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Health and Social Care Committee

Meeting Venue:
Committee Room 1 - Senedd

Meeting date:
21 January 2015

Meeting time:
09.15

Cynulliad Cenedlaethol Cymru
National Assembly for Wales

For further information please contact:
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Agenda – Supplementary Documents

Legislative Consent Memorandum: Medical Innovation Bill: Consultation Responses

Please note the documents below are in addition to those published in the main Agenda and Reports pack for this Meeting

6 Legislative Consent Memorandum: Medical Innovation Bill: consideration of evidence (10.30 - 10.50) (Pages 1 - 22)

LCM-LD10045 - Legislative Consent Memorandum Medical Innovation Bill
Medical Innovation Bill

National Assembly for Wales / Cynulliad Cenedlaethol Cymru
Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol

Legislative Consent Memorandum: Medical Innovation Bill / Memorandwm Cydsyniad Deddfwriaethol: Y Bil Arloesi Meddygol
Evidence from Royal College of Radiologists – MIB 01 / Tystiolaeth gan Coleg Brenhinol y Radiolegwyr – MIB 01

The Royal College of Radiologists

Response to:
Department of Health Consultation – *Legislation to encourage medical innovation*

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

   No, we have no evidence that doctors are deterred from innovation by fear of litigation.

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?**

   Individual doctors sometimes seek clarification about the circumstances in which they can safely innovate. Our advice is that when doubt exists, they should seek guidance from the relevant medical defence organisation.

3. **Do you agree with the circumstances in which the Bill applies, as outlined in clause 1(3)?**

   If the doctor considers that the proposed treatment would not have the support of a responsible body of medical opinion, as outlined in clause 1(3), and would therefore not satisfy the Bolam test if challenged in court, then the overwhelming likelihood is that the treatment will not be of value and there is a significant risk that it may be harmful.

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?**

   No comments.

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?**

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If the decision to offer an innovative treatment has been made within a multi-disciplinary team, as in 1 (7) (c), then it is highly likely that it would satisfy the Bolam test if challenged in court, therefore making this Bill unnecessary.

We are unclear about the reference in the draft to “the doctor’s responsible officer (if any)". If this refers to the role defined under revalidation structures, then clearly any doctor practising in the UK and requiring a licence to practise should also have a responsible officer. There is concern therefore, that the intent of the Bill is that those in independent practice would have greater flexibility and opportunity for innovation. This could have perverse effects as there might be fewer checks and balances to ensure that innovation is appropriate, safe and potentially effective.

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

   No comments.

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

   - An improved system of registration of innovative treatments, together with recording of outcome data, would be extremely valuable and would support responsible innovation.
   - Securing funding is also one of the biggest obstacles to innovation at present.

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

   We are very concerned that there could be serious unintended consequences of the proposed legislation. Existing governance mechanisms protect patients from inappropriate experimentation and protect doctors from pressure to innovate in ways which are potentially detrimental to their patients. Patients who are not satisfied with the response of a particular doctor to a proposed innovative treatment may seek a second opinion. Relaxation of these governance mechanisms, which this Bill proposes, risks exposing vulnerable and desperate patients to false hope, futile and potentially harmful (and expensive) treatments.

9. **Overall, should the draft Bill become law?**

   In our view the draft Bill should not become law.

   Fundamentally, we do not believe this legislation is needed. We do not feel that doctors are constrained as regards innovation and we believe that the current structures provide the appropriate checks and balances.

The Royal College of Radiologists
April 2014

National Assembly for Wales / Cynulliad Cenedlaethol Cymru
Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol

Legislative Consent Memorandum: Medical Innovation Bill / Memorandwm Cydsyniad Deddfwriaethol: Y Bil Arloesi Meddygol
Evidence from Patients Association – MIB 02 / Tystiolaeth gan Cymdeithas Cleifion – MIB 02

29th December 2014

The Patients Association response to the:

National Assembly for Wales (**Cynulliad Cenedlaethol Cymru):**
Health and Social Care Committee (Y Pwyllgor Iechyd a Gofal Cymdeithasol)

Evidence gathering on: **The Medical Innovation Bill**

The Patients Association is an independent national health and social care charity established over 50 years ago and has a long history of campaigning to ensure that the voice of patients is heard within the Health and Social care system. We achieve this through research, campaigns to support patients' rights, lobbying Government to address healthcare issues affecting patients and speaking up for patients and carers.

The Patients Association also provides an advisory national Helpline service to over 7000 patients each year who raise concerns about their experiences with healthcare providers. The nature of these enquiries cover issues such as poor care (particularly of elderly people in hospital), delayed or cancelled operations and problems with the complaints services.

This offers us a wealth of information, with a database currently consisting of well over 40,000 cases, spanning many years and giving us a unique insight into the diverse nature of concerns raised by patients themselves. In order to make the best use of this information, the Patients Association provides data analysis and statistical research to detect emerging trends and patterns, and any concerns can be targeted towards improving patient care.

