JOURNAL OF MEDICAL LAW AND ETHICS; VOL. 4, NR. 1, 1-21, PARIS LEGAL PUBLISHERS © 2016

# How could responsible surgical innovation be cultivated by new legislation?

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## Abstract

*The differences between surgery and medicine are deep-rooted and widely acknowledged. The area of innovation is no exception. Whilst medical advances usually involve well-regulated pharmaceutical innovation, surgical innovation is more haphazard, serendipitous and receives considerably less oversight than its more evidence-based counterpart. Consequently, surgical innovation relies heavily on the character type of the surgeon involved. Balancing patient safety with fostering advances in medical science is a recurrent theme in the surgical innovation literature. The Medical Innovation Bill (MIB) recently challenged the appropriate position of equilibrium between these finely balanced aims. This Bill rested on the cornerstone premise that deviation from evidence-based guidelines has become synonymous with negligence; therefore innovation is being crushed by a fear of litigation. The Liberal Democrats vetoed the Bill. However since their election losses, a new Access to Medical Treatments (Innovation) Bill (AMTB) has been introduced to the House of Commons. Such legislation has the potential to improve the surgical innovation field. This article presents current issues in surgical innovation, analyses the content for the new Bill and suggests the ethical considerations involved in surgical innovation. Application to the case study of cleavage-sparing mastectomy is then discussed.*

## Current Issues in Surgical Innovation

### Definition

To talk meaningfully about innovation, it must be defined. Rogers et al. identify lack of definition as a specific problem in surgical innovation.[1] The fundamental issue for surgical innovation is distinguishing between routine variation, innovation, and research. The Balliol Collaboration describe the stages of surgical innovation as encompassing all three in the IDEAL

* DOI 10.7590/221354016X14589134993893
Many thanks to Susan Bewley, Suzanne Shale, Jose Miola for comments on earlier drafts.

1 W. Rogers et al., 'Identifying surgical innovation: a qualitative study of surgeons views', *Annals of Surgery* 259:2 (2014), 273-278.

model.[2] Whereas Schwartz describes a surgical innovation continuum.[3] Additionally Hutchison et al. highlight that to enable timely oversight, a prospective definition is required.[4]

## Research

The overriding theme from the literature is that innovation and research are different in purpose. Innovation is performed to provide benefit for that specific patient, whereas research is performed to gather scientific knowledge by testing a hypothesis.[5] Reitsma and Moreno identified factors *surgeons* viewed as distinguishing features of research,[6] showing opinion varied and many factors were only applicable in hindsight. Similarly Rogers et al. found some surgeons could not distinguish between the two.[7] Hutchison et al. suggest surgeons are reluctant to identify their innovation as research, as it increases regulatory oversight. Consequently interventions are introduced as innovations, but published as research.[8] The two are closely linked; Rogers et al. state research should precede innovation as lab or animal experiments.[9] Also Schwartz suggests innovations should always be subject to formal research after the preliminary cases but prior to dissemination,[10] which concurs with the IDEAL model stages.[11]

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2 P. McCulloch, D.G. Altman, W.B. Campbell, D.R. Flum, P. Glasziou, J.C. Marshall, J. Nicholl for the Balliol Collaboration, 'No surgical innovation without evaluation: the IDEAL recommendations', *Lancet* 374 (2009), 1105-1112.

3 J. Schwartz, 'Innovation in pediatric surgery: The surgical innovation continuum and the ETHICAL model', *Journal of Pediatric Surgery* 49 (2014), 639-645 at 640.

4 K. Hutchison, W. Rogers, A. Eyers, M. Lotz, 'Getting clearer about surgical innovation', *Annals of Surgery* (2015), 1-6.

5 US department for health and human services, *The Belmont Repor*, www.hhs.gov/ohrp/humansubjects/guidance/belmont.html (accessed 13 March 2015); M.L. Eaton, D.L. Kennedy, *Innovation in Medical Technology: Ethical Issues and Challenges* (Baltimore: The Johns Hopkins University Press, 2007); E. Jackson, *Medical Law Text Cases and Materials* 3rd edn (Oxford: Oxford University Press, 2013), 453; P. Healy, J. Samanta, 'When does the learning curve of innovative interventions become questionable practice?', *European Journal of Vascular and Endovascular Surgery* 36:3 (2008), 253-257.

6 A.M. Reitsma, J.D. Moreno (eds.), 'Ethics of innovative surgery: US surgeon's definitions, knowledge and attitudes', in: *Ethical Guidelines for Innovative Surgery* (Maryland: University Publishing Group, 2006), 173-198, Table 2.

7 See note 1 above.

8 See note 4 above.

9 See note 1 above.

10 See note 3 above.

11 See note 2 above.

## Variation

Traditionally in surgery, significant changes in technique are regarded as modifications.[12] The Balliol Collaboration believes surgical innovation's most common route is via the iterative surgical practice of continually modifying technique to improve performance.[13] Rogers et al. recorded the features that surgeons used to distinguish between innovation and routine variation; newness/novelty, degree of change, risk level, impact on outcomes and requirement for formal processes.[14] The last criterion appears circular, as one must have already identified the intervention as an innovation for it to require formal processes such as external review. The impact on outcomes is problematic as it is retrospective and excludes innovations with negative outcomes. The Macquarie group posit alternative and prospective distinguishing criteria; the likely outcomes are unknown, if successful the outcomes will be publishable or suitable for uptake generally, and special preparations should be undertaken by the surgeon or surgical team.[15] They also created a tool to help clinicians to make the distinction.

## Consensus definition

The surgeons' most useful definition comes from the Macquarie Group.[16] They define innovation as use of a technique or device, which is altogether new, new to the anatomical location, or new to the patient group.[17] To produce a practical definition, one must combine this with the features that distinguish innovation from variation, and the purpose of innovation being for individual patient benefit.

## Regulation

Another key issue in surgical innovation is regulation. Innovative pharmaceuticals and medical devices are already governed by the Medicines

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12 A.M. Reitsma, J.D. Moreno, 'Ethical regulation for innovative surgery: the last frontier?', *J. Am. Coll. Surg.* 194 (2002), 792-801; D. Sabiston, 'The Boundaries between biomedical research involving humans subjects and accepted routine practice of medicine, with particular emphasis on innovation in the practice of surgery', *Belmont Report.* DHEW publication number (OS) 78-0014, Appendix II, 177.

