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Regulating Innovative Treatments: Information, Risk Allocation and Redress

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Regulating Innovative Treatments: Information, Risk Allocation and Redress

This special issue features papers culminating from a six seminar ESRC series 'Liability versus innovation: Unpacking Key Connections,' convened between December 2015 and September 2017 at Keele, QUT (Brisbane, Australia) and Durham universities.[1] The seminar series was conceived in response to perceptions of scientists and clinicians that, despite the pro innovation rhetoric in Government policy documents,[2] the threat of malpractice liability might stifle innovative treatment (IT).

Such perceptions are supported by two related claims common in medico-legal literature – that the threat of legal liability following adverse outcomes causes defensive medicine,[3] and that the threat of legal liability stifles innovation.[4] The extent of these problems remains disputed. In particular, the Bolam-Bolitho test of clinical negligence in England – which excludes liability for clinical decisions accepted as proper by a responsible body of skilled medical peers unless such practice is illogical[5] – is arguably problematic in terms of incentives to engage in IT. An IT is by definition less likely to accord with accepted practice. So, while policy-makers encourage and pay considerable lip service to innovation, tort law might give the opposite incentive to clinicians. Or so goes the argument.

This debate is topical in terms of policy making. For example: in the UK, the Access to Medical Treatments (Innovation) Act 2016 (AMTIA), formerly the Medical Innovation Bill (MIB), introduced, until its final stages, a pre-treatment peer approval 'defence' to protect responsible innovation; in Australia, the statutory defence based on Bolam/Bolitho was introduced, despite judicial reluctance to adopt Bolam's deference

[1] See: 'Liability v Innovation: Unpacking Key Connections, An ESRC Seminar Series' <https://liabilityinnovation.wordpress.com/> (accessed 26 October 2018). The support of ESRC towards this research is acknowledged.

[2] For example, Government of United Kingdom, 'Innovate UK' <https://www.gov.uk/government/organisations/innovate-uk> (accessed 26 October 2018).

[3] Daniel Kessler and Mark McClellan, 'Do Doctors Practice Defensive Medicine?' (1996) 111(2) The Quarterly Journal of Economics 353; Gijs van Dijck, 'Should Physicians be Afraid of Tort Claims? Reviewing the Empirical Evidence' (2015) Journal of European Tort Law 282.

[4] Gideon Parchomovsky and Alex Stein, 'Torts and Innovation' (2008) 107 Michigan Law Review 285; Anna B. Laakmann, 'When Should Physicians Be Liable for Innovation?' (2015) 36 Cardozo Law Review 913.

[5] Bolam v Friern Hospital Management Committee [1957] 1 WLR 582; Bolitho v City and Hackney Health Authority [1996] 4 All ER 771.

to 'common professional practice';[6] and in the US, the 'right to try' new drugs legislation is enacted.[7]

The investigators - Tsachi Keren-Paz (Principal Investigator), Alicia El Haj, Tina Cockburn, Michael Fay and Richard Goldberg - identified the following questions which highlight gaps in knowledge which the seminar series aimed to fill, or create research networks and collaborations to address:

1. Empirical questions: what is the extent of defensive medicine and of stifled innovation; is this a real problem; and if so, in what areas of medicine?

2. Methodological questions: how to define and measure innovation; the extent to which changes in legal rules affect levels of defensive medicine and innovation; and the relative weight of tort liability and of disciplinary proceedings in causing defensive medicine and stifled innovation.

3. Normative questions: how to balance the interests of clinicians, patients and society; how best to encourage responsible innovation; whether the regulation of ITs and research should change and/or be more closely aligned.

The seminars brought together the main stakeholders: physicians, researchers, policy makers, regulators, specialist medical malpractice solicitors and barristers, insurers and patients' advocacy groups.

Seminar One examined the broader question of whether fear of tort liability causes defensive medicine,[8] explored the relationship between defensive medicine and innovation and introduced an Australian perspective. An emergent theme was that tort liability, or even law, may not trigger defensive practices, but rather there may be other causes such as unrealistic societal expectations about acceptable levels of risk and fear of damage to professional reputation (including disciplinary action).[9]

Seminar Two had four related aims. First, to learn from anecdotal evidence of regenerative medicine and other clinicians and researchers suggesting that the problem exists. Second, to examine conflicting findings in the literature about whether or not liability stifles innovation. Third, to explore, mainly from a health economics perspective, the methodological difficulties involved in defining and measuring levels of innovation. Finally, to scrutinize assumptions, methodologies and findings about the

[6] Civil Liability Act 2003 (Qld) s 22(1); Civil Liability Act 2002 (NSW) s 50, 5P; Civil Liability Act 1936 (SA) s 41(1); Civil Liability Act 2002 (Tas) s 22(1); Wrongs Act 1958 (Vic) s 59(1); Civil Liability Act 2002 (WA) s 5PB(1).

[7] Denise Meyerson, 'Medical Negligence Determinations, the "Right to Try," and Expanded Access to ITs' (2017) 14 (3) Journal of Bioethical Inquiry 385. In 2017, the Federal Right to Try Act was enacted.

[8] We see the stifling of innovation as one potential manifestation of defensive medicine, which is, hence, the broader question.