The Patients Association welcomes the opportunity to contribute to the National Assembly for Wales's inquiry on the Medical Innovation Bill. We hope that our insights and expert advice are able to help shape the health and social care landscape for the benefit of patients.

1.1 The Patients Association supports any innovation that saves lives and provides better outcomes for patients; who deserve access to high quality, safe care. While medical innovations are important to provide the highest quality of healthcare possible, the Patients Association would like to highlight a number of key points which should be emphasised in the discussions regarding the implementation of the Medical Innovation Bill.

1.2 As an organisation that represents patients and their carers, we strongly believe that the underlying motivation behind the Medical Innovation Bill should be to improve patient care, interventions, experience and outcome. Ensuring the safety and dignity of all patients at all times, it is important that the proposals put forward for the Bill are not driven by commercial, financial or staffing interests. Any diversion of focus away from the interests of the patient is likely to compromise the quality, safety and dignity of the patient. It is essential that doctors only offer treatments which are believed by both doctor and patient on reasonable grounds to be in their best interests, and to offer a reasonable prospect of doing more good than harm.

2.1 The Patients Association would like to stress the importance of informed patient consent. In all cases, prior consent must be sought from the patients concerned, with the risks and benefits of procedures associated clearly communicated to patients and/or their relatives. Patients must be involved in the decision making process and be fully informed of any risks and benefits of the treatment. Patients and their relatives need this information in a clear unambiguous way so that they may make an informed decision. This is particularly important when they are offered innovative and untried treatments.

2.2 A significant number of calls to our confidential Helpline are made by patients and their relatives concerned about matters relating to consent. A substantial proportion of callers seek access to their medical records in order to make a complaint, very often regarding a misdiagnosis.

2.3 Furthermore, it is vital that due consideration is given to patients that may have communication difficulties due to language barriers or cognitive issues. We are also particularly concerned about patients in especially vulnerable situations, including frail and elderly people seeking medical attention. Every attempt must be made to discuss the treatment with the patient and the next of kin or other individuals identified by the patient. Many such patients are not aware of their rights and entitlements.

3.1 While the NHS Constitution grants these rights to all patients, in our experience, the NHS Constitution is poorly promoted within the NHS both to

patients and NHS employees. For these patients, it is vital that consent is clearly communicated and that they are made aware of the risks, benefits and implications of the treatments involved.

3.2 The Patients Association advocates for a patients' right to complain if they are not satisfied with the medical care received. We receive many calls to our Helpline from people asking how to complain and it is important to note that people who are not offered the chance of medical innovation may want to complain about unfairness.

4.1 The Patients Association accepts that the possibility of litigation may, on occasions, deter doctors from innovation. While we do not have any direct evidence or experience of a lack of clarity for doctors in carrying out innovations, we do have ample evidence as gathered from our Helpline to suggest that there is often a lack of effective communication between healthcare professionals and patients, resulting in gaps in the way the patient is involved and engaged in their care and how care is provided. Based on this, we believe there is a need to ensure clarity and clear guidelines about the circumstances under which innovation can be applied and the process to be carried out to avoid any ambiguity.

4.2 We believe that it is vital to ensure that staff will speak out when they witness poor care or unacceptable practices that puts patients at risk. The Patients Association would like to stress the importance of creating a culture of learning, clarity in procedures and ensuring the competence of doctors in order to avoid any unnecessary risks to the patient. It is also crucial to highlight the importance of clear communication channels to ensure that the patient is actively involved and empowered to make the appropriate decisions.

5.1 We support the aspiration to encourage 'responsible innovation' in medical treatments. However, we see challenges in ensuring a consistent and uniform application of the Bill. The Patients Association would like to emphasise the importance of innovative medical procedures applied consistently across clinical conditions, patient groups and geographical areas to avoid variations in the quality of care.

5.2 In our view the decisions regarding innovation should always be for the benefit of the patient and not driven by systems, staff or other considerations. These decisions should be consistent across the patient groups and clinical conditions and should have a clear audit trail. Every doctor carrying out medical innovation should be appropriately trained in doing so with adequate peer supervision. In addition we would like to see the responsibility applied to the multi-disciplinary teams rather than just one person, as in our experience, poor patient care is due to a lack of coordinated team effort. It is vital that the

Duty of Candour is applied in such situations and members of the team must feel able to speak out if there are concerns about patient care, innovation and inappropriate procedures or treatments.

6.1 The Patients Association welcomes the acknowledgement that a 'proper process' must be undertaken before a decision to carry out innovative treatment can be reached. These are positive steps as accountability and transparency are prominent themes for patients calling our Helpline. However we do have concerns about the process itself if it only involves the doctor and the patient as we are not convinced that the conversations or decisions made in such situations would be at equal level. The patient may feel obliged to agree to the clinician's decision due to a feeling that the doctor "must be right".

6.2 This is particularly true for patients who are frail and elderly or are in vulnerable situations due to their clinical condition. Indeed, we are strongly in favour of stringent measures to ensure clear accountability for decisions, both during and after the treatment has taken place. We also feel that there should be a clear definition of what constitutes accountability in such circumstances. The bill in its current form does not provide this clarity.

