Department of Health

Legislation to encourage medical innovation

A consultation

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A consultation

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Annexes

Written Ministerial Statement, 22 November 2013

Medical Innovation (No. 2) Bill

The Secretary of State for Health (Mr Jeremy Hunt): Medical innovation has been vital to the dramatic rise in life expectancy of the last century. This country has a proud heritage of medical innovation from Alexander Fleming and the discovery of penicillin to Sir Peter Mansfield's enabling of magnetic resonance imaging.

The Government should do whatever is needed to remove barriers that prevent innovation which can save and improve lives. We must create a climate where clinical pioneers have the freedom to make breakthroughs in treatment.

The Medical Innovation (No. 2) Bill, sponsored by my hon. Friend the Member for Northampton North (Michael Ellis), and the comparable Bill introduced by my noble Friend Lord Saatchi in the other place, correctly identify the threat of litigation as one such barrier. Their hope is that legislation to clarify when medical innovation is responsible will reduce the risks of clinical negligence claims. Their argument is that with this threat diminished, doctors will be confident to innovate appropriately and responsibly. This innovation could lead to major breakthroughs, such as a cure for cancer.

Their cause is a noble one, which has my wholehearted support. My noble Friend Lord Saatchi, in particular, is a great example of a parliamentarian motivated by conscience.

It is precisely because this issue is so important, because it affects us all, that we need a full and open consultation. A consultation that gets the views of patients on the right balance between innovation and safeguards. A consultation that hears from clinicians on the problems they face in innovating and how to overcome them. We are grateful to my hon. Friend the Member for Northampton North and my noble Friend Lord Saatchi for their own work to understand and address these issues.

So the Government commit today to carrying out a full consultation, working with my noble Friend Lord Saatchi and my hon. Friend the Member for Northampton North. This will draw on the wide engagement and discussions that they have already carried out with the public, patients and the legal and medical professions. Such a consultation will enable an open debate on medical innovation, as well as highlighting its vital importance. The Government expect to launch this consultation in January 2014 and to respond by May 2014.

My second commitment is that the Government will seek to legislate at the earliest opportunity, subject to the results of the consultation.

We all owe a debt to my hon. Friend the Member for Northampton North and my noble Friend Lord Saatchi for the great effort they have already expended on this issue. The Government will work closely with them to bring this to a satisfactory conclusion.

1. Introduction

1.1 This consultation paper has its origins in the written Ministerial statement made to the House of Commons by the Secretary of State for Health on 22 November 2013 (see opposite) and has support from the sponsors of the Private Members' Bills mentioned there.

1.2 Medical innovation (that is, departure from established treatments) has helped increase life expectancy over the last century. Boys and girls born in 1912 were expected to live for 53 and 56 years respectively. By 2012, life expectancy at birth was 79 years for boys and nearly 83 years for girls.[1] To continue this progress, it is important to ensure doctors continue to look for effective innovations and to carry out research.

1.3 As explained in chapter 2 of this consultation paper, case law on clinical negligence currently gives doctors a good basis for innovating where there is support for their decision from a responsible body of medical opinion. However, where a doctor is not confident that there would be such support if the matter came to court, the doctor may feel that there is pressure not to innovate. This consultation therefore asks:

- should legislation clarify what a doctor may responsibly do in that situation?
- and if so, what should the details of the legislation be? Chapter 3 sets out the Government's proposals.

1.4 We welcome comments on the proposals from all interested parties – including, in particular, doctors, patients and the public, and the legal profession. Comments should reach the Department of Health by 25 April 2014. There is information about how to submit comments in Annex E at the end of this document.

1.5 The Government aims to respond to the consultation as soon as possible and, subject to the results of the consultation, to seek an opportunity for legislation to be brought forward thereafter.

1.6 The Government remains committed to supporting and encouraging responsible innovation by means other than that considered in this consultation paper, including through NHS England's work on *Innovation, Health and Wealth*.[2]

1 Historic and Projected Mortality Data from the Period and Cohort Life Tables, 2010 and 2012-based, UK, Office of National Statistics.

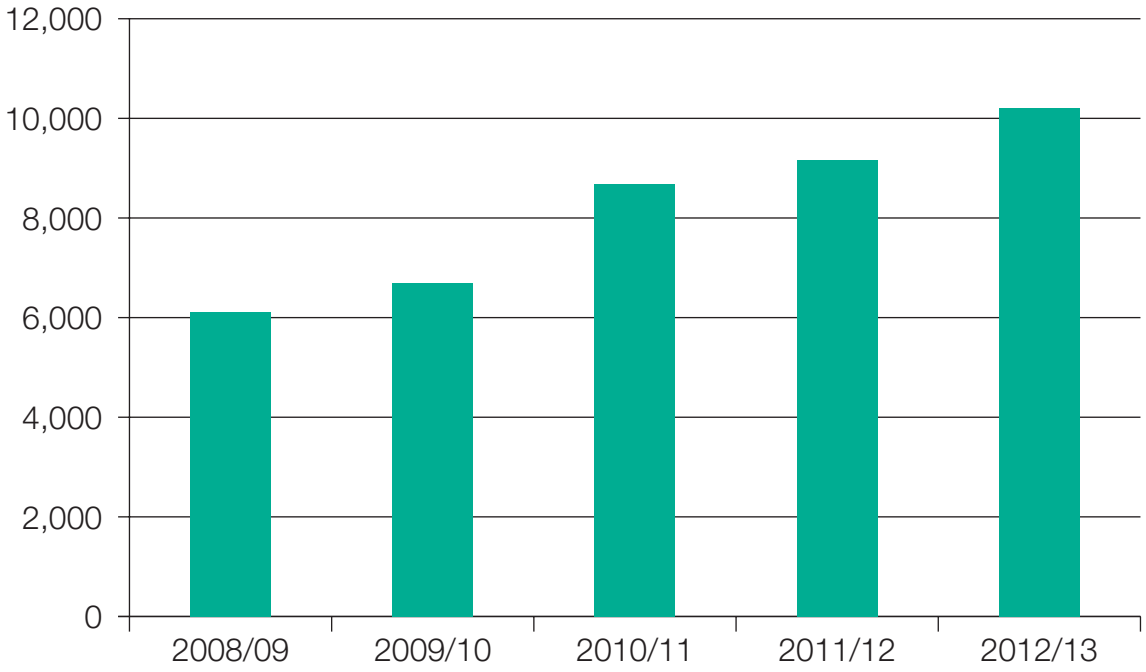
2 NHS England plans to publish an update on *Innovation, Health and Wealth* during 2014. Meanwhile, the most recent publication on the topic is that issued by the Department of Health in December 2012, *Creating Change: Innovation, Health and Wealth one year on*.

2. The issue

The current legal position

2.1 A potential barrier to departing from established procedures and carrying out an innovative treatment is the possibility of a clinical negligence claim. Some argue that our increasingly litigious culture (see Figures A and B) puts pressure on doctors to practise defensive medicine.