[9] See: 'The Defensive Medicine Debate', QUT, (17 December 2015) <https://liabilityinnovation.wordpress.com/seminars/seminar-1/> (accessed 26 October 2018).

effect of changes in malpractice liability rules on levels of innovation. A major finding was that while anti innovation bias might exist under American law (although this is disputed), English law differs so that there is no reliable evidence or robust assumption that negligence law stifles innovation. Another conclusion was that developing reliable methodology to measure innovation and the effects of changes in the legal rules on levels of innovation is not straightforward and requires further work. In particular, there is a need for further empirical research to assess whether fear of liability (including civil claims and disciplinary action) stifles innovation. [10]

Seminar Three examined the defence proposed by the MIB, which hinged on a pre-treatment peer review of the benefits and risks of the proposed treatment, alternative treatments, and no treatment. The seminar explored the proposal's significance and desirability, and the best way forward. Although MIB team representatives declined invitations to participate, the stakeholders, including Nigel Poole QC and academic researchers, most notably Jose Miola, concluded that: (a) there is no evidence that the existing legal framework stifles innovation; (b) the reform proposed by the MIB defence was ill-founded because it exposed patients to irresponsible innovation without achieving its prime goal of providing a de facto pre-ruling immunity to IT practitioners; and (c) there was no consensus on whether better crafted reform proposals, such as moving forward in time the Bolam/Bolitho scrutiny before the innovative treatment is administered, were necessary or feasible. While the focus of reform proposals has related to issues concerning standard of care in the context of determining whether innovative treatment is negligent, there was some agreement that attention should also focus on issues relating to consent to innovative treatment and provision of information to patients to enable informed choice.[11]

Seminar Four considered the effect of disciplinary proceedings on innovation because although most defensive medicine research focuses solely on tort liability and neglects disciplinary proceedings, clinicians are likely to be warier of disciplinary proceedings than civil claims. While participants agreed that there is anecdotal evidence that clinicians are generally more concerned about disciplinary action than civil claims, they concluded that there is no evidence that the threat of disciplinary proceedings stifles innovation. There are limited examples of disciplinary proceedings relating to IT.[12] The

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[10] See: 'Does Liability Stifle Innovation? Economic Models and Anecdotal Findings', Keele, (18 April 2016) <https://liabilityinnovation.wordpress.com/seminars/seminar-2/> (accessed 26 October 2018).

[11] See: 'The Medical Innovation Bill and the Access to Medical Treatments (Innovation) Bill: Significant Change, or Much Ado About Nothing?', Durham, (15 September 2016) <https://liabilityinnovation.wordpress.com/seminars/seminar-2/> (accessed 26 October 2018).

[12] In Australia, see: Health Care Complaints Commission v Chen [2018] NSWCATOD 73; Health Care Complaints Commission v Reid [2018] NSWCATOD 162; Medical Board of Australia v Hocking; Hocking v Medical Board of Australia [2015] ACAT 44. In England**:** GMC v Paterson 2703453 (25 July 2017); GMC, Comment on the decision to strike off Dr Ian Paterson (GMC, 25 July 2017) <https://www.gmc-uk.org/news/news-archive/comment-on-the-decision-to-strike-off-dr-ian-paterson> (accessed 26 October 2018); Paul Bradley, 'Professor James Richardson Cleared of Wrong-Doing after Man Dies During Knee Surgery' (Birmingham Mail, 17 February 2013) <https://www.birminghammail.co.uk/news/local-news/professor-james-richardson-cleared-wrong-doing-1325420> (accessed 26 October 2018).

risk of registration suspension or cancellation following disciplinary action is low and most cases result in no further action. Given this, there was general agreement that the development of professional standards/codes of conduct and definitional consensus relating to medical innovation is necessary to enable effective regulation for patient safety.[13]

Seminar Five explored: (a) the case for strict liability towards patients injured by ITs; and (b) deviation from the patient's best interest as the sole determinant of standard of care and damages in favour of determining liability based on benefits to third parties. The MIB's proposed solution operated within the confines of received wisdom: fault-based liability, full compensation and the patient's best interest as governing principles to determine whether offering the IT is negligent. Seminar five questioned this received wisdom. While there was a fairly strong consensus against reducing damages to injured patients to reflect benefits to third parties, the proposal that those injured by ITs should receive compensation regardless of fault – on either a strict liability basis or a no-fault scheme - received considerable support because it was generally regarded as affordable, fair and unlikely to stifle innovation.[14]

Seminar Six examined the relationship between the regulation of research, and of ITs and the effects on innovation. Issues addressed included: the distinction between IT and research; the relative threat of tort law and regulation on innovation in research; and whether the level of compensation to research subjects stifles innovation. There was consensus that the blurred boundaries between IT and research created regulatory challenges, and discussion of whether the concept of liminality may assist. While there was no evidence that the regulation of research stifles innovation, participants expressed concern that an overly burdensome regulatory regime may lead to circumvention, for example, by using compassionate measures to disguise research as IT. It was also recognised that, particularly in the case of access to IT by children, hospital ethics committees have an important role to play.[15]

The questions explored in the seminar series were at the crossroads of five debates regarding tort law, and four additional debates external to tort law, pertaining to the regulation of the medical profession and the relationship between tort law and other modes of regulation. Beginning with tort law, the main and first debate is whether the threat of tort liability brings more harm than good, by contributing to defensive medicine. Defensive medicine can involve: (a) care-decisions aimed at minimizing exposure to liability, for example by ordering futile or harmful tests, rather than providing optimal care; or (b) lower practitioner participation in high-risk specialties and/or procedures, due to insurance premium increases.[16] In theory, any beneficial

[13] See: 'The Effect of Disciplinary Proceedings', QUT, (22 February 2017) <https://liabilityinnovation.wordpress.com/seminars/seminar-4/ > (accessed 26 October 2018).