6.3 In addition the accountability should extend to the multidisciplinary teams involved in care of patients to avoid any gaps or misunderstandings during and after the procedure. This could take the form of a signed consensus from the team to clearly document and demonstrate that the patient's clinical and non-clinical needs have been considered and the resulting decision would benefit the patient in the short term as well as in the long term. It is positive to see clause 1(7) drawing particular attention to discussing the relevant treatment with the patient. The needs, desires and concerns of the patient should be of paramount importance throughout the process. As mentioned above, due consideration must be given to the patient's ability to understand and consent before making any decisions about the care and treatment. We hear many cases where patients and their carers have either not been involved in the decisions or have not been given adequate and meaningful information to ensure informed consent.

Conclusion

The Patients Association does see the merit of medical innovation and is wholeheartedly in favour of new procedures that enhance healthcare and improve outcomes for patients. However, as advocates for patients' experiences, we are mindful of the undesired consequences to patients due to a lack of robust governance and scrutiny. It is essential therefore, that any change to medical practice is implemented with the patients' best interests at heart. It is vital that the safety and dignity of every patient is assured in all circumstances. This is particularly important as the issues here are likely to affect people when at their most vulnerable.

As things stand at the moment, the Patients Association would oppose this Bill. The Patients Association would like to see a wide ranging public debate that would allow the profile of this issue to be raised. Only in this way can the views of all interested parties including the public, practitioners and pharmaceutical companies be taken into account. Without this, the Patients Association would be concerned that medicine would be moving into grey areas where issues such as responsibility, accountability, understanding and outcomes become blurred.

National Assembly for Wales / Cynulliad Cenedlaethol Cymru
Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol
Legislative Consent Memorandum: Medical Innovation Bill / Memorandwm Cydsyniad Deddfwriaethol: Y Bil Arloesi Meddygol
Evidence from Medical Defence Union - MIB 03 / Tystiolaeth gan Undeb Amddiffyn Meddygol - MIB 03

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Mr David Rees
Chair
Health & Social Care Committee
National Assembly for Wales
By email

Date: 23 December 2014

Dear Mr Rees

Re: Medical Innovation Bill

Thank you for inviting a submission from the Medical Defence Union about the Medical Innovation Bill.

The MDU does not support the Bill. The law in England and Wales is already very clear and there is no need for new legislation. We fear that the Bill will only serve to introduce confusion and delay in circumstances where they do not currently exist and that could be harmful for patients. The submission below is taken from the MDU's briefing ahead of the report stage of the Bill and begins by explaining the MDU's expertise and experience in this area before describing our concerns about the Bill. We hope it is helpful.

MDU experience of clinical negligence claims

The MDU is a mutual non-profit making organisation owned by our members who include around 50% of the UK's GP and hospital doctors. We provide medico-legal benefits including assistance with and indemnity for clinical negligence claims arising from clinical practice to GPs and doctors in independent practice. We also provide medico-legal advice and if the Medical Innovation Bill were to become law we would expect members to seek our advice about its correct interpretation.

Although the Bill has been comprehensively amended, our principal concern remains that there is no need for such a Bill. If there was a gap in the law that left doctors unprotected and prevented them from innovating in the interests of patients, we would support the Bill. Indeed we would have been clamouring for legislation on behalf of our members and their patients a very long time ago. However, our experience of clinical negligence litigation makes it clear to us there is no need for the Bill. We cannot support it because it would not aid innovation but would be more likely introduce confusion and delay where they do not currently exist. This would be to the potential detriment of our members and their patients.

The current law and ethical (GMC) guidance is clear – there is no need for a Bill

The indemnity the MDU provides for medical members extends to innovative treatment. It is well recognised there must be departures from accepted practice so that medicine can evolve

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and develop, and the current law and ethical requirements do not prevent that. There is no gap and the law is already very clear. There is no need for a Bill. Our medico-legal experience leads us to believe new legislation would only add confusion and delay while doctors got to grips with yet another piece of legislation affecting their clinical work. This is not in patients' interests and contrary to what the Bill proposes to achieve.

Potential for delay – a particular concern in emergencies

A serious concern is that the Bill proposes to introduce a defined procedure with which doctors will be unfamiliar. In some cases this may not be in patients' interests because it could prevent doctors from providing innovative treatment, while they check whether what they propose is compliant with the Bill; whereas currently they know what to do and, with the patient's consent, get on with it without delay. This is particularly important because the Bill does not cover emergencies. In an emergency, doctors know they must act in their patients' best interests. The Bill does not prevent that but it is silent on the matter. However, delay could be fatal if doctors believe innovative treatment is necessary but delay in order to seek advice about the Bill's requirements.