13 J.S. Barkun, J.K. Aronson, L.S. Feldman, G.J. Maddern, S.M. Strasber for the Balliol Collaboration, 'Evaluation and stages of surgical innovations', *Lancet* 374 (2009), 1089-1096.

14 See note 1 above.

15 See note 4 above, Table 2.

16 See note 4 above, Table 1.

17 See note 4 above, Table 1.

Act 1968[18] and research involving them is regulated by the Medicine for Human Use (Clinical Trials) Regulations 2004.[19] The definition of a clinical trial in these regulations does not include surgical procedures.[20] The Early Access to Medicines Scheme,[21] and section 9 of the Medicines Act 1968[22] allow access to innovative pharmaceuticals, with no similar scheme for surgery. The existing oversight for surgery consists of procedure-specific guidance produced by NICE. This covers the safety of the procedure, whether efficacy is sufficient for routine use and whether special arrangements are needed for consent.[23] Alongside this, many trusts have specific guidance for introduction of procedures a fully trained clinician has not performed before. If no specific NICE guidance exists most policies require an alternative evidence base, alongside other restrictions.[24]

Therefore introduction of a truly novel procedure may not fall under these oversight mechanisms, as it will not yet have an evidence base. In consequence some procedures are governed only by the surgeons' 'ethics and conscience'.[25] In fact there is 'greater oversight protection in place for laboratory animals than there is for testing innovative surgeries in humans'.[26] Once an innovative surgical procedure is presented as a case series 'there's no turning back'.[27] Academic guidance fills the void, such as the ETHICAL model.[28] The issue of how and when to regulate innovations is therefore a current concern for the surgical community.

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18 The Medicines Act 1968 (London: TSO, 1968).

19 *The Medicines for Human Use (Clinical Trials) Regulations 2004*, SI 1031 (London: TSO, 2004).

20 See note 19 above, Regulation 2, 2 (1).

21 Gov.uk, *Apply for the Early Access to Medicines Scheme (EAMS)* , https://www.gov.uk/apply-for-the-early-access-to-medicines-scheme-eams (accessed 8 March 2015).

22 See note 18 above, Section 9.

23 National Institute for Health and Care Excellence, *NICE interventional procedures guidance*, https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance (accessed 10 March 2015).

24 J. Osborne, *Policy for introducing new interventional procedures into routine practice* (Bristol: University Hospitals Bristol NHS Foundation Trust, 2008); M. Inglis, *Policy for the introduction of new interventional procedures* (Forth Valley; NHS Forth Valley, 2010); A. Lowery, *New Clinical Interventional Procedures Policy* (Gateshead: Gateshead Health NHS Foundation Trust, 2012); M. Perry, *New Clinical Interventional Procedures Policy* (East Cheshire: East Cheshire NHS Trust, 2013).

25 See note 3 above.

26 C.E. Margo, 'When is surgery research? Towards and operational definition of human research', *JME* 27 (2001), 40-43.

27 V. Brower, 'The Ethics of Innovation', *EMBO reports* 4 (2003), 338-340.

28 See note 3 above.

## Consent

The nature of informed consent may differ in surgery,[29] especially due to its permanence.[30] The standard of consent obtained for innovative surgical procedures is a current issue. In 2002, Reitsma and Moreno reported only 75% of authors who published surgical innovation papers believed the patients knew they were undergoing an innovative procedure. Only one third of these specifically mentioned innovation in the consent form.[31] Eaton and Kennedy highlight the problem that patients might assume all new procedures are better.[32] They also question if informed consent can ever be given if risks and benefits are unknown[33], as do the Academy of Medical Royal Colleges.[34] Informing a patient about uncertainty may be difficult, but is not impossible.

The Balliol Collaboration[35] suggests only once a procedure is no longer considered experimental can it not require special consent. Specific consent requirements for surgical innovations have been suggested, for instance Healy and Samanta suggest it must include 'specific reference to the experimental and possibly unique dimension of the procedure'[36] and information about how much experience the surgeon has in that particular procedure. The ETHICAL model also suggests net harms and how experienced the surgeon is should be discussed.[37] Similarly Angelos says the learning curve must be explicitly discussed with patients. He also says surgeons must explain uncertainty better, as surgeons 'although often wrong are rarely in doubt'.[38]

## Analysis of the Access to Medical Treatments (Innovation) Bill

The Access to Medical Treatments (Innovation) Bill is fundamentally very similar to the previously vetoed Medical Innovation Bill. The

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29 P. Angelos, 'Surgical Ethics and the Challenge of Surgical Innovation', *The American Journal of Surgery*208 (2014), 881-885.

30 M.L. Eaton, D.L. Kennedy, *Innovation in Medical Technology: Ethical Issues and Challenges* (Baltimore: The Johns Hopkins University Press, 2007).

31 A.M. Reitsma, J.D. Moreno, 'Ethical regulation for innovative surgery: the last frontier?', *J. Am. Coll. Surg.* 194 (2002), 792-801.

32 See note 30 above, at 62.

33 See note 30 above, at ix.

34 Academy of Medical Royal Colleges, *Medical Innovation Bill* (London: AoMRC, 2014).

35 See note 13 above.

36 P. Healy, J. Samanta, 'When does the learning curve of innovative interventions become questionable practice?', *European Journal of Vascular and Endovascular Surgery* 36:3 (2008), 253-257.

37 See note 3 above.

38 See note 29 above, at 885.

'checklist' provided for doctors to determine whether their innovation would be considered responsible remains virtually unchanged. Similarly the changes to the 'effect on the existing law' section are minimal. However there are several positive improvements in the structure of this recent Bill. For instance; provision of a definition of innovation for the purposes of the Bill, and an increased emphasis on the need for a Database of Innovative Treatments.

### Definition of Innovation

Section 2(2) of the AMTB defines treatment as innovative if it 'involves a departure from the existing range of accepted medical treatments for the conditions'.[39] This would broaden the scope of innovation beyond that considered in surgical innovation literature. Any difference in definition between the Bill and the surgical community may mean the Bill is not deemed relevant to surgical practice. It could also increase confusion for surgeons regarding the definition of innovation, so hinder rather than encourage responsible innovation. To allow surgeons to pre-emptively identify the Bill as relevant to their practice it should include a prospective definition that fully reflects the surgical consensus.