[14] See: 'Thinking outside the Box: Strict Liability and Offsetting Risks', Keele, (4 May 2017) <https://liabilityinnovation.wordpress.com/seminars/seminar-5/> (accessed 26 October 2018).

[15] 'The Regulation of Research', Keele, (14 September 2017) <https://liabilityinnovation.wordpress.com/seminars/seminar-6/> (accessed 26 October 2018).

[16] Tara Bishop and Michael Pesko 'Does Defensive Medicine Protect Doctors against Malpractice Claims?' (2015) BMJ 351.

innovation foregone due to the risk of tort liability is a type of (b), although it could also be considered as typifying (a), by providing sub-optimal care. This debate intersects with a fault line between law and economics and law and society, specifically legal consciousness. While models of economic analysis of law predict that defensive medicine ought to be a problem, the empirical support is disputed.[17] Certainly in the UK, in the context of innovation, the majority of stakeholders participating in the seminars believed that no such problem exists, or at least that there is no credible evidence supporting its existence. Observations that clinicians might wrongly perceive that liability might stifle innovation echo both doubts expressed in behavioural law and economics findings on bounded rationality [18] and legal consciousness studies, suggesting that even professionals have very limited knowledge and understanding of the relevant legal rules which regulate and constrain them.[19] Another observation, that fear from peers' negative response is a stronger constraint than tort liability, is taken forward by Sarah Devaney in her contribution, by exploring the potential of reputation enhancing regulation to reduce instances of research misconduct driven by the high stakes of successful innovation. Further, as Jose Miola and Tsachi Keren-Paz demonstrate in previous writing and in their contributions: (a) the prediction that liability will stifle innovation should be examined empirically, allowing for jurisdictional differences; and (b) the models should be critically examined to ensure that they account for reduced harm from irresponsible innovation deterred by fear of liability, rather than uncritically assuming that all innovation has positive social value. [20]

A second tort debate is the proper extent of the court's deference to expert opinion, which in the torts context translates to whether the standard of care is a question of fact, law, or a mixture of the two.[21] In the UK, there are the twin questions: what was the general effect of Bolitho's gloss on Bolam?; and what was the effect on ITs? With respect to the effect of Bolitho, has the possibility of rejecting the peer professional endorsement of the clinician's decision as illogical led to: (a) significant (or any?) change in exposure to/extent of liability; and (b) any change in clinical practice? In

[17] Gijs van Dijck, 'Should Physicians Be Afraid of Tort Claims? Reviewing the Empirical Evidence' (2016) 6 Journal of European Tort Law 282.

[18] Christine Jolls, Cass R. Sunstein and Richard Thadler, 'A Behavioral Approach to Law and Economics', (1998) 50 Stanford Law Review 1471.

[19] See for example: Ahmad Adi and Mohammad Mathbout, 'The Duty to Protect: Four Decades After *Tarasoff*' (2018) <https://doi.org/10.1176/appi.ajp-rj.2018.130402> (accessed 26 October 2018); Tess Neal, Psychologists' Reasoning in Forensic Cases is Affected by Cognitive Biases (paper presented at the American Law and Society Association, Toronto, (9 June 2018).

[20] Tsachi Keren-Paz, 'Liability Regimes, Reputation Loss and Defensive Medicine' (2010) 18(3) Medical Law Review 363; Tsachi Keren-Paz and Alicia El Haj, 'Liability versus Innovation: The Legal Case for Regenerative Medicine' (2014) 20(19-20) Tissue Engineering Part A 2555; Jose Miola, 'Bye-bye Bolitho? The Curious Case of the Medical Innovation Bill' (2015) 15(2) Medical Law International 124 <https://doi.org/10.1177/0968533215605667> (accessed 26 October 2018).

[21] Strictly speaking, it is a question of fact, but it clearly involves a normative value judgment by courts which is not bound by general practice: Baker v Quantum Clothing Group [2011] UKSC 17.

terms of the effect on innovation, it is unclear whether the Bolitho gloss increases or decreases the clinician's prospects of being liable for injury from IT, and consequently, whether there are more or less ITs offered after Bolitho. Reasonable conjectures could be made either way, but the questions await robust empirical inquiry. On the one hand, Bolitho reduces deference to medical peers by allowing courts to find the defendant liable notwithstanding expert evidence suggesting that they conformed to acceptable peer practice. Some commentators argue that the shift to Bolitho increases liability.[22] However, Bolitho arguably shifts liability determinations to a more substantive examination of the treatment's risks and benefits[23] in lieu of the putative (and disputed) anti-innovation bias of Bolam where deviation from existing practice is indicative of negligence. If this is true, there is perhaps a better chance that courts would find ITs to be reasonable, despite their deviation from existing practice.