Background

During 2013, the MDU's advisory team answered over 33,000 calls from members, and our claims handling team opened 20% more medical files than in 2012. Even with all this activity, there is no evidence to suggest there is or that our doctor members believe there is lack of clarity or certainty about the circumstances in which they can innovate without fear of litigation. Enquiries about innovation are not common but the MDU receives a few each month. Members generally ask about consent and how much information patients need, as well as asking about GMC guidance, for example about the use of unlicensed drugs. Generally calls do not relate to innovation through surgical or other invasive procedures but cover practice the Bill does not mention, such as moving away from face-to-face consultations and exploring use of computer consultations or apps, or setting up web-based discussion forums. Members principally seek advice about ethical matters and their legal concerns are generally about compliance with data protection legislation.

Our experience is that if it is a doctor's clinical opinion that it is in a patient's best interests to try innovative surgical or medical treatment, and he or she has discussed the proposed treatment fully with the patient and answered all questions, and complied with any research protocol, doctors go ahead. If problems arise they are not particular to innovation but medico-legal problems that can arise in all cases: for example the patient did not fully understand the proposed procedure and was unhappy with the outcome, or the surgeon was unfamiliar with the technique and made a mistake, or there was a problem with the dose of the drug.

With best wishes

Yours sincerely

Mary-Lou Nesbitt

Mary-Lou Nesbitt
Head of Governmental & External Relations

National Assembly for Wales / Cynulliad Cenedlaethol Cymru
Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol

Legislative Consent Memorandum: Medical Innovation Bill / Memorandwm Cydsyniad Deddfwriaethol: Y Bil Arloesi Meddygol
Evidence from Lord Saatchi - Member in Charge of the Medical Innovation Bill in the House of Lords – MIB 04 / Tystiolaeth gan Yr Arglwydd Saatchi – yr Aelod sy'n gyfrifol am y Bil Arloesi Meddygol yn Nhŷ'r Arglwyddi – MIB 04

NATIONAL ASSEMBLY FOR WALES

LEGISLATIVE CONSENT MOTION

IN RESPECT OF THE

MEDICAL INNOVATION BILL [HL] 2014-15

HEALTH AND SOCIAL CARE COMMITTEE INQUIRY

INTO THE LEGISLATIVE CONSENT MEMORANDUM

LAID BY THE MINISTER FOR HEALTH AND SOCIAL SERVICES

DECEMBER 2014

SUBMISSION OF LORD SAATCHI

SUBMISSION OF LORD SAATCHI TO THE INQUIRY

INTO THE LEGISLATIVE CONSENT MEMORANDUM

FOR THE

MEDICAL INNOVATION BILL [HL] 2014-15

Introduction

1. This submission is made, to the Health and Social Care Committee's Inquiry, on behalf of Lord Saatchi as the Member in Charge of the Medical Innovation Bill in the House of Lords.

2. The submission responds to the Legislative Consent Memorandum laid by the Minister for Health and Social Services in December 2014.

Legislative Competence of the National Assembly for Wales

3. Lord Saatchi—

   (a) understands that the position of HM Government is that the Medical Innovation Bill does not deal with matters within the legislative competence of the National Assembly for Wales,

   (b) also understands the contrary view of the Welsh Government set out at paragraph 12 of the Legislative Consent Memorandum, and

   (c) makes this submission on the basis that if the National Assembly is to debate the question of legislative consent it will want to have as clear an understanding as possible of the policy objectives of the Bill.

Purpose of the Bill

4. The purpose of the Bill is to give doctors and patients clarity at the point of treatment about what amounts to a responsible and lawful approach to innovation in medical treatment.

5. At present, the common law *Bolam / Bolitho* test requires doctors to wait and see whether they are threatened with legal or disciplinary proceedings if results from an innovative treatment turn out to be disappointed. At that point, the claimant patient and the defendant doctor each pay for two or more medical witnesses to go into the witness box, one to argue that the innovation was what a responsible body of medical opinion would have done and the other to argue the contrary. The arguments are played out in court and the judge decides between the two sets of witnesses. There is an inevitable element of unpredictability, as with all litigation.

6. The key policy driver for the Bill is to "bring forward" the *Bolam* test to the point of treatment. For the first time, the Bill summarises existing best clinical practice to articulate a set of principles by reference to which doctors and patients can determine with confidence and statutory authority, at the time when innovative treatment is offered, whether it is being offered in a responsible way.

Safeguards

7. The principles to be considered in determining responsible innovation include a series of safeguards designed to protect patients. The Bill has always contained a list of safeguards, but it has been re-fashioned during the course of the Bill's Parliamentary passage. In particular, the Secretary of State for Health commissioned Professor Sir Bruce Keogh, the Medical Director of NHS England, to draw up a revised list of safeguards, which was taken into the Bill by amendment at the Lords Committee Stage.

8. Principal among the list of safeguards is the requirement to obtain the views of appropriately qualified colleagues and to have regard to those views in a responsible professional manner. This is in effect the "responsible body of medical opinion" test used in *Bolam*, but brought forward to the point of treatment to enhance clarity and certainty.[1]

9. The other key requirements are transparency and accountability in decision-making around innovation. The latest version of the Bill includes a requirement for the patients' notes to include a record of the views of colleagues obtained.