Figure A – Number of Clinical Negligence Claims 2008/09 to 2012/13 in England (Source: NHS Litigation Authority)[3]



3 In Wales, clinical negligence claims are managed by Legal and Risk Services, NHS Wales Shared Service Partnership.

Figure B – Clinical Negligence Payments made 2008/09 to 2012/13 in England, in Billion £s (Source: NHS Litigation Authority)

2.2 Currently, there is no Act of Parliament that indicates the meaning of responsible medical innovation or that sets out a test of clinical negligence. Instead, the existing law governing negligence is to be found in case law (decisions by the courts).

2.3 The main case law is in the case of *Bolam v Friern Hospital Management Committee*,[4] which was later refined in *Bolitho v City and Hackney Health Authority*.[5] These cases establish that to avoid a successful claim in negligence a doctor should be able to demonstrate support for a decision from a responsible body of medical opinion (*Bolam*) and that the opinion is capable of withstanding logical analysis by the courts (*Bolitho*).

2.4 Subsequently, in the case of *Simms v Simms*,[6] which concerned innovative treatment for variant Creutzfeldt-Jakob disease, Lady Butler-Sloss was satisfied that support from a small but well-informed body of experts was sufficient to meet the *Bolam* test. She also said:[7]

"The *Bolam* test ought not to be allowed to inhibit medical progress. And it is clear that if one waited for the *Bolam* test to be complied with to its fullest extent, no innovative work such as the use of penicillin or performing heart transplant surgery would ever be attempted."

4 (1957) 1 WLR 582.
5 (1998) AC 232.
6 [2003] FAM.83.
7 At paragraph 48.

The implications for treatment decisions

2.5 The current legal position gives doctors a clear basis for innovating where they have support from a responsible body of medical opinion (in other words, where they can satisfy the *Bolam* test).

2.6 But, notwithstanding the remarks of Lady Butler-Sloss, questions have been raised about how the law will be applied in cases where there may not be a responsible body of medical opinion that supports a decision to carry out an innovative treatment. Some have argued that there are at least two different ways in which the current law might be interpreted in such cases:

- on one reading, the current test for a responsible decision requires a doctor to demonstrate that there is a body of medical opinion to support that decision. A court will make sure that this opinion is logical (*Bolitho*). A doctor who could not present any such support is more likely to be found negligent;
- on another reading, if the courts are faced with a case where there is no body of medical opinion to support the decision taken by the doctor, then it is possible they might look to medical best practice to determine if the doctor has acted responsibly and thus not negligently.

2.7 In whichever way the current law is viewed, it is easier for a doctor to feel confident of support from a responsible body of medical opinion when the treatment decision is based on a well-trodden path. The more commonplace the treatment, the less anxious a doctor will be about a possible negligence claim. The further away a doctor moves from common procedures, the more uncertainty there will be about how to show that the decision is responsible and not negligent. It is this lack of clarity that might deter doctors from offering innovative treatment, and which the draft Bill aims to address.

2.8 A doctor who is not confident of being able to satisfy the *Bolam* test may feel obliged to follow standard treatments, even where those standard treatments have poor outcomes. The vignette in Box A illustrates this.

Box A – Vignette Part One

Dr A is the consultant in charge of treating Patient B for a heart condition. At a meeting with Patient B, B's wife mentions having seen reference in the press to a new kind of non-surgical treatment that is thought to be more effective than anything currently available and that might make surgery (with its attendant risks) unnecessary. Dr A agrees to investigate.

On investigation, Dr A finds that the new treatment has not been tested in clinical trials. She is not aware of any other doctors using that treatment in relation to heart disease and does not know if other doctors would support her use of that treatment. But she recalls reading a paper on the use of a similar treatment for cancer, based on which she thinks there are good reasons why it might be an effective treatment for heart disease in certain circumstances.

At present, Dr A may feel that the safest course is simply to report back to B and his wife that the new treatment is not used as far as she is aware by other doctors, and that she is therefore unable to advise anything other than the standard surgical procedure. She will be worried that, if she applies the new non-surgical treatment and B dies earlier than would be expected statistically with surgical intervention, disciplinary or legal proceedings may be taken against her. She may be worried that should that happen the court might conclude that departing from "standard treatment" is negligent.

2.9 We are keen to hear views, especially from doctors, on whether medical innovation is being unduly constrained by the possibility of litigation. We also want to hear from patients whose experience suggests that the possibility of litigation has been a factor in their doctor's attitude to possible innovation.

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

3. The proposed legislation

3.1 The draft Bill that the Government proposes is at Annex A to this consultation paper, with explanatory notes at Annex B.

What the Bill aims to do

3.2 If the draft Bill is put in place, its aim would be to encourage responsible innovation in medical treatment in certain circumstances. It would do this by providing that, in those circumstances, it is not negligent for a doctor to depart from the standard medical treatment for a condition if the decision to do so is taken responsibly. The draft Bill aims to provide clarity about what requirements should be met in those circumstances if the doctor is to be able to demonstrate that a decision to depart from standard practice has been taken responsibly, and therefore not negligently. The Bill also aims to protect patients by deterring doctors in those circumstances from carrying out an innovative treatment unless they meet the requirements set out in the Bill.

3.3 The Bill does not change the position on consent to treatment. Nor does it permit a doctor to carry out treatment for research purposes or for any purpose other than the patient's best interests.

How the Bill achieves its aims

3.4 Clause 1(1) says the purpose of the Bill is to encourage responsible innovation in medical treatment, and accordingly to deter innovation which is not responsible. It is relatively unusual in UK law to have a purpose clause, but the statement of purpose is linked to the Bill's aim of providing clarity for doctors and their insurers, for patients and the public and for the courts.

3.5 Clause 1(2) makes clear that the Bill deals, not with all the circumstances in which a decision to carry out innovative medical treatment might be taken, but with certain circumstances only. This takes account of the fact that the Bill is not intended to replace the *Bolam* test. Where a doctor is confident that, if the matter came to court, the treatment would have support from a responsible body of medical opinion, the doctor[8] could still seek to justify and defend the decision on that basis, rather than under the processes set out in the Bill.

3.6 Clause 1(2) also says that, in the circumstances covered by the Bill, it is not negligent for a doctor to depart from the existing range of accepted treatments for a condition if the decision to do so is taken responsibly. The protection from a negligence claim provided

8 Clause 2(1) makes clear that "doctor" means a registered medical practitioner. This is defined in the Interpretation Act 1978 as meaning a fully registered person within the meaning of the Medical Act 1983 who holds a licence to practise under that Act.

by clause 1(2) is for more than just the decision to depart from standard practice. There is unlikely to be a negligence claim about the decision on its own (unless the decision is not to provide treatment). The protection covers both the decision and what the doctor does as a direct result of the decision (the putting of the decision into effect). The protection is not for how the doctor puts the decision into effect. (For example, if the decision, although taken responsibly, is implemented incompetently, the incompetence could be the subject of a negligence claim.)

3.7 Clause 1(3) then spells out that the circumstances in which the Bill applies are where, in the doctor's opinion:

- it is unclear whether the medical treatment that the doctor proposes to carry out has or would have the support of a responsible body of medical opinion (that is, the doctor is unclear if the proposed treatment would satisfy the *Bolam* test if challenged in court); or
- the proposed treatment does not, or would not ,have such support (that is, the doctor considers that the proposed treatment does not, or would not, satisfy the *Bolam* test if challenged in court).

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.