The empirical question was not authoritatively answered during the series and awaits research, which should aim to compare both diachronically the same jurisdiction before and after a change of the governing legal rule, and synchronically jurisdictions operating under different rules. Having said this, the weight of evidence to the MIB consultation clearly suggested that the major stakeholders did not believe that the Bolam/Bolitho test stifles innovation.[24] The relevance of Bolam and Simms v Simms[25] to IT is discussed in this special issue, by Jean McHale and Jonathan Montgomery.

In the US context, the question also relates to expert evidence admissibility rules which partially take into account professional peer opinion.[26] Professional peer opinion, and the extent of deference it ought to command are questions of self-regulation. As such, these questions converse with both legal pluralism (how tolerant the legal system is/should be to competing normative orders)[27] and sociology of the profession (the preservation of the privileges that an elite profession has acquired and resistance to

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[22] Rachael Mulheron, 'Trumping Bolam: A Critical Legal Analysis of Bolitho's Gloss' (2010) 69(3) Cambridge Law Journal 609; Oliver Quick, 'Patient Safety and the Problem and Potential of Law' (2012) 28(2) Journal of Professional Negligence 78 (who observed that of the 29 reported medical negligence cases decided since Bolitho, 16 were decided in the claimant's favour).

[23] This is disputed. See: Mulheron ibid; Evans Chan, 'Legal and Regulatory Responses to Innovative Treatment' (2013) 21 Medical Law Review 92; Keren-Paz and El Haj (n 20).

[24] The consultation did not ask, and consultees did not answer what, if any, was the effect of the shift from Bolam to Bolitho on innovation.

[25] [2002] EWHC 2734 (Fam). This (pre-Mental Capacity Act) decision concerned the application of Bolam and the best interests tests to two incapacitated patients (aged 16 and 18) in relation to access to IT for variant Creutzfeldt-Jakob disease.

[26] Frye v United States 293 F. 1013 (D.C. Cir. 1923); Daubert v Merrell Dow Pharmaceuticals,Inc., 509 U.S. 579 (1993); General Electric Co. v Joiner 522 U.S. 136 (1997); Kumho Tire Co. v Carmichael, 526 U.S. 137 (1999): discussed by Parchomovsky and Stein, (n 4) 296-8.

[27] Sally Merry 'Legal Pluralism' (1988) 22(5) Law and Society 881; Lee J Black, 'Ethics and Law, and Ethics as Law: Legal Pluralism and the Normative Relationship between the State and the Medical Profession' (Ph.D. Dissertation, McGill, 2017) <http://digitool.library.mcgill.ca/webclient/StreamGate?folder_id=0&dvs=1531478644857~742> (accessed 13 July 2018).

outside scrutiny and control.)[28] Conversely, Bolitho's gloss could be understood as an attempt by another elite profession—the judiciary, and more broadly lawyers—to ensure that they, rather than clinicians, have the last say in medical malpractice matters.

A third tort debate relates to the role of consent and patients' autonomy in medical care. This is a broad issue, pertaining to medical law beyond tort law,[29] and to tort law in non-medical contexts.[30] In the IT context, two questions present themselves: (a) whether there is a need for a different test for informed consent to ITs given their special features (potential conflict of interests, similarity with research, reduced foreseeability and optimism bias),[31] and what is the relationship between the reasonableness of the offered treatment and the patient's consent; and (b) given that the acceptability of the risk to benefit portfolio is essentially subjective, can a patient consent to something that objectively is considered as reckless or futile?[32]

Several contributions tackle both the role of consent in ITs and its relationship with the reasonableness of offering IT (Tina Cockburn and Michael Fay, Jonathan Montgomery, Tsachi Keren-Paz), and the relationship between IT and research (Nayha Sethi, Jean McHale and Sarah Devaney). The most sustained treatment of consent to ITs is offered by Cockburn and Fay, who criticise the MIB for practically ignoring the issue of consent in the suggested reform. They highlight the possibility that an undisclosed financial gain from the treatment might vitiate consent altogether and give rise to liability under battery, argue that the fact the treatment is innovative and the risks unknown is material and should be disclosed, and stress the relevance of the distinction between innovation where conventional treatment has failed, and where innovative therapies are arguably unnecessary because lower risk alternatives exist.

Keren-Paz highlights three special features of ITs which are relevant to informed consent and its relationship with professional peer review of the treatment. First, 'known unknowns' may increase treatment risks; second, optimism bias—of both patients and clinicians—might undermine patients' ability to provide informed consent; and third, a SIROT pattern—significantly improved results over time—might exacerbate optimism bias, might reflect a potential conflict of interests affecting the clinician, and problematise the evaluation of the treatment as in the patient's best interests. Understanding ITs as typically involving SIROT might also elucidate the relationship between the clinical acceptability of the treatment (the Bolam/Bolitho test) and informed consent, including whether informed consent can transform what is otherwise an unreasonably risky treatment to a reasonable one.

Jonathan Montgomery also considers the relationship between the clinical acceptability of the treatment, and the patient's informed consent. On his analysis, the former is a

[28] Dietrich Rueschemeyer, 'Professional Autonomy and the Social Control of Expertise' in Robert Dingwall and Philip Lewis (eds), The Sociology of the Professions: Doctors, Lawyers and Others (Quid Pro, LLC 2014) 38.

[29] Sidaway v Board of Governors of the Bethlem Royal Hospital Governors [1985] AC 871; R v Ian Paterson [2017] EWCA Crim 1625.

[30] James Goudkamp, Tort Law Defences (Hart 2013).

