consider the population of patients that they serve and are also required to take account of evidence-based guidance as to clinical utility and cost-effectiveness from external bodies such as NICE; it is important that the draft Bill does not result in raising the expectations of patients to unrealistic levels to the extent that they might come to 'expect' innovative care as a matter of course, regardless of cost. Clinical options are restricted by funding considerations and these considerations have a significant impact on the type of care available to patients in the NHS, whether diagnosis or treatment. It is unclear how the draft Bill might affect care options where those options are constrained by cost-effectiveness criteria, and this is not explicitly addressed in the consultation.

Distinction between research and clinical activities; developing safety systems

Although specifically noted in the consultation that the draft Bill itself does not permit treatment to be carried out for research purposes, it does blur the distinction between research and clinical activities. Indeed, the distinction between medical innovation and research is inherently blurred. It has been noted by one clinical oncologist in reference to the draft Bill that *"the distinction between clinical research with no direct benefit to the patient and innovative treatment intended to benefit the patient is an artificial one"*⁴.

It could be argued that, in both cases, a doctor has a hypothesis that a particular procedure might improve the condition of their patient but lacks the evidence to determine whether the hypothesis is correct or incorrect, and so tests the hypothesis. The distinction therefore rests on whether this is done primarily to gather knowledge (research) or primarily in the best interests of the patient (care). Doing so as 'research' requires certain procedures are followed (and assessment by independent research ethics committees) to safeguard patient interests. Doing so primarily for an individual patient as a form of 'innovative care' attempts to improve their patient's condition, but without the controls and oversight, and involving only one participant.

Increased use of innovative care for individual patients will only improve outcomes for patients more widely if the process is to some extent formalised. For this to be achieved each instance of medical innovation would need to be documented and aggregated. That information could then be used to determine which innovations were consistently proving to be effective and also to ensure that there are not repeat instances of failure that went undetected.

Recommendations

Paragraph 2.1 of the consultation document notes that there is an increasingly litigious culture in England. Few would argue that this is a positive development. However, even if it were possible to show that such a culture is inhibiting the pursuit of innovative and beneficial medical care, it is not necessarily the case that new laws are the best way to change behaviour.

Other options include:

1. Facilitating access to drugs which are not routinely funded (such as with the Cancer Drugs Fund)
2. Expedition of decision-making processes (more money to MHRA/NICE to increase capacity)
3. Expedition of clinical trials process by encouraging multicentre trials
4. Consideration of new ways to improve research methodologies where, for example, full randomised control trials are not feasible (e.g. rare diseases)
5. If the draft Bill becomes law, we recommend also that consideration be given to how instances of medical innovation might be registered and aggregated and that information used to help improve overall patient outcomes (see section 4.4, above)
6. Finally, participation in suitable research should be encouraged; reminders are already in place in the NHS Constitution.

Footnotes

* (1995) 25 BMLR 51, [1995] 6 Med LR 108, CA.

** 1955 SC 200, 1955 SLT 213.

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