3.8 Clause 1(4) then says that a decision to depart from the existing range of accepted medical treatments, taken in the circumstances covered by clause 1(3), is taken responsibly if it is based on:

- the doctor's opinion that there are plausible reasons why the proposed treatment might be effective; and
- the doctor's consideration of all the matters listed in clause 1(5), and of any other matter that appears to the doctor to be appropriate to take into account in order to reach a clinical judgement.

3.9 Clause 1(5) then lists the matters that the doctor must consider. The matters listed are based on discussions between the sponsors of the Private Members' Bills and medical practitioners about what reflects best practice (though as made clear below, we welcome suggestions for refining them). They are:

a) the relative risks that are, or can reasonably be expected to be, associated with the proposed treatment and other treatments;

b) the likely success rates, in the doctor's reasonable judgement, of the proposed treatment and other treatments;

c) the likely consequences, in the doctor's reasonable judgement, of carrying out, or failing to carry out, the proposed treatment and other treatments;

d) opinions or requests expressed by or in relation to the patient;

e) opinions expressed by colleagues[9] whose opinions appear to the doctor to be appropriate to take into account.

3.10 On one reading of the current law (see paragraph 2.6 above), clause 1(4) and (5) would change the current law by introducing other statutory matters for the court to consider in determining whether a decision was responsible or not, shifting the focus from peer support to the process of decision-making by an individual doctor. A doctor who could not demonstrate support from a responsible body of medical opinion would need to be able to demonstrate that the decision was based on consideration of all the matters set out in clause 1(5) as well as of those in clause 1(4)(a) and (b)(ii).

3.11 Alternatively, it might be argued that clause 1(4) and (5) would make the current law clearer. On this reading, it is thought that, if the courts are faced with a case where there is no body of medical opinion to support the decision taken by the doctor, then they could be expected to look to medical best practice to determine if the doctor has acted responsibly and thus not negligently. Medical best practice is what the matters listed in clause 1(4) and (5) seek to represent.

3.12 In whichever way the current law is interpreted, the Bill would provide clarity to doctors as to what rules would be applied in cases where they depart from standard treatment but where there may not be support from a responsible body of medical opinion. It would also provide similar clarity – and reassurance – to patients and the public.

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?

3.13 Clause 1(6) says that a responsible decision to depart from standard practice is one made in accordance with a process which is accountable, transparent and allows full consideration by the doctor of all relevant matters. The Bill is intended to avoid litigation, so "accountable" here is intended to ensure that the doctor's decision involves internal professional accountability, such as creating an audit trail that could be examined by other doctors.

3.14 Clause 1(7) identifies factors that may play a key part in determining whether the process followed meets the requirements of clause 1(6). These are whether the proposed treatment has been discussed between the doctor and the patient, and what explanation the doctor has given the patient of the treatment; whether the decision has

9 Support from other doctors for a treatment decision in the absence of any clear research or evidence base is not sufficient on its own to establish that a decision is a responsible one. However, the views of colleagues are clearly an important part of responsible decision-making and are one criterion that should be considered. The reference to colleagues does not specify that they must be medical colleagues: the proposal is that "colleague" should be given its fullest natural meaning in the context. For example, it could be reasonable, if a doctor were considering whether to use a treatment that had been tested on animals, to regard veterinary surgeons with knowledge about that as colleagues.

been made within a multi-disciplinary team; and whether notification has been given in advance to the doctor's responsible officer.[10]

3.15 It will not always be feasible for a process to include each of the elements listed in clause 1(7). For example, a patient may not have capacity to discuss treatment; multi-disciplinary teams are more frequently found in some specialties than in others; and a doctor in private practice might not have a responsible officer. For that reason, clause 1(7) does not say that these steps must be taken. But in a situation where they could be considered, the doctor would need to decide whether the steps mentioned are relevant and should be taken as part of reaching a responsible decision. The expectation would be that a doctor would need to have good reason for not taking any of these steps where it is feasible to do so.

3.16 The process provisions in clause 1(6) and (7) are also based on discussions that the sponsors of the Private Members' Bills have had with the medical profession, and again we welcome suggestions for refining them.

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?

3.17 Clause 1(8) makes clear that the Bill does not alter the law of consent; nor does it permit a doctor to carry out treatment for research purposes or for any purpose other than the patient's best interests. This ensures that important safeguards remain in place. For example, the reference to a patient's best interests ensures that decisions relating to patients who lack capacity continue to be made in accordance with the Mental Capacity Act 2005, and decisions relating to children in accordance with the common law, as now. The conduct of research remains governed by a range of legislation depending on the subject matter of the research: for example, clinical trials of medicines are subject to their own form of regulatory regime.

3.18 Although the Bill itself does not change the law on consent, it is worth adding that, as part of the decision-making process, the Department of Health expects proper weight to be given to the views of the patient and the patient's family (see Box B). Clause 1(5)(d) requires the doctor to consider opinions or requests expressed by or in relation to the patient.

10 "Responsible officer" is defined in clause 2(2). In England and Wales, the regulations made under the Act identified there (the Medical Act 1983) are currently the Medical Profession (Responsible Officers) Regulations 2010 (Statutory Instrument 2010/2841). Regulation 10 makes provision so that most doctors will have a responsible officer. So, for example, for general medical practitioners in England it is NHS England; for those in employment it is the employer. Regulation 11 sets out the responsible officer's functions, which relate to evaluating fitness to practise (and making recommendations to that effect to the General Medical Council) of doctors within their remit. Some doctors, such as those who are self-employed, do not have a responsible officer.

Box B – The Importance of Shared Decision-Making

In the traditional, paternalistic, model of healthcare, the doctor told the patient what treatment would be carried out. But this meant the patient's expertise and experience of the illness, and the patient's attitude to risk, were not considered. The Government therefore advocates shared decision-making, defined as "clinicians and patients working together to clarify treatment, management or self-management support goals, sharing information about options and preferred outcomes with the aim of reaching mutual agreement on the best course of action".[11] As a matter of policy, we would expect shared decision-making to happen in decisions on innovative treatment.

3.19 Similarly, it is worth adding that, although the Bill itself does not permit treatment to be carried out for research purposes, the Department of Health would expect any doctor considering whether to follow the procedures set out in the Bill to consider, where practical in the circumstances, whether participation in research, under a properly approved and applied protocol, might be an alternative that would benefit the patient more (see Box C). Clause 1(5)(a) and (b) require the doctor to consider how the proposed treatment compares, in terms of risks and likely success rates with other treatments.

Box C – The Importance of Clinical Research

It is Government policy that, wherever possible, it is best to address uncertainty about the best treatment by testing alternative treatments in a structured, robust and reliable way. This means research, through which lessons can be learned to inform care for future patients. Doctors can initiate and lead clinical research, or participate in studies led by others, to answer questions about what is the best treatment.

The UK Government supports clinical research in the NHS in England through the National Institute for Health Research. In Wales, support is available through clinical trials units, registered research groups and NHS infrastructure funded by the Welsh Government through the National Institute for Social Care and Health Research.

Patients can find out about trials going on through the UK Clinical Trials Gateway[12] and doctors can seek advice from research-active colleagues about designing new research, or from the Research Design Service.[13] A clinical research study means developing the protocol, getting appropriate resources and getting approval that a study is safe, ethical and legal.