[31] Chan (n 23); Parchomovsky and Stein (n 4), Keren-Paz and El Haj (n 20).

[32] Keren-Paz and El Haj (n 20).

question of the validity of offering an IT, and the latter, of accepting it. The latter's validity is determined both by capacity to consent and by the requirement that such consent be informed. Montgomery applies and develops this model to the special cases, such as of Charlie Gard, where the patient is an incapacitated minor, and therefore a question arises as to the parents' capacity (and the role of court oversight) to accept an IT with questionable efficacy. Central to Montgomery's article is analysing the Charlie Gard case through the lenses of tragedy in its Greek/ Shakespearian form: hubris and refusal to compromise reasonably with what the protagonists see as evil leading to consequences which are deeply destructive, despite good intentions.

A fourth tort law debate the series contributes to concerns tort reform. While the term is American, similar debates exist in the UK under the banner of 'compensation culture'.[33] The politics underlying calls for tort reform is a right-wing concern for protecting business from (often exaggerated) costs of liability, accompanied by an individualistic ideology which champions victim's responsibility to protect themselves from the injury or its consequences. This exists alongside a state minimalism ideology which favours limiting the role of tort law (which is perceived as a state mechanism to redistribute the costs of accidents, or the costs of doing business). [34] Tort reform is critiqued from the left (or centre-left) as regressive, empirically unfounded, providing unjustified subsidy to businesses, and therefore inefficient, and undermining civil liberties—access to courts—and by consequence, unconstitutional.[35]

Against this context, the MIB, and the AMTIA could be understood as failed attempts to curtail the normal protection afforded by tort law through a reform, which, if successful, would have left patients with reduced protections against irresponsible treatment. The contribution of Jose Miola - a leading academic voice against such reform - continues to converse with the tort reform debate (while also contributing to an analysis of the dividing line between research and ITs). Miola focuses on the database of ITs seemingly created by AMTIA, observing that: this was not an idea conceived by the creators of the MIB (and was only reluctantly adopted); the AMTIA only permits the Secretary of State to create a database of ITs; and the desirability of the database could be questioned. The two main issues discussed by Miola (in addition

[33] Richard Lewis, Annette Morris, and Ken Oliphant, 'Tort Personal Injury Claims Statistics: Is There a Compensation Culture in the United Kingdom?' (2006) 14 (2) Torts Law Journal 158.

[34] George Priest, 'The Current Insurance Crisis and Modern Tort Law' (1987) 96 Yale Law Journal 1521; Deborah J. La Fetra, 'Freedom, Responsibility and Risk: Fundamental Principles Supporting Tort Reform' (2003) 36(3) Indiana Law Review 645; Philip K. Howard, The Collapse of the Common Good: How America's Lawsuit Culture Undermines Our Freedom (Ballantine Books 2001).

[35] See e.g., Koenig, Thomas and Michael Rustad, 'His and Her Tort Reform: Gender Injustice in Disguise' (1995) 70 Washington Law Review 1; Geoff Boehm, 'Debunking Medical Malpractice Myths: Unraveling the False Premises Behind "Tort Reform"' (2005) 5 Yale Journal of Health Policy, Law and Ethics 357; J. Chase Bryan and others, 'Are Non-Economic Caps Constitutional?' (2013) 80 Defence Counsel Journal 154. Morton Horwitz famously described the purpose and effect of 19th century American tort law as providing subsidy to enterprise (the railway companies were a prime example) from claims by employees and customers: Morton Horwitz, The Transformation of American Law 1970-1960 (Oxford University Press 1992).

to costs) are the potential undermining of patients' confidentiality and the possibility that by enabling easier dissemination of results of ITs, the database might undermine the incentive to undergo clinical trials. These problems tie in with the general approach of the MIB/AMTIA, which is almost exclusively doctor-centric. As noted above, this focus on defendants/business' interests is emblematic of a tort reform agenda.

And yet, positioning the MIB/AMITA as an example of tort reform might be doubted because the relevant 'industry'- the UK medical establishment - almost entirely opposed the reform.[36] That the draft legislation was ill-suited to achieve its intended effect - a pre-ruling which would eliminate the risk that ex-post court scrutiny would find the intervention negligent - could also explain why the reform did not come to pass.[37] Yet, the question which remained unresolved after Seminar Three is whether other reform was necessary and feasible. We have mentioned above the questions of judicial versus medical autonomy in setting the required standard and the gap between theoretical economic models and empirical findings. Innovators (and clinicians in general) might be operating under optimism bias (and several other biases, such as availability bias), but a well-known critique of the negligence standard is that it is subject to a hindsight bias.[38] Which bias creates the greatest distortion is an empirical question that requires further research. It is still an open question, whether a more robust mechanism of peer review (Bolam) and judicial scrutiny (Bolitho) could take place prior to the decision to proceed (and hence prior to the injury) thereby preventing hindsight bias while still securing patients' safety. But is this suggestion manageable and feasible? Moreover, if as the evidence suggests, current rules of tort law do not stifle innovation, why fix what ain't broken?