Other details of the Bill

10. The Appendix to this submission includes a link to the Bill Team's Explanatory Notes to the Bill, which explains other details of the Bill.

Who wants the Bill?

11. The Department for Health ran a public consultation on the Bill in 2013/14. Over 20,000 individuals – including many patients and doctors – responded to support the Bill, based on many individual stories of the deterrent effect on innovation that the fear of litigation or disciplinary proceedings exerts.

12. Within the House of Lords, there has been strong support from all sides of the House, and from peers representing medical, legal and patient interests. Concerns raised early on in the Bill's passage have been met by amendments made in Committee and on Report. Proceedings so far have been entirely consensual, and it is hoped and cautiously expected that the same can be achieved for the Bill's final Lords' stage, Third Reading. The Appendix to this submission includes links to the debates on the Bill so far.

[1] The *Bolam* test is necessarily uncertain in the sense that it is applied only if and when a doctor is sued or charged with malpractice; and even when it is applied it is far from clear – for a recent illustration of its complexity see McGovern v Sharkey [2014] NIQB 117.

Data registration

13. Support for the Bill in the case of a number of organisations is conditional upon the Bill being amended to include provision for compulsory registration of the results of innovative treatment, positive and negative.

14. Lord Saatchi is strongly in favour of the inclusion of provision of that kind, which could result in the Bill being a major advance in the world of medical research. It is generally acknowledged by senior medical professionals that data arising out of innovative treatments could be of enormous benefit to patients and doctors, including being used to help determine which treatments should be tested by way of controlled clinical trial.

15. The introduction of a requirement for registration of the results of innovation would be an exciting breakthrough, replacing anecdotal evidence with a systematic database in a range of areas. Although structurally secondary to the primary purpose of the Bill – providing certainty and clarity in relation to responsible decisions to innovate – the creation of the database could be of at least equal practical importance for patients.

Opposition to the Bill

16. As recorded in the Legislative Consent Memorandum, a number of organisations have expressed concerns about the Bill. While some have been met by amendments in Committee or on Report, a degree of opposition remains, strong in some quarters.

17. In online commentary circles some of the strongest opposition has come from medical negligence lawyers. Leigh Day, in particular, have campaigned strongly and at considerable cost against the Bill. As noted above, the present system of uncertainty in the law makes it possible for medical negligence lawyers to advise large numbers of claimants to sue, not because there is clear evidence of malpractice but simply because the vagaries of litigation make it possible that the claimant's witnesses will be preferred to the defendants' on the day of trial. Much "no win no fee" or similar litigation is supported on this basis. When the Bill receives Royal Assent, the certainty which it brings will make it more difficult to bring wholly speculative claims: a doctor who has followed the transparency and accountability requirements of the Bill in a clearly rigorous and responsible way will be able to be confident of not being sued (while a quack will be more at risk of litigation or disciplinary proceedings, as he or she will be able to be shown as having failed to follow statutorily approved best clinical practice).

18. Apart from the concerns of the medical negligence legal sector about the loss of business, a number of legitimate concerns have been expressed about how the Bill will work in practice. The Bill team have worked with those expressing concerns to meet them through amendments tabled or to be tabled in the Lords.

Conclusion

19. Lord Saatchi hopes that the Committee will recommend that the Assembly should approve the Legislative Consent Motion.

20. Lord Saatchi and his advisers will be very happy to provide the Committee with any further information or assistance that would be helpful.

21. The Appendix to this submission provides links to additional sources of information about the Bill.

Daniel Greenberg
Parliamentary Counsel to the Bill Team
7th January 2015

APPENDIX

FURTHER READING

Bill as amended on Report - http://www.publications.parliament.uk/pa/bills/lbill/2014-2015/0070/lbill_2014-20150070_en_1.htm

Explanatory Notes to the Bill - http://www.publications.parliament.uk/pa/bills/lbill/2014-2015/0004/en/15004en.htm

2nd Reading House of Lords 27 June, 2014 - http://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/140627-0001.htm#14062743000565

Committee Stage House of Lords 24 October, 2014 - http://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/141024-0001.htm#14102458000643

Report Stage House of Lords 12 December, 2014 - http://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/141212-0001.htm#14121229000622

Medical Innovation Bill Team Website - http://medicalinnovationbill.co.uk/

Frequently Asked Questions - http://medicalinnovationbill.co.uk/get-the-facts/

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Evidence from Royal College of Physicians - MIB 05 / Tystiolaeth gan Coleg Brenhinol y Meddygon (Cymru) - MIB 05

Legislative Consent Memorandum: Medical Innovation Bill

RCP (Wales) evidence

Key points

- The RCP welcomes the overarching aims of the Medical Innovation Bill and subsequent debate. However, the RCP does not support the progression of the Bill in its current form. Instead, the RCP calls for:
    - **Mandatory reporting** - the Bill should be amended to ensure that all results of innovation must be centrally recorded, reported and be publicly accessible
    - **'Responsible doctor'** - statutory guidelines outlining how a 'responsible doctor' should consider medical opinions should be developed
    - **Peer review** - more robust safeguards should be put in place to prevent doctors from innovating inappropriately
    - **Safeguards and promotion of innovation** - we support the statutory best practice checklist as a safeguard against irresponsible innovation
    - **Communication** - a clear implementation strategy should be developed which ensures the Bill is understood by the profession and the public
    - **Removing existing barriers to innovation** - alternative routes to achieving the aims of the Bill should be explored