11 Angela Coulter and Alf Collins, *Making Shared Decision-Making a Reality: No decision about me, without me*, King's Fund, 2011.

12 See http://www.ukctg.nihr.ac.uk/default.aspx

13 See http://www.nihr.ac.uk/research/Pages/ResearchDesignService.aspx

The practical difference the Bill could make

3.20 Box D continues the vignette introduced in chapter 2 and illustrates the difference that the Bill could make.

Box D – Vignette Part Two

Under the Bill, if Dr A were impressed by the arguments in favour of the new treatment, she would be able to use clause 1(4) to (7) of the Bill as, in effect, statutory support for her decision. In particular, in relation to clause 1(5) —

She will consider the risks and likely success rates of the treatment proposed, for which purpose she may be able to draw on adverse-reaction or other data in relation to the cancer treatment.

She will consider how urgent the surgical intervention is and whether delay pending investigation of the possible effects of the new treatment might make it impossible to carry out the surgery if it then became indicated.

She will consider the strength of B's feelings and those expressed by his wife; and she will build into the process by which she usually obtains informed consent an appraisal of the media piece that they originally found, and an analysis of their hopes and expectations, from a medical perspective.

Dr A will also consider the implications of the process requirements in the Bill when taking her decision whether to apply the new treatment. Depending on her position within a clinical team within a hospital, she will apply an appropriate process for consulting her seniors (if any). If she is the most senior and experienced doctor in her hospital, she may decide to hold minuted telephone consultations with one or more respected colleagues in other hospitals, noting their agreement or disagreement with her reasoned inclination towards or against administering the new treatment. Her hospital may have put in place a system for cascading proposals to other disciplines and expertise within the hospital, in which case she will comply with that procedure.

Dr A will be able to contact her insurers and explain to them that she proposes to depart from the standard treatment in B's case; she will be able to explain that she is following the Bill's procedure, and she will be able to provide them with written records following clause 1(4) to (7) showing how the decision is being taken and the considerations on which it is based. She will not have to use any special form for those records, and will be able to use the notes that, as a responsible clinician, she would have expected to take in any event. (As experience of operating under the Bill develops it is possible that a degree of standardisation of documentation might emerge; but there is no intention or expectation that it will be lengthier or more demanding than that indicated by best practice at present.)

Finally, Dr A will return to B and explain her decision. They will talk it through, and a signed copy of the audit trail will form an annex to the informed consent form which B will be asked to sign in the normal course of events before treatment (whether standard surgical intervention or the new form of treatment) is commenced. Dr A will be confident that, should the treatment be challenged later in the light of B's experience, she will be able to show the courts that her decision was based on the statutory codification of clinical best practice; and that the courts will review her decision in the light of how and why it was taken. (As experience of the Bill develops, she may also become confident that lawyers are less likely than at present to recommend litigation in a case where the statutory process has been rigorously followed.)

Geographical scope

3.21 Clause 3(1) makes clear that the draft Bill would be law in England and Wales. The law of tort in relation to medical negligence is not within the legislative competence of the National Assembly for Wales, but the Welsh Government has been consulted in the preparation of this consultation paper and the UK Government will again seek its views before deciding what action to take in the light of this consultation.

3.22 The law of tort (or delict in Scotland) in relation to medical negligence is within the legislative competence of the devolved legislatures in Northern Ireland and in Scotland. The devolved administration for Northern Ireland has indicated that it wishes to consider the results of this consultation before deciding whether it wishes to clarify the law in Northern Ireland in the way suggested in this consultation paper.

Bringing the legislation into operation

3.23 Clause 3(2) sets out how clauses 1 and 2 would come into force. The Department of Health believes that it would be desirable for the clarification they provide to have effect as soon as possible. But there is also a case for allowing professional bodies a reasonable amount of time before the legislation comes into force so that they can produce guidance that takes account of it. Clause 3(2) therefore provides for clauses 1 and 2 to come into force on a date (or dates) to be set by order after the Bill receives Royal Assent. The Government's current thinking is that this date might be two months after Royal Assent.

3.24 Given that the problem we are trying to solve is doctors being deterred from using new treatments for fear of litigation, the legislation will only have its intended effect if it is communicated effectively to doctors. So we are keen to hear ideas on the best way to do this.

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

3.25 There is a wider Government programme of action to reduce the costs of civil litigation, including clinical negligence. This includes Part 2 of the Legal Aid Sentencing and Punishment of Offenders Act 2012, which addressed the high costs of "no win no fee" conditional fee agreements in particular. Provisions in the Act, which came into force on

1 April 2013, reduce the costs that claimant lawyers can charge a defendant (such as the NHS) in successful "no win no fee" claims. These reforms will reduce costs and should discourage unmeritorious litigation. In addition, the NHS Litigation Authority's safety and learning service supports the NHS in England to learn from claims so that patient harm is reduced and claims are not repeated.

3.26 We would welcome views on whether, to reinforce this Bill, there are other steps that should be taken to encourage responsible innovation. These steps might be aimed at tackling concerns about litigation or any other potential obstacle to responsible innovation.

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

Impact of the proposed legislation

3.27 A draft initial impact assessment and equality analysis are at Annex C. We would welcome comments and evidence about the potential benefits, costs and risks of the Bill. This could take the form of case studies.

3.28 In particular, we would welcome evidence and comments on:

- effective innovative treatments that could be encouraged by, or achieved sooner than they otherwise might be, as a result of the Bill. Is further action needed to maximise the benefit of such treatment? For example, should steps be taken to ensure that the results of innovative treatments carried out as a result of the Bill are publicised in some way?
- the implications of the proposed legislation for the conduct of research. The Bill itself does not deal with the conduct of research, but is there a risk that it might result in involvement in research being inappropriately deemed unattractive for individual patients, or that it might deter researchers from embarking on trials? If so, what action might be taken to mitigate these risks?

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

3.29 Finally, we would like your views on whether the draft Bill should become law.

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

Annex A: The draft Bill

Medical Innovation Bill

CONTENTS

A

B I L L

TO

Make provision about innovation in medical treatment.

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

1 Responsible innovation

(1) The purpose of this section is to encourage responsible innovation in medical treatment (and accordingly to deter innovation which is not responsible).

(2) It is not negligent for a doctor to depart from the existing range of accepted medical treatments for a condition, in the circumstances set out in subsection (3), if the decision to do so is taken responsibly.

(3) Those circumstances are where, in the doctor's opinion—

(a) it is unclear whether the medical treatment that the doctor proposes to carry out has or would have the support of a responsible body of medical opinion, or

(b) the proposed treatment does not or would not have such support.

(4) A responsible decision for the purposes of subsection (2) is one which is based on—

(a) the doctor's opinion that there are plausible reasons why the proposed treatment might be effective, and

(b) consideration by the doctor of—

(i) all the matters listed in subsection (5), and

(ii) any other matter that appears to the doctor to be appropriate to take into account in order to reach a clinical judgement.