### Database of Innovative Treatments

Section 2 of the AMTB is devoted to the establishment of a Database of Innovative Treatments. Section 2 (1) states 'The Secretary of State may by regulations make provision conferring functions on the Health and Social Care Information Centre ("the HSCIC") in connection with the establishment, maintenance and operation of a database containing information about –

*a.* innovative medical treatments carried out by doctors in England, and
*b.* the results of such treatments'.[40]

This provision addresses concerns in the academic community. Pich et al. identified in 2003 that only 21% of approved clinical trials were published in a peer-reviewed journal.[41] Participants in unpublished trials are exposed to risk without benefit, and negative results must be published to prevent risk duplication. This is a greater problem for innovations as fewer instances proceed to publication. Attempts to rectify publication bias exist. In 2004 the International Committee of Medical Journal Editors published a statement making pre-trial

39 Access to Medical Treatments (Innovation) Bill (London: TSO, 2015) Section 2(2).
40 See note 39 above.
41 J. Pich et al., 'Role of a research ethics committee in follow up and publication of results', *Lancet* 361:9362 (2003), 1015-1016.

registration a condition of publication.[42] However this does not guarantee publication. Similarly a European Union (EU) directive[43] established a now publicly accessible EU clinical trials register. The 2012 Commission Guideline[44] makes it mandatory that results are published on the database within one year of trial completion. However this database does not include trials of surgical procedures so is of minimal use to surgeons. The Balliol Collaboration recommends use of an online database, with automatic reporting of negative and positive results.[45] Similarly many responses to the MIB consultation recommend data is collected from innovations performed under the Bill.[46] Inclusion of this requirement is consequently responsive to real surgical need.

An innovation database would provide an invaluable resource for surgeons treating rare diseases, or using unusual treatments by collating previously unpublished anecdotal reports into usable evidence. It would also make innovations more responsible as they would provide both patient benefit, and contribute to the evidence base. The database could prevent repetition of failed innovations, and therefore another patient's disappointment or harm. Additionally it may increase patient safety, as Schwartz points out 'the best antidote to cavalier surgical experimentation is outcome transparency'.[47]

There are disadvantages to a register. A primary concern is that it could enable patient identification. The case of *Department of Health v. The Information*

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42 C. De Angelis, J. Drazen et al., 'Clinical Trial Registration: A statement from the international committee of medical journal editors', *Annals of Internal Medicine* 141:6 (2004), 477-478.

43 The European Union, *Directive 2001/20/EC of the European Parliament and of the Council*, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF (accessed 19 April 2015) Article 11.

44 The European Union, *Commission Guideline – Guidance of posting and publication of results related information on clinical trials in relation to the implementation of Article 57(2) of regulation (EC) no. 726/2004 and Article 41 (2) of the regulation (EC) no. 1901/2006*, http://ec.europa.eu/health/files/eudralex/vol-10/2012_302-03/2012_302-03_en.pdf (accessed 19 April 2015).

45 See note 2 above.

46 See note 34 above; Cancer research UK, Cancer Research UK response form, http://scienceblog.cancerresearchuk.org/wp-content/uploads/2014/05/Cancer-Research-UK-consultation-response-draft-Medical-Innovation-Bill.pdf (accessed 14 March 2015); BMA, *Legislation to encourage innovation – a consultation British Medical Association Response* (London: BMA, 2014); Association of Medical Research Charities (info@amrc.co.uk), *Legislation to encourage innovation: a consultation*, Email to: Medical Innovation Consultation Team (Medicalinnovation-bill@dh.gsi.gov.uk) 25 April 2014; NICE, *Response to consultation questions on the Medical Innovation Bill*, https://drive.google.com/file/d/0B-BtKyoD6dXVcFRDZzhhbolvN3c/edit (accessed 14 March 2015); NHS Health Research Authority, *Health Research Authority (HRA) Response to 'Legislation to encourage medical innovation: a consultation'*, www.hra.nhs.uk/documents/2014/05/health-research-authority-hra-response-legislation-encourage-medical-innovation-consultation.pdf (accessed 19 April 2015); NHS Litigation Authority, *Legislation to encourage innovation – a consultation* (London: NHS Litigation authority, 2014); Royal College of Physicians, *Medical Innovation Bill* (London: RCP, 2014).

47 See note 3 above.

*Commissioner*[48] sets a precedent for this situation. Here the Department of Health refused to publish ground E abortion figures if there were less than ten occurrences, fearing it could lead to patient identification. The court ruled publication was appropriate as the data was not personal. There are also practical issues associated with the register; for instance how it will be funded long-term and whether it will be publicly accessible. Also whether a patient who refuses to allow their information on the register would be unable to access innovative treatment. Additionally Martin Elliott warns that the publication of the results of surgeons who copy an innovation is essential, as the results of those with different surgical skills are important in outcome assessment.[49]

## Responsible Innovation

Section 3 of the AMTB attempts to establish what is intended by 'responsible innovation'. Section 3 (2) creates a 'checklist' which surgeons could use to determine whether their innovation would be considered responsible, and therefore not negligent under the Bill. The following sections discuss components of the checklist in more detail.

### Appropriately qualified doctors' opinion

The checklist states that for a decision to be responsible, a doctor must 'obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment',[50] and 'take full account of the views ... in a way in which any responsible doctor would be expected to take account of such views'.[51] The legal and colloquial meanings of 'consult' differ. The definition of a lawful consultation is found in *R v. Brent London Borough Council Ex p Gunning*; it must (a) take place when proposals are still at a formative stage, (b) give reasons for any proposal so as to permit intelligent consideration and response, (c) give adequate time for consideration and response, and (d) give the product of the consultation conscientious consideration.[52] However surgeons will be unaware the legal term differs from their everyday use, therefore may not fulfil the criteria for consultation in the legal sense, but mistakenly believe they are still protected by the Bill. The legal meaning of consultation also still fails to prevent a surgeon performing a procedure under the Bill that those consulted

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48 *Department of Health v. The Information Commissioner* [2011] EWHC 1430 (admin).

49 M. Elliott, *The Ethical Challenges of New Treatments in Children: Could we do now what we did then? Lecture Transcript*, www.gresham.ac.uk/lectures-and-events/the-ethical-challenges-of-new-treatments-in-children-could-we-do-now-what-we-did (accessed 19 April 2015).

