Health Research Authority (HRA) Response to “Legislation to encourage medical innovation: a consultation”

Introduction:
The HRA welcomes the opportunity to comment on the Department of Health’s consultation on “Legislation to encourage medical innovation”.

Background:
The HRA was established in December 2011 to protect and promote the interests of patients and the public in health research, and to streamline the regulation of research. We make sure that health research involving them is ethically reviewed and approved, that people are provided with the information they need to help them decide whether they wish to take part, and that their opportunity to do so is maximised by simplifying the processes by which high quality research is assessed. In doing this, we will help to build both public confidence and participation in health research, and so improve the nation’s health. The HRA has set out an ambitious programme of work and is widely recognised as having a pivotal role for health research in the UK.

HRA comments on the consultation:
The HRA welcomes innovation but we strongly hold the view that good quality research should remain the gold standard and that this principle should not be undermined. Where there is uncertainty this should be resolved through research.

The existing legal framework allows for innovation in the NHS. Clinical ethics committees in Trusts can approve experimental treatment where a clinician believes this is in the best interests of the patient, where established treatments are not suitable and a research trial is not available. For example, a drug that is showing promise in a different clinical presentation.

We recognise that the fear of litigation may influence behaviours of clinicians. However the evidence available indicates that claims in relation to research are a very minor proportion of those handled by the NHS Litigation Authority (NHSLA). Dr Jonathan Sheffield OBE, Chief Executive of the National Institute for Health Research (NIHR), has researched this issue and found that in the 15 year period to 2010, litigation associated with clinical research accounted for 0.01% of the all the NHSLA’s payments. The HRA therefore considers that innovation, and studies to resolve uncertainty, in a research setting protects against litigation.
The HRA is concerned that where innovation becomes experimentation then this leads to an absence of published data. This in turn means that the opportunity to resolve uncertainties about treatments is lost. In line with its transparency agenda, the HRA would propose that it is a requirement for all such innovations to publish results, both where it is reported that intervention was successful and, as importantly, where it was not.

The General Medical Council (GMC) publishes good practice guidance for general medical practice and for research. The GMC guidance on ‘Good Practice in Research’ is clear that “Research involving people directly or indirectly is vital in improving care and reducing uncertainty for patients now and in the future, and improving the health of the population as a whole.”. However, in the latest update of its guidance on Good Medical Practice in 2013, the GMC removed the duty on doctors to “help resolve uncertainties about the effects of treatments”. The HRA is in correspondence with the GMC on this change, which is against the wider policy context to provide patients access to research and the aims of the NHS Constitution in this respect.

In conclusion, the HRA is of the view that the current legal framework provides for innovation in the NHS and that good quality research is, and should remain, the gold standard for the NHS where there is uncertainty. We accept though that there will be occasions when there is no remaining treatment option and a research trial is not available to an individual patient and the HRA fully supports that clinicians should be able to use innovation without fear of litigation.

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Chief Executive, Health Research Authority.