No-fault (Strict Liability) for Injuries from Innovative Treatments: Fairness or also Efficiency?

Tsachi Keren-Paz [a]*

[a] Professor of Private Law, Sheffield University

t.keren-paz@Sheffield.ac.uk I would like to thank Jane Bazeby, Tina Cockburn, Gregory Keating, Jose Miola Ariel Porat and Wendy Rogers for excellent comments on a previous draft and to Yaar Dagan and Bushra Jalil for excellent research assistance.

No-fault (Strict Liability) for Injuries from Innovative Treatments: Fairness or also Efficiency?

Innovative treatments (ITs) have a distinct SIROT pattern: they often show, and are expected to show, significantly improved results over time. Of the four IT categories discussed, two stand out: SIROT treatments which are currently not in the patient's best interest (BI) but will become superior treatment over time (category 3), and treatments which are already arguably BI but will clearly become the superior option as they improve with time (category 2).

There is a strong fairness argument to compensate patients injured from ITs because their injury brought about the improved knowledge benefitting future patients. By analogy to private necessity, IT patients should be regarded as 'rescuers' entitled to reimbursement of their costs, since future patients received an incontrovertible benefit inextricably linked to their loss. Crucially, category 2 patients also deserve compensation, notwithstanding that the treatment was in their BI.

From efficiency perspective, patients should avoid only irresponsible ITs (category 4) but they are not well-placed to identify these treatments. Patients' incentives to submit to ITs are no worse, and perhaps slightly improve under strict liability (SL): SL might provide a gentle extra incentive to undergo a treatment whose prospect as BI is in doubt but is likely to be SIROT. Finally, while under SL (but not negligence) category 2 cases yield liability, thus arguably deterring physicians from offering them, reputation loss under SL is smaller, so physicians' incentives to offer ITs might even improve and they have strong non-legal incentives to offer them.

Keywords: negligence, restitution, rescue, private necessity, clinical research

This article examines two main justifications for no-fault (strict) liability[1] towards patients injured from innovative treatments (ITs): fairness and efficiency. One contribution is analytical: identifying the special features of ITs by focusing on both their unique portfolio of risks and benefits—they typically benefit future patients due to having a pattern of significantly improved results over time (SIROT)—and informational

[1] I explain the difference between the two terms in Part 2.4.

problems affecting physicians, patients and courts. My main normative argument is that there is a strong fairness justification for strict liability (SL). The injury to early patients in ITs was a necessary and reasonable cost to confer an incontrovertible benefit on future patients: improved medical results. While I focus on ITs, the argument is largely extendable to participants in clinical trials. My second normative claim is that there is no efficiency case against SL and there might be a case for it. Physicians' incentives seem to improve due to lessened reputation loss under SL, and patients' incentives are not undermined and possibly even improve. Crucially, the analysis is sensitive to doubts whether tort law unduly stifles innovation and to the distinction between ir/responsible innovations. A central thesis I advance is that even if there is no need on efficiency grounds to tinker with the existing liability system to ensure that useful innovations sufficiently occur, there is still a strong fairness argument for SL, which is also affordable and in no way likely to produce results undesirable from a policy perspective.

The article develops two themes from my previous work. One, relating to fairness, is defending SL for injury from unforeseeable risks in a conventional treatment where the new knowledge gained from the injury advanced the state of the art.[2] Here I argue that this restitutionary rationale is even more convincing in the context of ITs and I explain the differences between ITs and unforeseeable injuries from routine treatments. The second theme, relating to efficiency, is that physicians are likely to be unaffected by the size of damages paid for their negligence since their premiums are not experience-based; but they are affected by the reputation loss triggered by being found liable; under strict lability, reputation loss for each individual physician found liable is smaller in

[2]Tsachi Keren-Paz, 'Injuries from unforeseeable risks which advance medical knowledge: restitution-based justification for strict liability' (2014) 5 Journal of European Tort Law 275.

comparison to being found liable under negligence, since there is doubt whether liability is based on negligence; therefore, physicians are likely to prefer SL over negligence.[3]

1. Special features of innovative treatments

ITs[4] have two unique features which require special attention. First, uncharacteristically to most routine treatments (but in common with immunisation programmes and treatment of contagious diseases), they might confer benefits on third parties. Second, by definition, the results of the treatment, in terms of both potential harms and benefits are less foreseeable that that of conventional treatments. I will discuss each feature in turn.

1.1 The costs and benefits of innovative treatments

The crux of ITs is that they typically offer a different, and more volatile benefits to risks profile compared with existing (including no) treatments. Typically, they would offer a high risk of complication and mortality with a small chance of significant improvement in life expectancy and quality of life. Moreover, and this is crucial, in many cases, ITs will show a pattern of significantly improved results overt time (SIROT). The reason is that the hoped-for benefit from the IT initially does not realise due to reasons which might or not be foreseeable. In response to the early failures, further medical and scientific progress is made with the ultimate result that the IT proves itself to be clearly superior to alternative treatments, to the benefit of later patients, and becomes a routine best practice.