(5) The matters mentioned in subsection (4)(b)(i) are—

(a) the relative risks that are, or can reasonably be expected to be, associated with the proposed treatment and other treatments,

(b) the likely success rates, in the doctor's reasonable judgement, of the proposed treatment and other treatments,

(c) the likely consequences, in the doctor's reasonable judgement, of carrying out, or failing to carry out, the proposed treatment and other treatments,

(d) opinions or requests expressed by or in relation to the patient, and

(e) opinions expressed by colleagues whose opinions appear to the doctor to be appropriate to take into account.

(6) A responsible decision for the purposes of subsection (2) is one made in accordance with a process which is accountable, transparent and allows full consideration by the doctor of all relevant matters.

(7) The factors that may be taken into account in determining whether a process satisfies the requirements of subsection (6) include, in particular—

(a) whether the doctor has discussed the proposed treatment with the patient and given the patient the explanation that the doctor would in the circumstances be expected to give of the doctor's reasons for carrying out the treatment,

(b) whether the decision has been made within a multi-disciplinary team, and

(c) whether the doctor has given notification in advance to the doctor's responsible officer (if any).

(8) Nothing in this section permits a doctor—

(a) to provide treatment without consent that is otherwise required by law, or

(b) to carry out treatment for the purposes of research or for any purpose other than the patient's best interests.

2 Interpretation

(1) In this Act—

(a) "doctor" means a registered medical practitioner;

(b) a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction).

(2) The reference in section 1(7)(c) to a doctor's responsible officer is to the responsible officer (or one of the responsible officers) nominated or appointed under section 45A of the Medical Act 1983 for a designated body with which the doctor has a prescribed connection for the purposes of section 45A of that Act.

3 Extent, commencement and short title

(1) This Act extends to England and Wales only.

(2) Sections 1 and 2 come into force on such day or days as the Secretary of State may by order made by statutory instrument appoint.

(3) An order under subsection (2) may—

(a) appoint different days for different purposes;

(b) make transitional or saving provision.

(4) This section comes into force on the day on which this Act is passed.

(5) This Act may be cited as the Medical Innovation Act 2014.

Annex B: Draft explanatory notes

B.1 These explanatory notes relate to the draft Medical Innovation Bill at Annex A. They have been prepared by the Department of Health in order to assist the reader of the draft Bill. They do not form part of the draft Bill and have not been endorsed by Parliament.

B.2 The notes need to be read in conjunction with the draft Bill. They are not, and are not meant to be, a comprehensive description of the draft Bill.

Background and summary

B.3 The idea for the draft Bill originates in Bills introduced by Private Members in the House of Lords and the House of Commons in the 2013/14 session of Parliament. The Government is carrying out a public consultation on the draft Bill in early 2014.

B.4 If the draft Bill is put in place, its aim would be to encourage responsible innovation in medical treatment in certain circumstances. It would do this by providing that, in those circumstances, it is not negligent for a doctor to depart from the standard medical treatment for a condition if the decision to do so is taken responsibly. The draft Bill aims to provide clarity about what requirements should be met in those circumstances if the doctor is to be able to demonstrate that a decision to depart from standard practice has been taken responsibly, and therefore not negligently. The Bill also aims to protect patients by deterring doctors in those circumstances from carrying out an innovative treatment unless they meet the requirements set out in the Bill.

B.5 The Bill is not intended to apply to all the circumstances in which medical innovation might take place. Specifically, it is not intended to replace or abolish the *Bolam* test, established in case law; that is, in order to avoid a successful claim in negligence, a doctor should be able to demonstrate support for a decision from a responsible body of medical opinion. So where a doctor is confident that, if the matter comes to court, there would be support for an innovation from a responsible body of medical opinion, the doctor could still seek to rely on that support to defend the innovation against a charge of negligence, rather than following the steps which make the decision to innovate a "responsible" one under the provisions of the Bill.

B.6 The Bill does not change the position on consent to treatment. Nor does it permit a doctor to carry out treatment for research purposes or for any purpose other than the patient's best interests.

Overview of the structure

B.7 The draft Bill consists of 3 clauses. The main substance of the Bill is in clause 1. Clause 2 deals with interpretation of terms used in the Bill, and clause 3 chiefly with the arrangements for bringing it into force.

Territorial extent and application

B.8 Clause 3 sets out the territorial extent of the Bill. It would be law in England and Wales.

Commentary on clauses

Clause 1

B.9 *Clause 1(1)* says the purpose of the Bill is to encourage responsible innovation in medical treatment, and accordingly to deter innovation which is not responsible. It is relatively unusual in UK law to have a purpose clause, but the statement of purpose is linked to the Bill's aim of providing clarity for doctors and medical insurers, for patients and the public and for the courts.

B.10 *Clause 1(2)* makes clear that the Bill deals, not with all the circumstances in which a decision to carry out innovative treatment might be taken, but with certain circumstances only. This takes account of the fact that the Bill is not intended to replace the *Bolam* test. Where a doctor is confident that, if the matter came to court, the treatment would have support from a responsible body of medical opinion, the doctor could still seek to justify and defend the decision on that basis, rather than under the processes set out in the Bill.

B.11 Clause 1(2) also says that, in the circumstances covered by the Bill, it is not negligent for a doctor to depart from the existing range of accepted treatments for a condition if the decision to do so is taken responsibly. The protection from a negligence claim provided by clause 1(2) is for more than just the decision to depart from standard treatment. There is unlikely to be a negligence claim about the decision on its own (unless the decision is not to provide treatment). The protection covers both the decision and what the doctor does as a direct result of the decision (the putting of the decision into effect). The protection is not for how the doctor puts the decision into effect. (For example, if the decision, although taken responsibly, is implemented incompetently, the incompetence could be the subject of a negligence claim.)

B.12 *Clause 1(3)* then spells out that the circumstances in which the Bill applies are where, in the doctor's opinion:

- it is unclear whether the medical treatment that the doctor proposes to carry out has or would have the support of a responsible body of medical opinion (that is, the doctor is unclear if the proposed treatment would satisfy the *Bolam* test if challenged in court); or
- the proposed treatment does not, or would not, have such support (that is, the doctor considers that the proposed treatment does not, or would not, satisfy the *Bolam* test if challenged in court).

B.13 *Clause 1(4)* then indicates that a decision to depart from the existing range of accepted medical treatments for a condition, taken in the circumstances covered by clause 1(3), is taken responsibly if it is based on:

- the doctor's opinion that there are plausible reasons why the proposed treatment might be effective; and
- the doctor's consideration of all the matters listed in clause 1(5), and of any other matter that appears to the doctor to be appropriate to take into account in order to reach a clinical judgement.

B.14 *Clause 1(5)* then lists the matters that the doctor must consider. The matters listed in clause 1(4) and (5) are based on discussions between the sponsors of the Private Members' Bills and medical practitioners about what reflects best practice.

B.15 *Clause 1(6)* says that a responsible decision to depart from standard practice is a decision made in accordance with a process which is accountable, transparent and allows full consideration by the doctor of all relevant matters. The Bill is intended to avoid litigation, so "accountable" here is intended to ensure that the doctor's decision involves internal professional accountability, such as creating an audit trail that could be examined by other doctors.

B.16 *Clause 1(7)* identifies factors that may play a key part in determining whether the process followed meets the requirements of clause 1(6). These are whether the proposed treatment has been discussed between the doctor and the patient, and what explanation the doctor has given the patient of the treatment; whether the decision has been made within a multi-disciplinary team; and whether notification has been given in advance to the doctor's responsible officer.