The answer to this question also converses with tort theory, which is the fifth and last debate to which the series contributes. The content of tort rules about liability and compensation depends on tort law's goal(s). Ought its goal(s) be to compensate for losses,[39] annul wrongful losses,[40] rectify wrongs,[41] deter inefficient behavior[42] or vindicate rights?[43] On both the compensation and deterrence accounts, a crucial

[36] See: National Assembly of Wales Health and Social Care Committee, Report on Legislative Consent Memorandum for the Medical Innovation Bill, (29 January 2015), paras 17-20; David Hills, 'Bad Consultation, Bad Bill' (Wordpress, 23 January 2015) https://wanderingteacake.wordpress.com/the-saatchi-bill-2/bad-consultation-bad-bill/ (accessed 28 October 2018).

[37] José Miola, 'Bye-bye Bolitho? The Curious Case of the Medical Innovation Bill' (2015) 15(2-3) Medical Law International 124.

[38] See: Jeffery Rachlinski, 'A Positive Psychological Theory of Judging in Hindsight' (1998) 65(2) University of Chicago Law Review 571.

[39] Patrick Atiyah, The Damages Lottery (Hart Publishing 1997).

[40] Jules Coleman, Risks and Wrongs (Cambridge University Press 1992).

[41] Robert Stevens, Torts and Rights (Oxford University Press 2007).

[42] Steven Shavell, Economic Analysis of Accident Law (Cambridge University Press 1987).

[43] Norman Witzleb and Robyn Carroll, 'The Role of Vindication in the Law of Remedies' (2009) 17

Tort Law Review 16.

question is whether the costs of liability for medical mishaps are borne by the health care system (clinicians and institutions) or by the public, mainly by other patients? The answer might depend on the ways different health care systems are structured and funded (mainly, but not only, on whether the health care system is private or public), and on how liability is insured. This crucial question is often neglected in the literature, both in terms of insufficient jurisdictional sensitivity and by inconsistently assuming at some places that the costs are borne by the health care system and at others, by patients.[44] The MIB's underlying assumption was that reform was required to increase the supply of ITs not offered due to fear of liability. It implicitly assumed that (a) current law stifles innovation; and (b) that the net social value of the foregone innovation is positive (namely that the benefits from more useful and responsible innovations will outweigh the harm from increased irresponsible innovations). But even if the instrumental case for reform (in the direction of reducing liability) is unsound, perhaps tort theory's commitment to justice, can support a reform?

The choice between liability regimes, mostly between negligence and strict liability in the context of accident law is a major battleground in tort theory and the terrain covers arguments in terms of efficiency,[45] corrective justice,[46] fairness[47] and equality.[48] Two contributions focus mainly on fairness as justifying strict liability for injuries from ITs (Tsachi Keren-Paz, who also examines efficiency) and its limitations (Gregory Keating). Applying Stoljar's concept of unjust sacrifice to IT, Keren-Paz develops a restitution-based justification for strict liability (no-fault) towards injuries from ITs. The SIROT pattern makes it fair for future patients, who benefit from the knowledge gathered from injuries to first in time patients, to share the costs of the injuries which brought about this knowledge. The treating physician is a good proxy to the benefits captured by future patients so strict liability is fair.

Keating examines this case from the perspective of fairness, by situating it on a continuum spanning from rabies' treatments to universal immunization. For Keating, the crucial questions are identifying the relevant community of risk, intergenerational justice, the quality of consent and the related extent to which a lesser harm is pursued consciously (a rescue paradigm), and (following Tony Honore) the relevance of a political judgment in deciding the level at which risks should be distributed. This latter point opens up for further consideration whether strict liability is indeed to be equated with a no-fault scheme, as is implicitly assumed in Keren-Paz's argument.

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[44] See e.g., Ariel Porat, 'Offsetting Risks' (2007) 106 Michigan Law Review 243, 264-6 (discussing defensive medicine and assuming that costs of liability are internalised by physicians), 268 (the drawbacks from liability 'are shouldered by the patient, with the result that the excessive liability leads to a diminishment in the overall utility a patient can derive from her doctor's services').

[45] See e.g., Robert Cooter, 'Prices and Sanctions' (1984) 84 Columbia Law Review 1523.

[46] See e.g., Richard A. Epstein, 'A Theory of Strict Liability' (1973) 2 Journal of Legal Studies 151.

[47] George Fletcher, 'Fairness and Utility in Tort Theory' (1972) 85(3) Harvard Law Review 537; Gregory C. Keating, 'Distributive and Corrective Justice in the Tort Law of Accidents' (2000) 74 Southern California Law Review 193.

[48] See e.g., Tsachi Keren-Paz, Torts, Egalitarianism and Distributive Justice (Ashgate 2007).

Tort theory, especially from the law and society and legal realism lineage (and alongside other branches of legal theory), is also interested in the relationship between legal and non-legal sanctions, and in particular, the role of reputation in curbing anti-social behavior. A central question is whether and how reputational loss from the underlying event and/or the legal response should be taken into account by courts and regulators in setting sanctions. This is explored mainly in the context of repeat players such as businesses and professionals.[49] Sarah Devaney contributes to this debate by exploring the role of reputation in the regulation of medical research. Devaney explores, with a focus on recent high-profile research misconduct cases, how the 'winner-takes-all' paradigm pressures researchers and might lead some to unethical or scientifically dubious conduct. Situating her argument within the smart regulation literature, Devaney demonstrates how solidarity, which she identifies as a main feature of research communities, makes reputation - both positive and negative - a useful regulatory tool and offers several reforms to inculcate researchers' concern for reputation to reduce the incidence of research misconduct. Keren-Paz, in concluding that strict liability is unlikely to reduce efficiency (and might even be efficient, although any significant effect could be doubted[50]) also relies, in examining clinicians' incentives, on the reduced reputation loss that each finding of liability is likely to produce under a strict liability rule.[51]