50 See note 39 above, Section 3 (2) (a).

51 See note 39 above, Section 3 (2) (b).

52 *R v. Brent London Borough Council Ex p Gunning* [1985] 84 LGR 168 at 169.

advise against. This seems to give maverick surgeons considerable protection, without equal safeguards for vulnerable patients. More positively, requiring consultation prevents innovations occurring in secret. However, recent scandals indicate peer review of behaviour is insufficient to prevent wrongdoing.[53]

## Risk Disclosure and Consent

Section 3 (2) (c) states the doctor must 'obtain any consents required by law'.[54] From the case of *R v. Brown*[55] it is clear consent is actually no defence when bodily harm is caused, except in the case of 'proper medical treatment'.[56] The Attorney General's reference No. 6 of 1980[57] indicates that 'reasonable surgical interference'[58] can be justified as 'needed in the public interest'.[59] Therefore, for a surgical innovation to be legally distinguished from a crime under the Offences Against the Person Act[60] it must be proper medical treatment in the public interest, regardless of whether consent was obtained. Mustill LJ in *R v. Brown* writes 'someone who inflicts serious harm, because (for example) he is inspired by a belief in the efficacy of a pseudo-medical treatment ... is guilty of an offence notwithstanding that he is inspired only by a desire to do the best he can for the recipient'.[61] Surgical innovation without evidential backing could be considered pseudo-science, and therefore an offence against the person. This common-law approach is not altered by the AMTB and may provide protection from the quackery opponents anticipate will be legalised by such a Bill.

The GMC Consent guidance makes recommendations in the case of innovation. It states written consent should be obtained if the treatment is innovative,[62] and a patient should be given information they want or need.[63] The guidance also says that patients should be given information about 'potential benefits, risks and burdens, and the likelihood of success, for each options'[64] including if the benefits and risks are affected by which doctor is chosen to

53 Kingsley Napley, *Medical Innovation Bill Response to the Department of Health Consultation* (London: Kingsley Napley, 2014), 4.
54 See note 39 above, Section 2 (2) (c).
55 R v. Brown [1994] 1 AC 212.
56 See note 55 above, at 41.
57 Attorney General's reference No. 6 of 1980 [1981] QB 715.
58 See note 57 above.
59 See note 57 above.
60 Offences Against the Person Act 1861 (London: TSO, 1861).
61 See note 55 above, at 35.
62 GMC, *Consent: Patients and Doctors Making Decisions Together* (London: GMC, 2008), para. 49.
63 See note 62 above, para. 9.
64 See note 62 above, para. 9.

provide care.[65] This would clearly be relevant for surgical innovation as with a new procedure there is a learning curve and therefore a more experienced surgeon may be preferred.

For consent to serve as a defence it must be informed, voluntary and made by a person who has capacity.[66] The Bill does not alter current procedures for patients who lack capacity. Desperation may have a coercive power. However Skegg suggests 'few patients would consent to major surgery if it were not for the force of surrounding circumstances, and the knowledge that health or even life may be in jeopardy if they do not consent'.[67] Therefore the innovation situation does not differ from the usual.

For consent to be informed the patient need only know the nature of the proposed procedure in broad terms, shown by *Chatterton v. Gerson*.[68] Additional risk disclosure rests on the standard of care defined by negligence cases, rather than the possibility of vitiating consent. This is evidenced by May J in the Creutzfeldt-Jakob Disease Litigation, 'there is true consent when a person consents to the nature of the act done. There is no English law doctrine of informed consent, and a person may succeed in a claim for failure to inform or warn only if that failure amounts to negligence.'[69] It would be possible for a decision to depart from the existing range of treatment to be deemed not negligent under the Bill, but for the actual treatment to be negligent as the duty of care was breached by inadequate risk disclosure.

However the recent case of *Montgomery v. Lanarkshire*[70] altered the information standard required to protect from negligence to include disclosure of all risks a reasonably prudent patient in that situation would consider significant. This includes being informed of the risks of alternative treatments, *in order to decide between them*. Therefore risk disclosure and treatment decisions have become inextricably linked. This judgment was made in light of the increasing importance of self-determination, and the changes in the doctor-patient relationship since *Sidaway*.[71] The checklist requires consent to be obtained, but lacks a requirement for candid discussion of the risks of alternative options as part of a decision to depart from the existing range of treatments. Such a decision

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65 See note 62 above, para. 9.
66 E. Jackson, *Medical Law Text Cases and Materials*, 3rd edn. (Oxford: OUP, 2013).
67 P.D.G. Skegg, *Law Ethics and Medicine: Studies in Medical Law* (Oxford: Clarendon Press, 1984), 97.
68 *Chatterton v. Gerson* [1981] QB 432.
69 Creutzfeldt-Jakob Disease Litigation [1995] 54 BMLR 1 (QBD).
70 *Montgomery v. Lanarkshire Health Board* [2015] UKSC 11.
71 *Sidaway v. Board of Governors of the Bethlehem Royal Hospital* [1985] A.C. 871.

should be the informed patient's, not the doctors. Therefore the checklist reflects a paternalistic doctor-patient relationship, which seems incongruent with the court's ruling in *Montgomery* and current surgeon-patient relationships.

### Opinions of patient and others

The checklist indicates a surgeon must consider 'any opinions or requests expressed by or in relation to the patient'.[72] This seems discordant with the principle of patient autonomy. The NHS Litigation Authority rightly points out that doctors should not merely take account of patient opinions, but that the decision of a patient who has capacity is final.[73] This also gives the Bill a paternalistic nature, out of step with modern surgeon-patient relationships. Paradoxically introducing a legal duty to take account of the opinions of concerned, but non-expert relatives seems an assault on surgeon autonomy. Additionally the MPS fear this criterion will allow patients to demand treatment from doctors.[74] The precedent set in *R (on the application of Burke) v. GMC*[75] prevents patients demanding treatment. However the Bill could produce fear of negligence litigation in cases where requests are refused, encouraging inappropriate treatment, rather than responsible innovation.

### Risk

The surgeon also has to consider the actual or reasonably expected risks and benefits of the proposed treatment, usual treatment, and no treatment at all.[76] Prediction of risk and benefit may be possible for a known treatment which is a departure from the evidence-based guidelines, but difficult for innovations that fit the consensus surgical definition. These procedures naturally have unexpected, unpredictable outcomes. For instance IDEAL model stage one innovations, which have not yet reached trial stage, may be expected to have outcomes of 'disasters' or 'dramatic successes'.[77] This section of the checklist also does not require consideration of treatments available as surgical trials. The Bill should be altered to mandate that if patients are eligible for an existing trial, it remains the gold-standard option.