B.17 It will not always be feasible for a process to include each of the elements listed in clause 1(7). For example, a patient may not have capacity to discuss treatment; multi-disciplinary teams are more frequently found in some specialties than in others; and a doctor in private practice might not have a responsible officer. For that reason, clause 1(7) does not say that these steps must be taken. But in a situation where they could be considered, the doctor would need to decide whether the steps mentioned are relevant and should be taken as part of reaching a responsible decision. The expectation would be that a doctor would need to have good reason for not taking any of these steps where it is feasible to do so.

B.18 The process provisions in clause 1(6) and (7) are also based on discussions that the sponsors of the Private Members' Bills have had with the medical profession.

B.19 *Clause 1(8)* makes clear that the Bill does not alter the law of consent; nor does it permit a doctor to carry out treatment for research purposes or for any purpose other than the patient's best interests. This ensures that important safeguards remain in place. For example, the reference to a patient's best interests ensures that decisions relating to patients who lack capacity continue to be made in accordance with the Mental Capacity Act 2005, and decisions relating to children in accordance with the common law, as now. The conduct of research remains governed by a range of legislation depending on the subject matter of the research: for example, clinical trials of medicines are subject to their own form of regulatory regime.

Clause 2

B.20 *Clause 2* sets out how certain terms used in clause 1 are to be interpreted.

B.21 *Clause 2(1)(a)* makes clear that "doctor" means a registered medical practitioner. This is defined in the Interpretation Act 1978 as meaning a fully registered person within the meaning of the Medical Act 1983 who holds a licence to practise under that Act.

B.22 *Clause 2(2)* says that a "responsible officer" is the responsible officer nominated or appointed under section 45A of the Medical Act 1983 for a designated body with which the doctor has a prescribed connection for the purposes of section 45A of that Act. In England and Wales, the regulations made under that Act are currently the Medical Profession (Responsible Officers) Regulations 2010 (Statutory Instrument 2010/2841). Regulation 10 makes provision so that most doctors will have a responsible officer. So, for example, for general medical practitioners in England it is NHS England; for those in employment it is the employer. Regulation 11 sets out the responsible officer's functions, which relate to evaluating fitness to practise (and making recommendations to that effect to the General Medical Council) of doctors within their remit. Some doctors, such as those who are self-employed, do not have a responsible officer.

Clause 3

B.23 *Clause 3(1)* makes clear that the draft Bill would be law in England and Wales.

B.24 *Clause 3(2) and (3)* set out how clauses 1 and 2 would come into force.

Financial Effects

B.25 The direct financial effects of the draft Bill are minimal.

Public Sector Manpower

B.26 No changes in the staff of Government departments and their agencies are expected as a result of the draft Bill.

Impact Assessment

B.27 A summary impact assessment and equality analysis have been prepared to accompany the draft Bill.

Annex C: Draft impact assessment and equality analysis

Title: Medical Innovation **IA No:** 5188 **Lead department or agency:** Department of Health **Other departments or agencies:** N/A	**Impact Assessment (IA)** **Date:** 18/02/2014 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:** David Hackett
Summary: Intervention and Options	**RPC Opinion:** Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
N/A	£0m	£0m	No	NA

What is the problem under consideration? Why is government intervention necessary?

A potential barrier to improved treatment is the possibility of clinical negligence claims. An increasingly litigious culture may be putting pressure on doctors to practise defensive medicine. Consequently, doctors may feel obliged to follow standard treatments, even where those standard treatments have poor outcomes.

What are the policy objectives and the intended effects?

The overall intention of the draft Bill is to give confidence to doctors who want to carry out innovative treatment that they will not face a successful negligence action if they can demonstrate that they have acted responsibly. The Bill aims to provide clarity for doctors (and the courts and other stakeholders such as medical insurers) about the factors that should be considered in order to be able to demonstrate that a decision has been taken responsibly. The Bill also aims to discourage irresponsible innovation, and so to safeguard patients, by making clear what requirements should be met.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The consultation paper invites views on a proposal to clarify the law in order to encourage responsible medical innovation. Lack of clarity around how the current law concerning clinical negligence might be interpreted has been identified as a potential barrier to innovation in medical treatment and so the consultation focuses on this specific issue. The consultation asks for ways of communicating this proposed change to the medical profession as this will ensure that the change is effective. At this stage, no preferred option has been identified. Further information and evidence is sought as part of the consultation.

Will the policy be reviewed? It will/will not be reviewed. **If applicable, set review date:** Month/Year

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes/No	**< 20** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large** Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister ..... Date: 24th February 2014

Summary: Analysis & Evidence Policy Option 1

Description: Introduce medical innovation proposals

FULL ECONOMIC ASSESSMENT

Price Base Year N/A	PV Base Year N/A	Time Period Years N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** N/A

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	N/A	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Unknown		Unknown	**Unknown**

Description and scale of key monetised costs by 'main affected groups'

It has not been possible to quantify any costs at this stage.

The consultation seeks further information and evidence on the possible costs of the proposals.

Other key non-monetised costs by 'main affected groups'

One cost that could arise is from increased NHS treatment costs, from a greater number of innovative treatments. These costs could include a revised surgical procedure, a drug used in a certain treatment that is more expensive than one previously used or the use of new medical equipment that prolongs life for example. These possible costs will be dependent on commissioners releasing additional funding for these innovative treatments. They may be balanced by cost-savings (see benefits).

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	N/A	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Unknown		Unknown	**Unknown**

Description and scale of key monetised benefits by 'main affected groups'

It has not been possible to quantify any benefits at this stage.

The consultation seeks further information and evidence on the possible benefits of the proposals.

Other key non-monetised benefits by 'main affected groups'

Four main benefits could arise: (a) improved health-related quality of life to patients from successful innovative treatments, (b) quality of life benefit to similar patient group from dissemination of findings, and potentially to wider patient groups as well, (c) reduced number of clinical negligence claims as a result of less ambiguity over when it is appropriate to try out an innovative treatment, (d) reduced costs to the NHS in cases of appropriate innovative holding back of treatment.

Key assumptions/sensitivities/risks — **Discount rate (%)** N/A

Three possible risks could arise: (a) funding for innovative treatments is not made available by commissioners, (b) potential harm to patients due to unsuccessful innovative treatments, (c) inappropriate use of legislation, where doctors may engage in clinically inappropriate or risky behaviour without sufficient justification. (b) and (c) are mitigated in part through the Bill's provisions which require doctors to meet certain requirements before undertaking innovative treatment.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	NA

Evidence Base (for summary sheets)

Problem under consideration and rationale for intervention

1. One of the barriers to improved treatment is the possibility of clinical negligence claims. An increasingly litigious culture may be putting pressure on doctors to practise defensive medicine. Consequently, doctors may feel obliged to follow standard treatments, even where those standard treatments have poor outcomes.