[3] Tsachi Keren-Paz, 'Liability Regimes, Reputation Loss and Defensive Medicine' (2010) 18 Medical Law Review 363.

[4] I sidestep here important definitional issues and demarcation with clinical trials on the one side and routine treatments (including 'variation') on the other. See eg., Wendy Rogers et al., 'Identifying surgical innovation: a qualitative study of surgeons' views' (2014) 259(2) Ann Surg 273 and the contributions of Nayha Sethi and Jean McHale in this special issue.

Consider heart transplants as an example for SIROT: Two thirds of the first 100 heart transplant patients died within three months. Only after the introduction of endomyocardial biopsy by Caves in 1973 and the classification of histological rejection by Billingham results have improved. One-year survival following heart transplantation in the era 1967–1973 was 30%, in the era 1974–1980, 60%, and in the current era, it approaches a remarkable 90%.[5] Even when initial results were poor, the procedure's initiators viewed it as ethically robust since '20 percent of the people were alive' and healthy following the procedure 'would clearly be dead' without it.[6] Crucially, methods of immunological control were improved to lead to the current successful procedure in response to the experience gained from the problems of rejection. At early stages, the procedure was thought as a failure, with only two research groups continuing with heart transplants after the initial poor results.[7] As for the existing alternatives, the average heart failure patient survival estimate according to a validated medical model is about 10 years. For those with advanced forms of heart failure (for whom HT is most likely), nearly 90% die within one year.[8]

As this example demonstrates, ITs could be classified into four groups. One axis of the examination is whether at the time the IT was given it was in the patient's best interest

[5] See Christopher Watson and John Dark, 'Organ transplantation: historical perspective and current practice' (2012) 108(S1) British Journal of Anaesthesia i29, i30 <www.sciencedirect.com/science/article/pii/S0007091217321645?via%3Dihub>; Makoto Tonsho et al, 'Heart Transplantation: Challenges Facing the Field' (2014) 4(5) Cold Spring Harb Perspect Med 1 <www.ncbi.nlm.nih.gov/pmc/articles/PMC3996379/> these and all other e-journals and online sources were last accessed on 20 August 2018.

[6] See Larry Thompson, '20 Years of Heart Transplants' the Washington Post (Washington D.C, 1 December 1987) <www.washingtonpost.com/archive/lifestyle/wellness/1987/12/01/20-years-of-heart-transplants/01ecbf3d-a594-4a38-b297-964ccb154545/?utm_term=.237049afdca9>.

[7] Ibid.

[8] See Jennifer Warner, 'Heart Failure Patients Too Optimistic' (WebMD, 2 June 2008) <www.webmd.com/heart-disease/heart-failure/news/20080603/heart-failure-patients-too-optimistic>.

(BI). For the treatment to be considered BI, in the context of a claim it was negligent, there should be responsible medical opinion which, based on the information available at time the decision to treat was made, does not reject the treatment, ie., believe the treatment offered was not clearly deficient to alternative treatments,[9] and that such view is not deemed illogical by the court.[10] The second axis is whether the treatment is SIROT or not—whether its results significantly improve over time. A SIROT pattern might exist for two reasons. One, is that the procedure needs to be modified to respond to risks, either foreseeable (as organ rejection in the heart transplant example) or unforeseeable. The other reason for SIROT is surgeons' learning curve. There is clear evidence that surgeons improve with practice, even if the IT does not undergo further modifications; it may take up between 20-750 cases for surgeon to reach peak performance.[11] From a fairness/restitutionary perspective, the case for spreading the costs of injury disproportionately borne by first-in-time patients on all those benefitting is very similar, regardless of the reason for the SIROT pattern.[12] I will deal with issues of foreseeability and the duty to inform patients later on, but it will be useful, at this stage, to think of these categories both when looked upon in hindsight, for what they really are, and in foresight, for what they were hoped to be when offered.

---

[9] Bolam v Friern Hospital Management Committee [1957] 1 WLR 582; Simms v Simms [2002] EWHC 2734 [48].

[10] Bolitho v City & Hackney Health Authority [1998] AC 232.

[11] Mahiben Maruthappu et al., 'The Influence of Volume and Experience on Individual Surgical Performance: A Systematic Review' (2015) 261(4) Annals of surgery 242 <www.ncbi.nlm.nih.gov/pubmed/25072442>.