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72 See note 39 above, Section 3 (2) (d) (i).
73 NHS Litigation Authority, *Legislation to encourage medical innovation – a consultation*, www.stopthesaatchibill.co.uk/wp-content/uploads/2014/06/NHS-Litagation-Authority.pdf (accessed 19 April 2015).
74 MPS, *MPS response to Legislation to Encourage Innovation: A consultation* (London: MPS, 2014).
75 R (on the application of Burke) v. General Medical Council [2005] EWCA Civ 1003.
76 See note 39 above, Section 3 (2) (d) (ii).
77 See note 2 above.

### Any Other Matter

Next the checklist vaguely states a doctor should consider 'any other matter that it is necessary for the doctor to consider in order to reach a clinical judgment, having regard in particular to the requirement of patient safety'[78] which implies other factors could be taken into account and leaves the legislation open to interpretation. An incomplete checklist will not encourage responsible innovation by removing fear of litigation, as a surgeon could still be subject to court examination with unknown variables taken into account.

### Accountability and Transparency

The final factor that makes a decision responsible is that the surgeon takes necessary steps to ensure the decision is 'accountable and transparent'.[79] The NHS already strives for an accountable and transparent culture. Inclusion of this seems non-specific, meaning it may need clarification by a court, so fails to remove fear of litigation. The transparency requirement may also already be covered by the statutory[80] and contractual duties of candour.[81] Additionally the inclusion of accountability may make resource allocation relevant to a responsible decision. It seems unlikely in a resource-scarce NHS that costly innovations will be considered accountable and responsible if there is opportunity cost. This criterion might reduce rather than encourage surgical innovation, as primary legislation would support managerial opposition. Within the NHS, accountability may be challenged via judicial review,[82] therefore the decision to innovate may again involve litigation proceedings, which the surgeon is said to fear.

### Effect on Existing Law

Opponents of the MIB were concerned it would alter current interpretation of negligence.[83] Section 4[84] of the AMTB addresses the issue of effect on existing law. However it only ensures section 3 doesn't prevent a surgeon departing from the existing medical treatments outside the Bill's protection.

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78 See note 39 above, Section 3 (2) (d) (iii).
79 See note 39 above, Section 3 (2) (e).
80 The Health and Social Care Act 2008 (regulated activities) regulations 2014, *SI* 2014/2936 (London: TSO, 2014), Part 3 Section 2 (20).
81 NHS England, *NHS Standard Contract 2014/15* (England: NHS, 2013), Section SC35.
82 K. Syrett, 'NICE and Judicial Review: Enforcing "accountability for reasonableness" through the courts?', *Med Law Rev.* 16:1 (2008), 127-140.
83 N. Poole, *The Saatchi Bill Would Not Preserve the Bolam Test*, www.stopthesaatchibill.co.uk/the-saatchi-bill-would-not-preserve-the-bolam-test/ (accessed 17 May 2015).
84 See note 39 above, Section 4.

Opponents of an Innovation Bill fear it will alter the duty of care for situations involving innovation by removing the Bolam test.[85] The AMTB specifically states 'it is not negligent for a doctor to depart from the existing range of accepted medical treatments for a condition if the decision to do so is taken responsibly'.[86] Therefore lack of support from a responsible body of medical opinion alone does not make the decision negligent. However *Clark v. MacLennan*[87] shows this may not differ from existing interpretation of negligence. In this case a surgeon operated one-month post partum, whereas the responsible body of medical opinion recommended waiting three months. The judge suggested this did not intrinsically breach duty of care, but may reverse the burden of proof so the defendant must prove why this action was not a breach. It could also be argued the Bolitho gloss allows a court to clear a defendant even if unsupported by the body of medical opinion. The Bill therefore only codifies what is already common law, which nullifies the need for it.

It could be argued that the checklist makes the Bolam test contemporaneous, rather than hypothetical and predictive. However, analysis of the checklist shows it fails to do this, as many factors that make a decision responsible are open to retrospective interpretation by the court. Additionally Miola suggested the MIB would remove the Bolitho gloss entirely, as it is impossible to both determine liability before treatment and allow the court to assess the content of the decision afterwards. The same could be said of the AMTB. Protecting surgeons from litigation, whilst also protecting the patient from harm seems fundamentally unworkable.[88] Ergo the current situation remains, albeit with an added checklist to complicate interpretation.

Lord Colwyn stated when talking of the MIB 'I fear the amended Bill will increase litigation, as the lack of clarity, contradiction and uncertainty of terms, and the fact that there are no definitions of key words, will require interpretation by judges in court and create an avalanche of satellite litigation'.[89] Kingsley Napley also suggest the Bill will produce satellite litigation, as patients who receive the standard treatment will demand the innovative treatments that comparable patients received.[90] This confusion will not encourage a surgeon to innovate as they may still be subjected to the traumatic court process.

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85 See note 83 above.
86 See note 39 above, Section 3 (1).
87 Clark v. MacLennan [1983] 1 ALL ER 416.
88 J. Miola, 'Saatchi is right to promote medical innovation but his bill is wrong way to do it', *BMJ* 350 (2015), h531.
89 Hansard HC, 27 June 2014, Coll 1462.
90 See note 53 above, at 3.

### South Africa Bill

The proposed Bill's faults do not mean all legislation attempting to encourage responsible innovation is flawed. South Africa also has a medical innovation Bill in progress, with aspects that could improve an English Bill. Section 3[91] restricts the Bill's coverage to pilot centres. This would make the innovations more controlled and accountable, and simplify data collection. Additionally these centres could become conglomerations of innovative energy, producing more innovation than if the Bill applied everywhere. Meanwhile section 4[92] of the Bill specifies that innovation protected by the Bill can only take place when evidence-based treatment is unavailable. Neither of the proposed English Bills stated this specifically, and doing so may improve clarity.

### Recommended Changes

In summary, the current Bill would not encourage responsible surgical innovation. It should be amended to include an explicit prospective definition of innovation incorporating the consensus surgical definition. The statutory checklist simultaneously fails to provide adequate protection for doctors from litigation and patients from harm. It is also open to challenge via satellite litigation. Therefore it should be amended. It should ensure a clear standard of information provision required to consent for innovative procedures. Specifically this should include informing the patient that the procedure is innovative, and that s/he understands the known risks and benefits, and alternatives. Most importantly the standard should include an understanding that the procedure's outcomes are unknown. If a skill-based procedure is being offered the patient should be informed of the concept of the learning curve, and where the surgeon sits on that curve.