Policy objective

2. The overall intention of the draft Bill is to give confidence to doctors who want to carry out innovative treatment that they will not face a successful negligence action if they can demonstrate that they have acted responsibly. The Bill aims to provide clarity for doctors (and the courts and other stakeholders such as medical insurers) about the factors that should be considered in order to be able to demonstrate that a decision has been taken responsibly.
3. The consultation paper invites views on a proposal to clarify the law in order to encourage responsible medical innovation. Lack of clarity around how the current law concerning clinical negligence might be interpreted has been identified as a potential barrier to innovation in medical treatment and so the consultation focuses on this specific issue. The Bill would apply to all medical practitioners, working in both the NHS and privately as it would be wrong to have different standards between the two sectors.

Description of option 1: introduce medical innovation legislation

4. The main intended driver of effects from the legislation is increased legal certainty. Doctors who wish to practise innovative medicine will know what steps need to be taken to demonstrate responsible decision making.
5. The intended effect of this is an increased number of such procedures and treatments. The numbers are expected to be small in initial years but growing over time as understanding of the legislation develops. The consultation seeks views on cases where innovative treatments may be introduced.
6. The proposals are intended to lead to an increase in the number of positive outcomes from innovative treatments. The effect of a change in treatment patterns is that some patients would benefit from successful innovative procedures and treatments. This is likely to be in terms of an extended length of life and/or quality of life. However, there is a risk that patients receive no benefit, or are harmed if the innovative treatment is unsuccessful. The consultation seeks views on the scale of the potential quality of life improvements that may result from successful innovative treatments, including case studies.
7. An increase in innovative treatments may lead to a net increase in costs for the NHS if they are on patients who are unlikely to receive other treatment. However, if the innovative approach involves the appropriate holding back of treatment (for example where the standard treatment would not benefit the patient), or the use of a more cost-effective treatment, it may lead to cost savings relative to doing nothing. The consultation seeks views on the potential costs (including cost-savings) that may result, for example in terms of length of stay in hospital, number of operations and drug costs, including from case studies.

8. It is difficult to assess balance of benefit and harm in the near term. For each successful innovative treatment, there is scope to learn from this, disseminate findings and test its applicability more widely. The findings may be applicable to other patients in a similar situation, leading to a larger benefit in the long term.

Costs, benefits and risks of option 1

9. The costs, benefits and risks are assessed relative to the do-nothing option, so are incremental. It has not been possible to identify the scale of the possible benefits, costs and risks at this stage. The following three sections outline the possible types of costs, benefits and risks that may arise, although the scale of these is not known. The consultation seeks further information and evidence.

Costs of option 1

10. One possible cost has been identified: increased NHS treatment costs, from a greater number of innovative treatments These costs could include a revised surgical procedure, a drug used in a certain treatment that is more expensive than one previously used or the use of new medical equipment that prolongs life for example.

11. These increased costs will be dependent on commissioners releasing additional funding for these innovative treatments (see risks section). These costs may be balanced by possible cost savings, due to appropriate innovative holding back of treatment or more cost-effective treatment (see benefits section).

12. It has not been possible to quantify the expected scale of these effects at this stage, so the consultation seeks views and evidence on this.

Benefits of option 1

13. Four possible benefits have been identified, although it has not been possible to assess the likely scale of these:

    a) Potential improved health-related quality of life to patients from successful innovative treatments

    b) Potential improved health-related quality of life to similar patient groups from dissemination of findings, and potentially to wider patient groups as well,

    c) Potential reduced number of clinical negligence claims as a result of less ambiguity over when it is appropriate to try out an innovative treatment,

    d) Reduced costs to the NHS in cases of appropriate innovative holding back of treatment or innovative use of more cost-effective treatments

14. These benefits may include an increase in the number of years a patient survives after diagnosis of a disease or an improved quality of life through the use of a drug or medical advice.

15. It has not been possible to quantify the expected scale of these effects at this stage, so the consultation seeks views and evidence on this.

Risks of option 1

16. Three potential risks have been identified, although it has not been possible to identify the likelihood and scale of these:

    a) Funding for innovative treatment is not made available by commissioners, meaning that the legislation has little effect,

    b) Possible unsuccessful innovative treatments, where patients experience no health benefit, or may experience a deterioration in their health-related quality of life compared with no treatment,

c) Potential inappropriate use of the proposed legislation, if doctors engage in clinically inappropriate or risky behaviour without sufficient justification. It is uncertain whether there will be any incremental risk of this over and above doing nothing, and the consultation seeks views on this.

17. Risk (a) is difficult to mitigate without further financing. Without funding for further innovative treatments, the effects of the proposals will be reduced, both in terms of benefits and costs. However, in this situation commissioners may prioritise funding those innovative treatments that are more likely to benefit the patient, improving the benefits while constraining any additional costs.

18. Risks (b) and (c) are mitigated through the the Bill's provisions which require doctors to meet certain requirements before undertaking innovative treatment: see in particular clause 1(4) and clause 1(5) of the Bill.

19. At this stage, it has not been possible to identify the likelihood and scale of these risks – the consultation seeks further information and evidence on this.

Direct costs and benefits to business calculations following one in two out (OITO) methodology

20. While the proposed legislation is expected to have an impact on the private sector (as it will apply to private medical professionals in the same manner as to NHS-based medical professionals), there is no direct impact on business. Costs of providing more treatments will be borne by patients. The expectation is that the number of clinical negligence claims will go down in the long run as a result of greater clarity as to when innovative treatment is appropriate (although there may be a small initial increase as a result of new "test case" legislation being introduced).

Wider impacts

21. Government might see a negligible operational impact on the courts as a result of introducing the Bill as it is focused on a highly specialised area and the volume of cases that result from the Bill will be incidental.

Summary and preferred option

22. At this stage, no preferred option has been identified. The consultation seeks further information and evidence on the impact of the proposals described in option 1.

Equality analysis

Title: Draft Medical Innovation Bill

What are the intended outcomes of the Bill?

To clarify the law of negligence in order to encourage responsible medical innovation in certain circumstances; and to discourage irresponsible innovation.

Who will be affected?

Potentially doctors and patients, both in the NHS and more widely, in England and Wales.

The Bill will be relevant, not to all the treatments carried out by doctors on patients, but where, in the doctor's opinion, it is unclear whether the medical treatment that the doctor proposes to carry out has or would have the support of a responsible body of medical opinion – or where in the doctor's opinion, it would not have such support – if the matter comes to court.

The Bill cannot guarantee that an innovative treatment carried out in such circumstances will be successful and therefore beneficial to the patient; but by setting out the processes required to make innovation in such circumstances responsible, it aims to maximise the likelihood of success and to discourage irresponsible innovation.

Evidence

Disability

The Bill could be of particular relevance to some disabled people, for example where their disability is related to a condition that might be the subject of an innovative treatment.

The Bill could also be of relevance to people who lack capacity because of their disability (as well as to those who lack capacity for other reasons): it preserves the current arrangements on consent to treatment for those who lack capacity.

Sex

Potentially both men and women could be affected by the Bill.

Race

The Bill could be of particular relevance to people from particular ethnic groups, for example if it encourages innovations in the treatment of rare conditions associated with certain ethnicities.

Age

Evidence about the effectiveness of a treatment might be lacking in relation to people at the ends of the age spectrum. (For example, clinical trials are rarely conducted on children.) The Bill could therefore be of particular relevance both to children and to older people. (The Bill preserves current arrangements on consent to treatment for those who lack capacity, so children without capacity, for example, could still receive an innovative treatment under the provisions in the Bill.)

