

Response form

Address: 407 St John Street, London, EC1V 4AD
Are you responding as an individual or on behalf of an organisation?
If as an individual, are you responding as:
a) a doctor?
b) a patient?
c) a lawyer?
d) other?
<p>If you are responding on behalf of an organisation, please give the name of the organisation and say who it represents:</p> <p>Cancer Research UK is the world's largest independent cancer charity dedicated to saving lives through research. We support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2012/13 we spent £351 million on research. We are a leading funder of clinical research in the UK, supporting around 250 clinical studies. In 2012/13, over 35,000 cancer patients were enrolled on Cancer Research UK supported studies.</p>

Cancer Research UK welcomes the opportunity to respond to this consultation. We have consulted with both patients and clinicians, including the Chairs of the National Cancer Research Institute Clinical Studies Groups, and have taken their comments on board in formulating this response.

There is clearly patient and clinician demand for more innovation to help treat people with cancer. We do sometimes see exceptional responses to treatments from individual patients, and therefore want to be in a position to innovate. Cancer Research UK is supportive of efforts to bring innovative treatments to patients faster and to improve the uptake of innovative treatments in the NHS.

Any new legislation seeking to promote innovation should be drafted to ensure doctors have to establish there is sufficient intellectual underpinning and safety data about a treatment before proceeding. There should also be appropriate consultation with other doctors in the same or a related field to ensure patients receive the best care at all times.

In our response we have set out the following safeguards that we would want to see introduced in any new Bill:

- A provision in the Bill's text to ensure that patients' opportunities for taking part in established clinical research are exhausted before another treatment pathway is considered.

- Whilst we understand that the Bill seeks to address circumstances where it is unclear whether a treatment has the support of a responsible body of medical opinion, we think the Bill should set out a requirement that considered intellectual underpinning and safety data about a treatment is available before doctors innovate.
- Clear definitions for what is meant by ‘reasonable judgement’ and ‘reasonably be expected’.
- Requirement for doctors to confer with, and seek agreement from at least two other qualified medical professionals, based in different centres delivering care, within the disease or specialist area in question, before the proposed treatment was taken forward with the patient.
- Requirements added to clause 1(6) such that data was collected on the clinical impact of the intervention.
- Additional safeguards brought into clause 1(7) to ensure recommendations to patients are based on considered intellectual underpinning.

To the extent that this Bill strengthens the case for the NHS to be more innovative we are supportive subject to **significant** modification.

In addition we recommend the Department of Health further considers the existing landscape in relation to innovation, and whether efforts should be focussed on other mechanisms to deliver innovation to patients, including those relating to funding and commissioning structures.

The questions posed in the consultation paper are as follows:

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

We have been unable to find evidence that fear of medical litigation is currently a barrier to innovation in cancer. The threshold for sufficient evidence to decide to treat clearly depends on the intervention, but within oncology the clinicians who fed into our response believe the threshold is sufficiently low to enable them to innovate within the current legislative framework.

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?

We have been unable to find evidence that cases have been brought, or led to compensation, based on a competent doctor attempting to use an innovative treatment with the consent of a patient.

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.

Clause 1(3) effectively outlines that the Bill would apply in circumstances where the medical treatment may not have the support of a responsible body of medical opinion. Any Bill should clearly state that considered intellectual underpinning and safety data about a treatment is available

before doctors innovate.

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?

There should be a clear stipulation for doctors to ensure there is considered intellectual underpinning and safety data on an intervention in place before trying a treatment. There should also be clear definitions for what is meant by 'reasonable judgement' and 'reasonably be expected'. There are similar definitions relating to risks of testing interventions that are in place in clinical trials legislation and we would consider these to be 'best practice'.
In addition there should be a clear requirement within the legislation to consult with at least two other qualified medical professionals, based in different centres delivering care, who work within the discipline in question, before the decision to try an untested intervention was taken. This would ensure the consensus of a wider clinical body was being taken into account and would enhance patient safety.

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?

Any new legislation should be written in a way which supports the development of treatments in a systematic and robust way. This should include publication of data detailing how a patient responds to the treatment in question. This would help ensure the body of evidence for newer treatments was being added to, for the benefit of future patients.

Any audit trail should include both legal information and that informing scientific opinion or the development of treatments. There should be a requirement to collect data on the clinical impact of the intervention. We consider this an essential part of responsible innovation.

We would like to see a legal requirement for doctors to consult with at least two other qualified medical professionals, based in different centres delivering care, who work within the discipline in question, before the decision to try an untested intervention was taken. This would mitigate concerns of the risk of a lone doctor acting in isolation, outside of agreed medical opinion.
As outlined in clause 1(7) it is important that the proposed treatment is discussed between the doctor and the patient. As outlined in 'vignette A', reports in the media have an impact on patients' interest in new treatments. Patients should have the opportunity to take part in established clinical trials before other treatment options are considered.

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

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

Within the area of cancer treatment there is clearly patient and clinician demand for a more flexible approach to access innovative interventions. Cancer Research UK is supportive of efforts to bring innovative treatments to patients faster and to improve the uptake of innovative treatments in the NHS – as one example please see our report from March 2014 on a Vision for Radiotherapy¹.

The main route for responsible innovation of new cancer interventions remains clinical studies. Clinical studies are currently the only route to collect sufficient evidence of a high enough quality on which to base technology assessments and the development of clinical guidance. Without clinical studies we would be unable to innovate on behalf of entire patient populations, as we would simply be innovating on a case-by-case basis. We therefore feel that the most important mechanism for encouraging responsible innovation in the UK is to continue to build a thriving clinical research environment.

There are a number of other mechanisms already in place that should be evaluated which, if further strengthened, could lead to significant improvements in medical innovation. These include:

- MHRA Early Access Scheme
- Adaptive licensing
- Cancer Drugs Fund
- Commissioning Through Evaluation
- Better use of data within the NHS

We can provide further detailed information on the above on request.

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

Further consideration should be made to existing mechanisms for patients to access innovative treatments, especially in cancer, in order to fully assess the potential impact of the proposed Medical Innovation Bill. In particular, we would draw attention to recent announcements on Adaptive Licensing², the Early Access Scheme³ and Commissioning through Evaluation⁴.

There should also be a more thorough assessment on the range of interventions which this Bill would apply to. Our experience in cancer is that the decision undertaken to innovate in the area of surgery is very different to the decision to innovate in radiotherapy (for example), and thus the barriers to innovation are also different. More consideration needs to be made as to what interventions it is intended for this Bill to apply to.

¹ Cancer Research UK and NHS England. Vision for Radiotherapy 2014-2024. March 2014.

² http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/03/news_detail_002046.jsp&mid=WC0b01ac058004d5c1

³ <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON404193>

⁴ <http://www.england.nhs.uk/2013/09/26/com-through-eval/>

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

Yes / Yes with modifications outlined in response to questions 3-5 / Yes with other modifications (please specify) /No

To the extent that this Bill strengthens the case for the NHS to be more innovative we are supportive subject to **significant** modification.

Our response outlines a number of safeguards that we would want to see introduced in order for the Bill to be able to achieve responsible innovation. We have also recommended that the Department of Health further considers the existing landscape in relation to innovation, and whether efforts should be focussed on other mechanisms to deliver innovation to patients, including those relating to funding and commissioning structures.

We also welcome any other comments you wish to make.