Additionally the checklist should remove the paternalistic requirement to consider views expressed by or in relation to the patient, which implies the patient's decision is not decisive. The vague 'any other matter' criterion should also be removed. The Bill should mandate that innovations introduced via the Bill cannot become mainstream treatments until they undergo formal research to provide an evidence base. Additionally the Bill should only apply if no suitable evidence-based treatment, or formal clinical trial is available. Importantly the Bill should restrict innovations to pilot centres. In response to concerns that the Bill will have negative effects on both patient care and research it should

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91 South African Parliament, *Medical Innovation Bill*, www.parliament.gov.za/live/commonrepository/Processed/20140414/567327_1.pdf (accessed 13 March 2015), Section 3.

92 See note 91 above, Section 4.

mandate a review of the legislation in five years' time, with the possibility of repeal if the net effect is considered negative.

## Alternatives to Legislation

Although changes could improve the Bill, primary legislation may not be the most appropriate method to encourage responsible surgical innovation. Many opponents disagree with the Bill's cornerstone premises, and suggest alternative barriers to innovation without legislative solutions. Without the cornerstone premises, the argument for legislation is weakened. Academic support for the premises exists. Greenhalgh et al.[93] describe problems with evidence-based guidelines; they are often unhelpful when patients have multiple co-morbidities, they are based on statistically not clinically significant benefits and the inflexible rules produce management-driven, rather than patient-centred care. They also identify the problem of algorithmic medicine; where attempts to automate evidence-based medicine using decision support systems and point-of-care prompts reduced quality of care. They state, 'inexperienced clinicians may (partly through fear of litigation) engage mechanically and defensively with decision support technologies'.[94] Specifically within the surgical literature there are references to fear of litigation.[95]

Conversely the summary of responses to the MIB's consultation states, 'NICE (and an individual doctor) had reviewed published literature in search of evidence that the possibility of litigation deters innovation, but with little result'.[96] From the available consultation responses 13[97] well-respected organisa-

93 T. Greenhalgh, J. Howick, 'Evidence Based Medicine: a movement in crisis?', *BMJ* 348 (2014), g3752.

94 See note 93 above.

95 P.L. Ergina, J.A. Cook, J.M. Blazeby, I. Boutron, P.A. Clavien, B.C. Reeves, C.M. Seiler for the Balliol Collaboration, 'Challenges in evaluating surgical innovation', *Lancet* 374 (2009), 1,097-1,104 at 1098; J.L. Knight, 'The Dark Side of Surgical Innovation', *Innovations* 7:5 (2012), 307-313; note 6 above; S. Westaby, K. Baig, J. Pepper, 'SSMD: and another thing', *The Bulletin* 97:5 (2015), 212-213.

96 Department of Health, *Report on the consultation on the Medical Innovation Bill* (London: DH, 2014).

97 See note 34 above; Association of Medical Research Charities (info@amrc.co.uk) *Legislation to encourage innovation: a consultation*, Email to: Medical Innovation Consultation Team (Medicalinnovationbill@dh.gsi.gov.uk) 25 April 2014; NHS Litigation Authority, *Legislation to encourage innovation – a consultation* (London: NHS Litigation authority, 2014); Royal College of Physicians, *Medical Innovation Bill* (London: RCP, 2014); Royal College of Surgeons, *Medical Innovation Bill* (London: RCS, 2014); Association of Personal Injury Lawyers, *Medical Innovation Bill threatens to erode patient safety*, www.apil.org.uk/press-release/Medical-Innovation-Bill-threatens-to-erode-patient-safety (accessed 14 March 2015); BMA, *Legislation to encourage innovation – a consultation British Medical Association Response* (London: BMA, 2014); R. Meyer, *British Pharmacological Society Response Form*, www.bps.ac.uk/SpringboardWebApp/userfiles/bps/file/About-BPS/Policy%20positions/BPS%20response_MedicinesInnovationBill_final.pdf (accessed 14 March 2015); Cancer Research UK, *Cancer Research UK response form*, http://scienceblog.cancerresearchuk.org/wp-content/uploads/2014/05/Cancer-Research-UK-consultation-response-

tions stated there was no evidence that litigation deters innovation. Research from Macquarie states surgeons specifically fear bureaucratic processes more than litigation.[98] Jonathan Sheffield provided evidence that from 1995-2010 litigation associated with clinical research accounted for only 0.01% of all litigation.[99] Kingsley Napley suggest 'blaming an external factor of the law may ... at times provide a convenient "hook" for a clinician to explain to a desperate patient or their family that the end of the road of rational treatment options has been reached'.[100] There is an additional theme in the literature that even if litigation were a deterrent, education rather than legislation would be an appropriate remedy.[101]

The fact that clinical negligence claims are usually directed at employers not individuals also has consequences for the cornerstone premises, as this suggests a need for legislation aimed at employers not surgeons. The NHS litigation authority reiterates that they indemnify clinicians for work undertaken in NHS Trusts, so there is no need to fear litigation as all costs are covered. This ignores the stress litigation causes and its impact on career, but makes a valid point. Raising awareness of this could reduce fear of litigation more than legislation.

One could argue that fear of litigation protects the patient, and should be retained. This view is present in the surgical innovation literature; Reitsma and Moreno state 'consent for innovative procedures may be obtained in a manner governed only by the risk of malpractice litigation',[102] and the Balliol Collaboration say 'in many cases, between the innovation and harm to the patient lies little more than a surgeon's sense of responsibility, dedication, and fear of medico-legal consequences'.[103]

Multiple barriers to innovation, other than a fear of litigation, have been identified. The Medical Protection Society (MPS) and the Association of Medical Research Charities say lack of innovation in medical education, and resultant

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draft-Medical-Innovation-Bill.pdf (accessed 14 March 2015); L. Rose on behalf of Healthwatch, *Response form*, www.stopthesaatchibill.co.uk/wp-content/uploads/2014/06/Med-innov-bill-HW-resp-v1.0-FINAL.pdf (accessed 14 March 2015); note 53 above; M. Nesbitt on behalf of the Medical Defence Union, *Response Form*, www.themdu.com/~/media/Files/MDU/Publications/Consultation%20responses/MDU%20response%20to%20consultation%20on%20Medical%20Innovation%20Bill.pdf (accessed 14 March 2015); note 74 above.

98 See note 96 above, para. 15.

99 J. Wisley, *Health Research Authority (HRA) Response to 'Legislation to encourage medical innovation: a consultation'* (London: HRA, 2014), 1.