Gender reassignment (including transgender)

Treatments covered by the Bill could potentially include gender reassignment.

Sexual orientation

We have not identified a particular impact that the Bill would have on people on grounds of their sexual orientation.

Religion or belief

Some treatments might be unacceptable to patients on grounds of religion or belief; but the Bill preserves existing arrangements on consent and does not license doctors to impose treatment on a patient.

Pregnancy and maternity

We have not identified a particular impact that the Bill would have on people on grounds of pregnancy and maternity.

Carers

If innovative treatments carried out under the Bill are successful, that could in some cases reduce the demands on carers.

Other identified groups

Section 1C of the NHS Act 2006 puts the Secretary of State under a duty, in exercising functions in relation to the health service, "to have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the health service". The same Act also puts duties to reduce inequalities on NHS England (section 13G) and clinical commissioning groups (section 14T). We have therefore considered the possible impact of the Bill on health inequalities in England.

The Bill could:

- reduce health inequalities if it results in the use of treatments that are more effective than those that would otherwise have been used; or

- exacerbate health inequalities if it results in the use of treatments that are less effective than the treatments that would otherwise have been used. It could also exacerbate inequalities if the take up of effective treatments is greater among some groups (for example, those with more education/access to the internet).

However, overall the Bill seems more likely to reduce than to exacerbate inequalities, because there will be no incentive to repeat treatments that have proved less effective than the others available, but every incentive to spread the use of treatments that have proved more effective.

Engagement and involvement

The consultation follows the Government's Consultation Principles (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255180/Consultation-Principles-Oct-2013.pdf)

How have you engaged stakeholders in gathering evidence or testing the evidence available?

The draft Bill was discussed informally with a variety of interests, both by the sponsors of the original Private Members' Bills and by the Department of Health in the development of the consultation paper. It is now subject to formal public consultation.

How have you engaged stakeholders in testing the policy or programme proposals?

As above.

For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

The Department of Health discussed the proposals informally with representatives of various medical, patient and disease-specific organisations during the development of the consultation paper. It plans to hold further engagement events during the formal consultation period.

Summary of Analysis

To the extent that people with protected characteristics make greater use of health services than others (for example, older people and children, disabled people whose disability relates to a long-term condition), the Bill has the potential to benefit them more than people without those characteristics. More generally, it could reduce health inequalities, as more effective treatments identified by following the requirements of the Bill are taken up more widely.

Eliminate discrimination, harassment and victimisation

The Bill would have no direct effect in terms of eliminating discrimination, harassment and victimisation.

Advance equality of opportunity

The Bill could advance equality of opportunity, for example by making it more likely that a treatment that has proved beneficial to people in one particular age group is offered to a person in another age group.

Promote good relations between groups

The Bill would have no direct effect in terms of promoting good relations between groups.

What is the overall impact?

Overall, the Bill seems more likely to be beneficial than otherwise, both to people with certain protected characteristics and in terms of reducing health inequalities more generally.

Addressing the impact on equalities

The analysis above has not identified a need to take action to reduce inequalities resulting from the Bill, but we will consider carefully any points made in responses to the consultation paper.

Annex D: List of those alerted to publication of this consultation paper

Comments on the proposals in the consultation paper are welcome from anyone with an interest.

The list below identifies those who have specifically been alerted to publication of the consultation paper.

Devolved administrations

The Welsh Government

The Northern Ireland Executive

The Scottish Government

Disease-specific organisations

Age UK

Beating Bowel Cancer

Bowel Cancer UK

Breakthrough Breast Cancer

Breast Cancer Campaign

Breast Cancer Care

British Heart Foundation

British Lung Foundation

Cancer Black Care

Cancer Research UK

Cancer52

Diabetes UK

Macmillan

Neurological Alliance

Pancreatic Cancer UK

Prostate Cancer UK

Rare Disease UK

Richmond Group

Stroke Association

Independent healthcare providers

Association of British Insurers

Association of British Healthcare Industries

Medical bodies

Academy of Medical Royal Colleges

Academy of Medical Sciences

British Medical Association

General Medical Council

Medical Royal Colleges

Medical defence bodies

Medical Defence Union

Medical and Dental Defence Union of Scotland

Medical Protection Society

NHS and related bodies

Clinical Commissioning Coalition

Foundation Trust Network

Human Fertilisation and Embryology Authority

Human Tissue Authority

Incisive Health

King's Fund

NHS Confederation

NHS IQ

Nuffield Trust

NHS bodies in England and Wales

NHS Scotland

NHS Litigation Authority

Health and social services bodies in Northern Ireland

NICE

Parliament

Health Select Committee

House of Commons Science and Technology Committee

House of Lords Science and Technology Committee

Patient organisations

Healthwatch England and local Healthwatch organisations

Faith groups, British Humanist Association

Action against Medical Accidents

Patient Opinion

Patients Association

Which?

Age UK

Pharmaceutical etc industry

Association of British Pharmaceutical Industry

BioIndustry Association

British In Vitro Diagnostics Association

Research-related bodies

Academic Health Science Centres/Networks

Association of Medical Research Charities

Centre for Advancement of Sustainable Medical Innovation

Health Research Authority

Institute of Cancer Research & the Royal Marsden Hospital

Medical Research Council

National Cancer Research Institute

National Institute for Health Research

Office for the Strategic Coordination of Health Research

UK Clinical Ethics Network

Legal bodies

The Law Society

The Bar Council

Federation of Insurance Lawyers

Association of Personal Injury Lawyers

The Professional Negligence Bar Association

Annex E: Responding to the consultation

How to respond

We welcome responses from any interested person, business or organisation. Please submit your response by 25 April 2014.

Respondents are encouraged to provide their views online but responses can be made in any of the following ways, by:

Visiting the Department of Health's Medical Innovation Bill website: www.medicalinnovationbill.dh.gov.uk

Emailing your response to: Medicalinnovationbill@dh.gsi.gov.uk

Posting your response to: **Medical Innovation Consultation Team, Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS**. If you are responding by post, you may find it helpful to do so using the form at the end of this annex, which reproduces the questions in this consultation paper.

Please ensure that your response provides your name and address. It would be helpful if you could provide your email and/or phone number, in case we need to contact you to clarify any aspect of your response. If you are responding as an individual, it would be helpful to know what particular expertise you bring to your response (for example, are you a doctor, patient or lawyer?). If you are responding on behalf of an organisation, please provide information about the organisation and who it represents.

Where possible, please include references to research or other evidence with your responses. If you want to answer some questions and not others, that is fine.

Alternative formats

If you wish to get a copy of this consultation document in an alternative format, or need to respond in an alternative format for accessibility reasons, please contact us using the email or postal addresses given above.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's **Information Charter.**

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An

automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please

contact Consultations Coordinator
Department of Health
2e08, Quarry House
Leeds
LS2 7UE

e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Response form

Name
Address
Email
Phone number
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?
If you are responding on behalf of an organisation, please give the name of the organisation and say who it represents:

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?

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?

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.

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?

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?

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?

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

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

We also welcome any other comments you wish to make.

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