For more information, please contact:

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From the RCP vice president for Wales
O'r is-lywydd yr RCP dros Gymru
Dr Alan Rees MD FRCP
[redacted]

From the RCP registrar
O'r cofrestrydd yr RCP
Dr Andrew Goddard FRCP
[redacted]

09 January 2015

Dear colleague,

Thank you for the opportunity to respond to your consultation on the Legislative Consent Memorandum in relation to the Medical Innovation Bill.

About us

The Royal College of Physicians (Wales) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in Wales and across the world with education, training and support throughout their careers. As an independent body representing 30,000 fellows and members worldwide, including 800 in Wales, we advise and work with government, the public, patients and other professions to improve health and healthcare.

Our response

The RCP welcomes the overarching aims of the Medical Innovation Bill and subsequent debate. However, the RCP does not support the progression of the Bill in its current form. Without amendments to the Bill to include mandatory recording of the results of all innovative treatments, the RCP believes that the Bill will not achieve its stated objectives of encouraging responsible innovation while protecting patients and clinicians from irresponsible actions. Suitable safeguards must be put in place, both for the clinician and the patient.

For example, the current wording of the Bill does not place a duty on clinicians to record, review or share the results of innovative treatments. This significantly undermines the accountability of the innovation process, the ability to provide safeguards to clinicians and patients, and the process of sharing learning from innovation. For this reason, the RCP will not support the progression of the Medical Innovation Bill unless it is amended to include the mandatory recording of all innovation treatments. We also urge clarity on how a 'responsible doctor' would be expected to consider the opinions of medical experts prior to undertaking an innovative treatment. In particular, we recommend:

1. **Mandatory reporting**
   The RCP is very concerned that the legislation does not place a duty on clinicians to record the results of innovative treatments. Without the mandatory recording of results of innovation, clinicians will be unable to share learning; irresponsible innovation will be more difficult to prevent; and accountability structures will be undermined. Including mandatory reporting of results as part of the innovation process will further ensure that learning from innovation can be shared. This will prevent harmful innovative practices from being repeated and encourage learning from good innovation. Mandatory recording will further provide evidence that the processes for responsible innovation have been followed. Thus providing safeguards for both clinicians and patients

   The RCP believes that the Bill should be amended to ensure that all results of innovation must be centrally recorded, reported and be publicly accessible. This must include both positive and negative results, information about small scale treatments and patient experience. Without the mandatory recording of results the public benefits of medical innovation will not be achieved. A clear strategy for achieving this must be developed if there is to be true innovation. The strategy must address patient confidentiality, accessibility, thresholds for reporting, and practicalities, such as the method of hosting the database and reporting results.

   The RCP understands that Oxford University has agreed to facilitate the dissemination of information from innovation treatments. However, this information will be collected on a voluntary basis. Unless there is a mandatory duty for results of all medical innovations to be recorded, data will not be collected in sufficient numbers to achieve the benefits of the medical innovation. This duty must be accompanied by statutory guidance that includes details on the process of mandatory recording of results. The statutory regulations must reflect a process that addresses patient confidentiality, accessibility, thresholds for reporting and practicalities.

2. **Responsible doctor**
   The RCP is concerned that the wording of Clause 1(3)(b) of the Bill, as amended at committee stage, does not sufficiently clarify the process of medical innovation. The current wording of the Bill states that the opinions of appropriately qualified doctors must be considered in a 'way in which any responsible doctor would be expected to take account of such views'. However, the RCP believes that this clause is too vague. It does not clarify how a 'responsible doctor' would be expected to consider these opinions. We urge the development of statutory guidelines outlining how a 'responsible doctor' should consider medical opinions and how the process will work.

3. **Peer review**
   There must be more robust safeguards in place to prevent doctors from innovating inappropriately. These should include:

   a. Stronger requirements for robust peer and ethical review before commencing treatment
   b. Stronger assurances for patients, carers and families
   c. Continued and active support for referral into larger NHS clinical trials.

4. **Safeguards and promotion of innovation**
   We support the statutory best practice checklist as a safeguard against irresponsible innovation. This could be supplemented by guidance designed to emphasise the benefits and mechanisms supporting innovation.

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

6. **Removing existing barriers to innovation**
   The Medical Innovation Bill aims to create an environment that enables innovation and discourages irresponsible innovation. The RCP recommends that alternative routes to achieving these shared aims should be explored, such as opportunities to remove existing barriers to innovation, or improving and streamlining the funding and approval processes.

For more information

If you have any questions, please contact our colleague, Lowri Jackson, RCP senior policy and public affairs adviser for Wales, at [redacted] or on [redacted].