100 See note 53 above, at 1.

101 See note 53 above, at 1; note 74 above.

102 See note 6 above.

103 See note 13 above.

lack of skills within the workforce is a barrier.[104] Similarly the Department of Health itself reports commissioners lack the skills to drive innovation.[105] The bureaucracy associated with funding applications and research approvals are considered inhibitors of innovation.[106] Rare diseases or those not in the public eye may be less likely to receive funding. Innovation also lacks financial incentives.[107] The forthcoming Rose Report is expected to conclude the NHS' over-complex management structure quashes initiative.[108] The Royal College of Psychiatrists supports this view, saying service providers see NICE guidelines as protocols to be followed regardless of context, and it is managerial fear of litigation that deters innovation.[109] Use of guidelines in this manner is not their intended purpose. For surgery specifically, barriers include lack of time in training programmes for innovation or research and undervaluing of innovation by seniors.[110] The Royal College of Surgeons suggests lack of role models and the surgical culture are stunting surgical innovation.[111]

Many of the barriers to innovation identified above could be overcome through alternatives to primary legislation. The Royal College of Surgeons suggests clinical innovation champions, a Department of Health training programme and alignment with NHS imperatives to convince managers of the need.[112] The Department of Health suggests linking innovation and financial reward via CQUINs.[113] Similarly development of ethical oversight 'could enhance patient safety as well as avert unnecessary legislation which may unduly impede progress'.[114] The NHS Health Research Authority suggests existing research ethics committees approve innovative treatments when no existing treatment or clinical trial is available.[115] The Academy of Healthcare Sciences alternatively

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104 Association of Medical Research Charities (info@amrc.co.uk), *Legislation to encourage innovation: a consultation*, Email to: Medical Innovation Consultation Team; note 74 above.

105 Department of Health, *Innovation, Health and Wealth: accelerating adoption and diffusion in the NHS* (London: DH, 2011), 10.

106 See note 30 above, at 34; note 74 above; note 34 above, at 1; Royal College of Physicians, *Medical Innovation Bill* (London: RCP, 2014), 2.

107 See note 105 above, at 10; The Academy of Medical Sciences, The Medical Research Council, Wellcome trust, *Department of Health Consultation: Legislation to encourage medical innovation*, www.acmedsci.ac.uk/viewFile/5360fb3f31baf.pdf (accessed 14 March 2015).

108 S. Westaby, K. Baig, J. Pepper, 'SSMD: and another thing', *The Bulletin* 97:5 (2015), 212-213.

109 See note 96 above, para. 16.

110 RCS, *From theory to theatre overcoming barriers to innovation in surgery* (London: RCS, 2011); Association of Medical Research Charities (info@amrc.co.uk), *Legislation to encourage innovation: a consultation*, Email to: Medical Innovation Consultation Team; see note 105 above, at 10.

111 RCS, *From Theory to Theatre Overcoming Barriers to Innovation in Surgery* (London: RCS, 2011).

112 RCS, *From innovation to adoption successfully spreading surgical innovation* (London: RCS, 2014).

113 See note 105 above.

114 See note 3 above.

115 NHS Health Research Authority, *Health research authority response to legislation a to encourage medical innovation – a consultation*, www.hra.nhs.uk/documents/2014/05/health-research-authority-hra-response-legislation-encourage-medical-innovation-consultation.pdf (accessed 14 March 2015).

suggests a new/novel procedure committee is established in each hospital.[116] Development of NICE or professional guidance is also advised.[117,{NOOT:See note 112 above.},118] Increasing access for all patient groups to the gold standard of formal research, rather than just increasing the number of trials may also reduce the need for innovation. Similarly increased reporting of clinical trial outcomes to pre-existing free databases such as FigShare[119] may be helpful. Supporting the Restoring Invisible and Abandoned Trails initiative[120] and encouraging widespread use of the IDEAL framework[121] and the ETHICAL[122] model may also increase surgical progress specifically.

## Ethical Guidance

Ethical guidance for surgeons regarding surgical innovation may encourage responsible innovation, irrespective of legal oversight. The reliance on a surgeon's conscience in innovation means discussion of character is relevant; therefore virtue ethics is applicable. The MIB campaign involved much assurance that 'the Bill stands squarely against the maverick and the quack'.[123] Ironically, great surgical innovators are often positively described as 'mavericks'. The link between the 'maverick' and 'innovator' is difficult to sever. Personality profiling indicates that 'innovators tend to be brimming with ideas, to flout the workplace rules, as well as to display little concern with bureaucratic details'.[124] Descriptions of surgical innovators concur with this view. It could be questioned whether innovation can exist within the rules. Perhaps an integral part of innovators' characters is a disposition to take risks. Whether this is considered a virtue or a vice may depend on context, therefore development of practical wisdom to decide when daring is appropriate may be a better focus to encourage responsible innovation than trying to curtail habitual risk taking.

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116 Academy for healthcare science, *Academy for Healthcare Science response to the medical innovation bill consultation*, (London: AHCS, 2014).

117 BMA, *Legislation to encourage innovation – a consultation British Medical Association Response* (London: BMA, 2014).

118 NICE, *Response to consultation questions on the Medical Innovation Bill*, https://drive.google.com/file/d/0B-BtKyoD6dXVcFRDZzhhbolvN3c/edit (accessed 14 March 2015).

119 FigShare, *Figshare*, http://figshare.com (accessed 16 May 2015).

120 P. Doshi, K. Dickerson, D. Healy, S. Vedula, T. Jefferson, 'Restoring invisible and abandoned trials: a call for people to publish the findings', *BMJ* 346 (2013), f2865.

121 See note 2 above.

122 See note 3 above, at 640.

123 Medical Innovation Bill, *Get the Facts*, http://medicalinnovationbill.co.uk/get-the-facts/ (accessed 22 April 2015).

124 N.G.A. Kwang, D. Rodrigues, 'A big 5 personality profile of the adaptor and innovator', *Journal of Creative Behaviour* 36:4 (2002), 254-268.