So far, we have discussed five conversations endemic to tort law, with which contributions to the special issue, and more broadly the seminar series, engage: deterrence, deference to expert opinion, the role of consent, tort reform and tort theory. However, the relationship between innovation and liability, is relevant to at least four conversations which are external to tort law. First, when tort law is understood (within an instrumental tradition, such as economic analysis of law) as one regulatory option, there is the question of its relationship with other regulatory tools such as disciplinary proceedings, professional/ethical codes of practice, criminal law and regulation.[52]

Second, tort law (and possibly law in general) has only a limited role to play in the advancement of innovation. An innovation agenda is political currency across jurisdictions, political economies and constitutional regimes and transcends the boundaries of medical or scientific innovation. The historian Yuval Noah Harari ties the commitment to innovation (and more generally reform and change) with modernity, commenting that it would be political suicide for a political party to endorse in its platform that it will attempt to maintain the status quo.[53] Commitment to innovation is found, for example, within academia, by using innovation as a criterion for assessing

[49] See e.g., Peter Cartwright, 'Publicity, Punishment and Protection: The Role(s) of Adverse Publicity in Consumer Policy' (2012) 32 Legal Studies 179.

[50] From patients' perspectives, because a treatment is hoped to be in their best interest, the positive externality to future patients involved in ITs is not likely to create a cooperation problem deterring them from submitting to the treatment.

[51] Keren-Paz (n 20).

[52] Peter Cane, 'Tort Law as Regulation' (2002) 31(4) Common Law World Review 305**;** Willem van Boom, Meinhard Lukas and Christa Kissling (eds), Tort and Regulatory Law (Springer 2007).

[53] Yuval Noah Harari, Sapiens: A Brief History of Humankind (Harper 2011) 365.

research and teaching excellence, and for making funding, promotions and recruitment decisions.[54] Broadly speaking, and being mindful of the well-known caveats, intellectual property, and especially patent law is all about rewarding and incentivising innovation. Within science, and especially medical science, the main barriers for innovation are funding and regulation[55] (here, narrowly conceived) rather than liability, as concluded in seminars one and six.

Third, in the medical context, the broader regulatory framework of innovation has to define 'treatment', 'IT' and research and appreciate the overlap between the three; and also decide how to regulate each, including consideration of whether a more unified approach is called for research/IT or innovative/standard treatment.[56] Finally, we have noted above the complex relationship between objective determinations of whether the treatment is appropriate (which is arguably another way of asking whether it is in the patient's best interests, which according to Bolam requires acceptance as appropriate by peers) and the patient's subjective wishes, which is a question of informed consent. These questions become especially thorny in the case of patients who lack capacity, for whom the law has to determine the validity and conclusiveness of advance healthcare directives (when available), the roles of proxies (such as parents for young children and infants) and the level of courts' oversight.[57] A subset of such cases involves incapacitated patients whose condition is fatal and for whom an IT or participation in a clinical trial is offered. The recent high-profile UK Charlie Gard case, which (alongside the Alfie Evans case) attracted global attention, is analysed by Jonathan Montgomery, together with the typical issues such cases pose to the regulation of (arguably innovative) treatment of incapacitated persons.

Several other articles in this special issue, as well as seminars Four (the role of disciplinary proceedings) and Six (regulation of research) contribute to these four debates. Despite the prediction that clinicians are likely to be more concerned about adverse findings in disciplinary proceedings than about civil liability in torts, there is no clear evidence that disciplinary proceedings stifle innovation. Accordingly, the

[54] The new organisation directing research funding in the UK is called UK Research and Innovation; and the quality of research outputs is assessed based on 'originality' (alongside rigour and significance). Innovation in learning and teaching is a criterion both in the new Teaching Excellence Framework <https://www.officeforstudents.org.uk/advice-and-guidance/teaching/> (accessed 28 October 2018) and in many universities' academic promotion proforma. There is also increased number of academic posts with 'innovation' in the post's title.

[55] See e.g., Shuai Xu and Aaron Kesselheim, 'Medical Innovation Then and Now: Perspectives of Innovators Responsible for Transformative Drugs' (2014) 42 Journal of Law, Medicine and Ethics 564; Justine Cadet, 'CRT: Lack of Funding is Stifling US Medical Innovation' Cardiovascular Business (Cardiovascular Business, 8 March 2011) <https://www.cardiovascularbusiness.com/topics/coronary-intervention-surgery/crt-lack-funding-stifling-us-medical-innovation> (accessed 28 October 2018).

[56] See e.g., Therese Murphy 'Repetition, Revolution and Resonance' in Therese Murphy (ed), New Technologies and Human Rights (Oxford University Press 2009) 1; Brierley and Larcher, 'Compassionate and Innovative Treatments in Children: A Proposal for an Ethical Framework' (2009) 94 Arch Dis Child 651.

[57] See e.g., Re B [1987] 2 All ER 206.

relative weight of disciplinary proceedings vis-à-vis tort liability (and the related question whether changes to the rules about the scope of civil liability are likely to matter as long as the exposure to responsibility under disciplinary proceedings remains intact) are yet to be explored, although the effect of disciplinary proceedings might be small.