With best wishes,

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Is-lywydd yr RCP dros Gymru

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SOLICITORS JOURNAL

Former Lord Chief Justice unable to substantiate argument for Medical Innovation Bill

LEGAL NEWS | 11 December 2014

Debate over consequences of Bill rages on while spokesperson for Saatchi says Bill has changed following feedback from doctors and lawyers

A 'sloppy' Lord Woolf cannot remember cases he believes would have benefitted from the divisive 'Saatchi Bill' after arguing their existence in a piece for The Telegraph.

Writing for The Telegraph in April, the former Lord Chief Justice of England and Wales stated: "What I do know about, from sitting as a judge, are the cases where doctors are sued for negligence because they have innovated in the treatment they offer, rather than following generally-accepted medical standards."

Having read this piece with some interest, Dr Anthony Barton, who is a co-editor of a text on clinical negligence, as well as a solicitor and medical practitioner, wrote to the high-profile supporter of the Bill requesting the case authorities relied upon by the peer in his article: "Your words are cited by supporters of the Bill. Would you be able to identify those cases where doctors are sued 'because they have innovated in the treatment'...In my professional experience as a clinical negligence practitioner, doctors depart from generally-accepted medical standards because of poor practice, not innovative practice," said Barton.

In an email received by Barton, and seen by SJ, the peer responded: "In the time available, I cannot find references to the cases I had in mind when I wrote the article for The Telegraph. I am afraid that it is most unlikely that I will be able to do so even if I had more time but I apologise and have to ask you to accept my recollection, which is of cases I was involved in very many years ago. My general position remains, however, [that] what is needed is protection available before the event and not a defence, the existence of which can only be determined after a doctor is accused of departing from proper standards of practice."

It clearly came as something of a surprise to Barton that the former Master of the Rolls could not remember, let alone substantiate, the specific cases he wished to rely upon in his argument. It is this argument that many supporters of the Bill have flocked to promote as clear evidence of why the proposed legislation is important. Unhappy with the email, the clinical negligence solicitor wrote to Lord Tebbit who, in another letter seen by SJ, responded: "Thank you for letting me see a copy of the reply you received from Lord Woolf. I wonder what he would have made of a witness who gave an answer like that!"

'Sloppy comment'

Commenting on Lord Woolf's article in The Telegraph, Terry Donovan, a clinical negligence specialist and spokesperson for the Association of Personal Injury Lawyers (APIL), said: "When I read Lord Saatchi's Bill I struggled to make sense of it. I can think of no case I have been involved in, and no reported case, where there has been an allegation of negligence after a doctor has 'innovated'. It just would not stack up. I think Lord Woolf made a sloppy comment. He was a great lawyer in his time and was responsible for some big reforms in the law but I struggle to think of a case where this has happened."

He continued: "In an allegation of negligence you are saying a doctor has failed to do some standard item that he should have done, has failed to follow the practice in the guidelines or the techniques that are set out in the medical literature, or failed to follow a standard of care that is regarded as being acceptable by experts in the field."I have never had a case where a doctor has defended an allegation by saying they were innovating. A lawyer acting for said doctor would call them 'barking'. They would be going off-piste and doing something that wasn't validated. In medicine that makes you a rogue. You don't try something out on vulnerable people. Innovation as described in Lord Saatchi's Bill is not good science. If a doctor innovated outside of a clinical study they would not only be sued but would also be in the GMC being struck off because it is unethical to experiment on somebody," concluded Donovan.

APIL, which has staunchly opposed to the Bill, has been unable to find any reference to cases where medical professionals have been sued for attempting innovative treatments. In October, the association produced a 'Myth vs Reality' report to debunk claims made by supporters of the Bill.

John Spencer, president of APIL and director of Spencers Solicitors, said at the time: "We are worried about the myth that the Medical Innovation Bill would only apply to dying people who are willing to give anything a chance. In fact, the Bill will affect all patients who, in their vulnerability, may be tempted to take risks at the hands of maverick doctors who are over-ambitious in their drive to make names for themselves."

He continued: "The Bill is both ill-conceived and completely unnecessary. We hear wonderful stories of medical breakthroughs every day, and have heard no cases of a doctor being sued for using an innovative treatment. The current legal requirement of doctors has been helping to protect patients for nearly 60 years. If a lack of understanding is in fact stopping some doctors from taking what could be the best course of action for their patients, then there should be an effort to educate, not legislate."

In November, while speaking at APIL's Autumn conference, Suzanne White, a partner in Leigh Day's medical negligence team and a member of the Stop the Saatchi Bill Alliance, said that lawyers need to 'wake up' to the potential impact of Lord Saatchi's Bill. She went on to warn the legal profession that in Lord Saatchi they had a real adversary able to sway public opinion due to his expertise in public relations.

White quoted the Conservative peer from an article he wrote for The Telegraph in May to illustrate her point: "In democratic politics, perception is reality. If the people perceive a problem, there is one." She concluded: "Saatchi is a PR man. It is very difficult to compete against a PR machine."