Pellegrino describes how a professional virtue is a 'trait of character that disposes its possessor habitually to excellence of intent and performance with respect to the [end] specific to a human activity'.[125] He was unconvinced that virtue ethics could apply to general ethics, however considered it suited medicine, where an agreed end exists: healing. Pellegrino suggested core virtues for doctors; fidelity to trust and promise, benevolence, removal of self interest, compassion and caring, intellectual honesty, justice and prudence, later adding courage.[126] These virtues seem the most informed assessment of a surgeon's virtues, even if not surgery specific. The virtues of surgical innovators may differ from those of conventional surgeons. Caniano applies virtue ethics specifically to the innovative paediatric bariatric surgery situation. She uses many virtues identified by Pellegrino, but adds self-effacement (humility).[127]

There are many criticisms of the virtue ethics approach that are specifically applicable to surgical innovation. Annas comments that virtues can be seen as selfish traits to achieve personal flourishing.[128] Clearly, when a patient is involved, the surgeon's personal flourishing should not be prioritised. Additionally surgical innovation often takes place in extreme situations; therefore extreme character traits may be appropriate and necessary to produce the creativity required for innovation. Another major criticism of virtue ethics comes from Doris who champions the idea that situational factors are better predictors of behaviour than character traits.[129] This is evidenced by situational psychology experiments. The surgical literature also supports this criticism. Cochran et al. demonstrated how situational factors such as complications during surgery and working with unfamiliar staff can lead to vice-like behaviour including verbal hostility and physical tantrums.[130] Similarly Riskin et al. found context to be just as important as personality in surgical innovation.[131] Consequently development of virtues may be irrelevant to encouraging innovation. Instead effort should be focussed on altering situational factors to promote innovative behaviour. This supports establishment of pilot centres where situational factors will favour innovation.

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125 E. Pellegrino, 'Toward a Virtue Based Normative Ethics for the Healthcare Professional', *Kennedy Institute Of Ethics Journal* 5:3 (1995), 253-277, at 268.

126 E. Pellegrino, 'Professionalism, profession and the virtues of a good physician', *The Mount Sinai Journal of Medicine* 69:6 (2002), 378-384.

127 D. Caniano, 'Ethical Issues in Pediatric Bariatric Surgery', *Seminars in Pediatric Surgery* 18:3 (2009), 186-192.

128 J. Annas, 'Virtue Ethics', in: *The Oxford Handbook of Ethical Theory* D. Copp (ed.) (Oxford: Oxford University Press, 2007), 530.

129 J. Doris, *Lack of Character* (Cambridge: Cambridge University Press, 2002).

130 A. Cochran, W.B. Elder, 'A model of disruptive surgeon behaviour in the perioperative environment', *J. Am. Coll. Surg.* 219:3 (2014), 390-398.

131 D.J. Riskin, M.T. Longaker, M. Gertner, T. Krummel, 'Innovation in Surgery a historical perspective', *Annals of Surgery* 244:5 (2006), 686-693.

## Cleavage-Sparing Mastectomy

The above discussion means little, unless applicable to tangible examples. So-called 'cleavage-sparing mastectomy' is such an example. This surgery was not identified as an innovation, but perhaps should have been. It involved leaving a small amount of breast tissue behind for cosmetic reasons. It is believed to increase risk of cancer recurrence and in many cases required 'shave' surgery to remove remaining hazardous tissue. The procedure appears to have been invented by West Midlands consultant breast surgeon Mr Paterson. Mr Paterson did not follow hospital guidelines for the introduction of a new interventional procedure. Colleagues expressed concerns about the procedure as early as 2003. However he only stopped performing it in 2007. Patients who received this procedure gave consent to a mastectomy, not the innovative procedure. Some patient relatives remembered Mr Paterson informing them his technique differed from other surgeons, but they did not understand the gravity of this deviation. Mr Paterson's character was described in the Kennedy report as 'charismatic and charming'[132] and much-liked by his patients. However it also states he was 'not a team player' and discouraged other surgeons from working at the hospitals because he disliked having strong colleagues.

The fundamental question is whether legislation would have improved this situation. Comparing Paterson's decisions to the AMTB checklist provides little evidence that decisions made using it are responsible. Paterson could have continued to offer the procedure as long as he consulted another appropriately qualified surgeon and took account of his/her views in the way a responsible doctor would, even if the other surgeon disagreed. The checklist also only specified a risk/benefit assessment is made; not that the outcome is reasonable. The consent requirement would have earmarked Paterson's decision as irresponsible as he obtained consent for mastectomy not the procedure he performed. However, the consent he obtained was *contemporaneously* insufficient, so the Bill would not alter the legality of his actions. The only aspect of the Bill that would have affected this innovation is the Medical Innovation Database. If Paterson had identified his surgery as innovative and published the data on the register, the breast cancer recurrence risk may have been detected earlier. More importantly data publication may also have alerted the surgical community to the procedure, inviting scrutiny.

Another question is whether ethical guidance or training would have helped or prevented this innovation. We can answer this by applying the surgical virtues

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[132] I. Kennedy, *Review of the response of heart of England NHS foundation trust to concerns about Mr Ian Paterson's Surgical Practice; Lessons to be learned; and recommendations* (Solihull; Solihull Hospital Kennedy Breast Care Review, 2013), Executive summary, paragraph 7.

to the situation. Paterson clearly broke the trust and implicit promises between patient and surgeon as harmful surgery was given. Failing to subject the surgery to *any* oversight indicates a lack of intellectual honesty, as it shows a refusal to accept there could be a point of clinical equipoise. Caniano also suggests that trustworthiness includes the physician grasping the patient's values. Paterson assumed that the women involved attached aesthetic value to their cleavage, but without asking the women themselves he betrayed their trust. Once the bad outcomes associated with Paterson's surgery were discovered a humble person would immediately stop operating and disclose the mistake. Perhaps he would publish the outcome to prevent others repeating the harm. The behaviour of Mr Paterson in actively attempting to prevent the appointment of strong surgical colleagues seems to have been an example of vice-like behaviour, where his interests in maintaining dominance were placed above those of the patients to have multiple competent surgeons available. Paterson was described as being much liked by his patients, suggesting he acted compassionately towards them. This suggests the virtue of compassion is less important than providing safe surgery when innovating. The case also indicates much professional cowardice as Paterson avoided subjecting the innovation to any oversight, and then ignored evidence from colleagues indicating potential harm to patients. This all indicates that cultivation of virtuous role models and a change in surgical culture, especially to encourage intellectual honesty and humility, would contribute to responsible innovation.

## Conclusion

Overall it is apparent that a combination of approaches, rather than primary legislation alone, is required to encourage responsible surgical innovation. However in the current political landscape the introduction of legislation seems likely. Therefore efforts of the surgical community should be focussed on contributing to producing legislation to ensure the result will cultivate not crush surgical innovation. There should also be a push to introduce adjunctive measures such as surgical culture change and greater ethical guidance to ensure truly responsible innovation occurs.