The role of criminal law, and of other regulatory tools, at times alongside tort law, is explored in contributions by Tina Cockburn and Michael Fay, Jean McHale, Sarah Devaney, and Nayha Sethi, with particular reference to Paulo Macchiarini and Ian Paterson. Thus Cockburn and Fay call for a better regulatory framework for ensuring meaningful consent to ITs; McHale calls for regulating innovating treatments in tandem with research under the auspices of the Health Research Authority (HRA); Sarah Devaney explores the potential of reputation-enhancing regulatory tools; and Nayha Sethi posits the usefulness of the concepts of continuum and liminality to understanding the relationship between treatment, innovation and research and to a superior regulatory approach. Definitional uncertainty, the barriers between research and IT and the case for a more aligned regulation of both are also discussed by McHale. The contested usefulness of the database of IT permitted by the AMTIA to the innovation/barriers agenda (alongside a broader discussion of the relationship between IT and research) is considered by Jose Miola.

The relationship between research and ITs and how the two should be defined and regulated is at the centre of Nayha Sethi, Jean McHale and Sarah Devaney's contributions. Sethi begins with exploring some of the ways in which the received treatment-research distinction is collapsing due to increasingly blurred boundaries within healthcare and health research, and that in order to better understand and regulate innovation, we must appreciate its relationship to treatment and research. She then argues how the anthropological concept of liminality, with its preoccupation with transformation, thresholds and processual and experiential dynamics could enable a better regulatory approach to ITs, treatments and research. This could be achieved by better acknowledging that standard treatment, IT and research are on a continuum, and, crucially, explicitly acknowledging that both therapeutic and research activities and intentions may coincide. Additionally, she argues that regulatory approaches need to better account for, and reflect the experiences of actors implicated within the innovation setting.

The blurred line between innovation and research, and the commonality of experimentation in both, is also highlighted by McHale. Noting the absence of an adequate regulatory framework for ITs, she supports applying aspects of the regulatory framework of research to IT, while acknowledging that the existing research framework is far from perfect. McHale views the existence of the database, authorised by the AMTIA as a potentially significant breakthrough in that it recognises the need for evidence-based medicine, embeds the idea that departure from 'accepted practice' needs to be documented, and could ultimately lead to enhanced transparency of decision making and enhanced availability of data regarding innovation. McHale's and Sethi's views are in some tension with Miola's skepticism about whether a database of IT is a good idea, and in particular, whether it is likely to undermine incentives to recruit participants in clinical trials. While acknowledging AMTIA's definitional challenges as to what ought to be included in the database, both McHale and Sethi consider the database as a potential positive step towards a more unified regulatory approach to ITs

and research (McHale) and an appreciation of IT as a liminal space (Sethi). Indeed, as McHale's call for better aligning (and improving) the regulatory framework of research and ITs attests to, a comprehensive regulatory framework ought to ensure that negative results are recorded and are easily accessible to enhance patients' safety, and minimize optimism bias and waste of resources. AMTIA's alleged increased oversight of ITs could also be contrasted with the likely effect of the MIB/AMTIA liability provisions, which would have likely reduced the oversight over IT, to the detriment of patient safety.

The role and relevance of new technologies—such as robots and artificial intelligence in diagnosis and treatment[58] - did not feature explicitly in the series. However, the general conclusions about the relationship between legal and professional liability and (1) willingness to innovate, (2) the required level of consent and (3) the appropriate level of redress are presumably pertinent here as well, although more detailed attention is required. As the emerging debate in the context of autonomous cars demonstrates,[59] artificial intelligence in particular might raise special questions with regards to the 'authorship' of mishaps and hence to the allocation of responsibility.

In the Australian case, Mount Isa Mines Pty Ltd v Pusey, Justice Windeyer acknowledged the challenges faced by the law in keeping up with medical innovation, when he described law as 'marching with medicine but in the rear and limping a little.'[60] The articles in this special edition engage in thoughtful discussion of the blurred boundaries between IT and research, issues relating to the provision of information, risk allocation and avenues of redress, including compensation and disciplinary action. The authors make important contributions towards the development of regulatory responses to IT which aim to balance the interests of clinicians, patients and society and encourage responsible innovation.

[58] See e.g., Fei Jiang and others, 'Review: Artificial Intelligence in Healthcare: Past, Present and Future' (2017) 2(4) Stroke and Vascular Neurology 230 <http://dx.doi.org/10.1136/svn-2017-000101> (accessed 28 October 2018); Michael Carson and Greg McEwen, 'Artificial Intelligence Misdiagnosis: Who is to Blame?' (Lawyer Monthly, 27 February 2018) <https://www.lawyer-monthly.com/2018/02/artificial-intelligence-misdiagnosis-who-is-to-blame/> (accessed 28 October 2018).

[59] See e.g., Kyle Graham, 'Of Frightened Horses and Autonomous Vehicles: Tort Law and its Assimilation of Innovations' (2012) 52 Santa Clara Law Review 1241; Kieran Tranter, 'The Challenges of Autonomous Motor Vehicles for Queensland Road and Criminal Laws', (2016) 16 QUT Law Review 59.

[60] (1970) 125 CLR 383, [3].