Open door

After reporting White's comments, the team behind the Bill got in touch with SJ to take up their right to reply.

"There has been much heat generated by the debate over the Medical Innovation Bill," said Dominic Nutt, the director of communications for the Bill, "only recently this magazine described the debate as a 'PR war'."

Nutt said that for two years, the Medical Innovation Bill team had been talking to doctors, lawyers and patients about how best to encourage medical innovation in order to facilitate better, faster and safe discovery of more effective treatments for currently incurable diseases.

"The Bill has changed in light of the feedback and challenges given," said Nutt, "we have listened and the door remains open to those who wish to offer opinions directly to the team. Indeed, we have held meetings with leading medical negligence lawyers and have adapted the Bill accordingly."

Nutt added: "It will allow more doctors to consider innovating as a matter of course, rather than defaulting to procedures that are known not to work. In this respect, the Bill acts as an agent of culture change." Nutt's full comment will be published in the first issue of SJ 2015.

Nevertheless, some still remain unconvinced. David Dawson, a consultant solicitor with Price Slater Gawne, is also of the belief the Bill, if passed, would become "bad law" leading to consequences "far beyond those which Lord Saatchi intends" and "tragedies for victims and their families". He points to the growing list of medical professionals who have spoken out against the Bill and his own recent experience of bringing claims against the NHS:

"As it stands [the Bill] has the potential for depriving victims of compensation they would otherwise obtain to which many would feel they are rightly entitled," said Dawson. "In 2004, my client was in her fourth pregnancy. Sadly she miscarried. To induce delivery, the doctors treating her gave her a drug, Misoprostol, which was not licensed for induction of labour. The drug caused a catastrophic brain injury. She remains in a state of minimal awareness and will require 24 hour care for the rest of her life."

According to Dawson, the NHS defended the claim for eight years before admitting full responsibility three weeks before trial in 2012. "The defence was that the use of Misoprostol was not prohibited in this situation," continued Dawson. "The NHS asserted that it was a 'common induction agent in cases of both intra-uterine death and live foetuses'. In other words, the NHS was setting up a defence based upon the long-standing Bolam principle, that the treatment would be considered reasonable by a responsible body of medical opinion."

It is Dawson's belief that had Lord Saatchi's proposed legislation already been law, the NHS may have argued the use of the drug was "innovative" treatment the Bill was designed to protect. He concluded: "My client's family would then have been left without the funding and help they so desperately needed to enable her to be properly cared for in a loving environment. The Bill should not be enacted."

SJ offered Lord Woolf the right to reply to this article but at the time of publication none has been received.

John van der Luit-Drummond is legal reporter for Solicitors Journal

[redacted]

SOLICITORS JOURNAL

Lord Woolf unrepentant over failure to substantiate support for Saatchi Bill

LEGAL NEWS | 5 January 2015 John van der Luit-Drummond is legal reporter for Solicitors Journal

"If you do not accept my word that is your problem, not mine," says former Lord Chief Justice

The former Lord Chief Justice, Lord Woolf, has said he is "not prepared to be cross-examined" over statements he has previously made in support of the divisive Medical Innovation Bill.

Speaking during the House of Lords report stage of the Saatchi Bill in December 2014, Lord Woolf said: "The progress of the Bill has been a remarkable example of this House at its very best. The Bill has been very carefully scrutinised by people who have immense knowledge of the areas covered in the Bill."

The former Master of the Rolls went on to say: "Those who have asked me to identify cases by name and reference so that they can analyse the cases and show how they do not help any particular argument might be relieved to hear me say that if they want to know where I come from, I wrote a little book called The Pursuit of Justice."

Solicitor and medical practitioner, Dr Anthony Barton, who had previously written to Lord Woolf requesting the case authorities relied upon by the peer following an article in The Telegraph from April 2014, has once again questioned the peer's support for the controversial Bill.

In a letter seen by SJ, Barton writes: "I have read your book and am unable to find the 'cases where doctors are sued for negligence because they have innovated'. Please advise where can I find the cases in your book? At page 332 you state: '...unsubstantiated opinions' which I agree would be a 'recipe for getting things radically wrong'..."

Barton continued: "Accordingly, please substantiate your opinion by identifying 'the cases where doctors are sued for negligence because they have innovated'. If you cannot identify such cases then please clarify your position."

In a combative email, also seen by SJ, Lord Woolf responded: "I am not prepared to be cross-examined further, I can only say that I am disappointed that your interest in forensic matters does not make you willing to accept that having been appointed a judge in 1979, and having tried many cases depending on medical evidence that I doubt were ever reported, it is now impossible for me to give you the information you seek and so if you do not accept my word that is your problem, not mine."

In a joint statement with Dr Michael J Powers QC, co-editor of the fifth edition of the legal textbook on clinical negligence, Barton continued to voice concerns about the proposed Medical Innovation Bill.

"The Bill's supporters have not provided any evidence that doctors are deterred from innovation by the threat of litigation," the pair state. "Parliamentary scrutiny requires solid evidence."