[12] The problem of increased risk to earlier patients due to learning curve outside of ITs seems to be adequately responded to in the law of negligence by insisting that the standard of care is insensitive to inexperience. See Wilsher v Essex AHA [1987] 1 QB 730; FB v Princess Alexandra Hospital NHS Trust [2017] EWCA Civ 334. However, there is evidence that inexperience is often not disclosed to patients; this might undermine patients' informed consent. See Bernadette Richards and Katrina Hutchison, 'Consent to Innovative Treatment: No Need for a New Legal Test' (2016) 23 Journal of Law and Medicine 938 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2828518>

1.1.1 BI, no-SIROT

These treatments are superior to existing alternatives even in the short run. Say that the initial poor results of heart transplants remain constant but the prospect of 20% success is still considered as superior to the alternative. In such a case, the treatment is both in the patient's BI and desirable overall. To generalise, if treatments are foreseeably BI, a decision to undergo them would not be negligent[13] whether or not a SIROT pattern is either foreseeable or discerned in hindsight. In fact, if it is foreseeable that the treatment is not SIROT, the treatment is not likely to be innovative. For reasons explained below, if a treatment was not foreseeably SIROT but turned out to be one, the no-fault restitution claim should still exist. Given both difference of expert opinion about the risk to benefit portfolio of alternative treatments and patients' autonomy to decide which risks are acceptable to them, it might be hard to agree whether a treatment was in the patient's BI (if this is litigated in the context of post-injury negligence claim). Is a 66% chance of dying within three months, coupled with a 20% (or less) chance of living normal life better or worse than a 90% chance of dying within a year, with the 10% chance of living longer but with a crippling heart condition?

1.1.2 BI, SIROT

In this category, the treatment is BI at the moment it is offered but still its results significantly improve over time. Heart transplants, as the figures above demonstrate, are clearly SIROT, so if one believes that even initially they were in the patient's BI, they are an example of a treatment which is both BI (even in the initial, less successful period) but clearly SIROT – the benefit to the later patients is clearly more significant than to early

[13] Simms (n 9).

patients, and (crucially for fairness purposes) this is not by chance: improved results were achieved in response to the initial high rate of failures in treating early patients.

1.1.3 SIROT, not-BI

These treatments are short term inferior to existing alternatives, and therefore are not in the patient's BI. However, in the long term they become a superior alternative given the lessons learnt from the first unsuccessful treatments. If, in the heart transplant example, the initial results are deemed as inferior to existing alternatives, such treatments are an example of this category.[14] If, before the IT is offered, or soon after, it is foreseeable that the treatment is not-BI, it is negligent to offer it (outside of a clinical trial). If the treatment was foreseeably BI and turned out to be not, and has a SIROT pattern, a case for no-fault compensation still exists.

1.1.4 No-SIROT, not-BI (irresponsible/inferior innovation)

These treatments are inferior to existing alternatives both in the short-run (and are therefore not in the patient's BI) and in the long run (and are therefore undesirable even from an aggregate perceptive). When they are foreseeably so, it will be negligent to offer them,[15] but an IT might be believed to be arguably BI at the time but prove as neither SIROT nor BI with hindsight. Here too, one can imagine either an overly risky treatment with no-SIROT pattern, or a very risky treatment, that while improving over time, still remains inferior to alternative treatments at the peak point (consider 90% mortality within

[14] Historically, there are many examples of SIROT (e.g. laparoscopic cholecystectomy) but many surgeons now agree that the way those ITs were introduced is unacceptable. For a contemporary IDEAL framework on evaluating surgical innovations see Allison Hirst et al., 'No Surgical Innovation Without Evaluation: Evolution and Further Development of the IDEAL Framework and Recommendations' (2018) Annals of Surgery (forthcoming, Epub ahead of print) <https://doi.org/10.1097/SLA.0000000000002794>.

[15] The synthetic trachea transplants offered by Paolo Macchiarini might be a good example. For discussion see Jean McHale's contribution in this special issue.

three months reduced to 60%, in comparison to 10 years of expected life with limited, yet bearable quality of life offered by alternative treatments). SIROT, therefore, could be understood either as any pattern of improved results over time, or as limited to cases in which a tipping point is reached, so a treatment which was initially inferior to existing alternatives becomes superior. In classifying the IT as inferior or not, one should distinguish between iatrogenic injuries—caused by the treatment itself—as distinct from adverse effects due to the underlying condition itself,[16] which is merely another way to say that the IT was unsuccessful, and perhaps, futile.

1.2 Foreseeability, biases, asymmetrical information and informed consent

In addition to the SIROT pattern which distinguishes ITs from most treatments, the uncertainty surrounding their results is another important feature bearing on the appropriate liability regime. This is relevant for determining whether both the treatment is foreseeably BI, and material risks were disclosed to the patient.[17] Whether ITs should give rise to strict, fault-based or no liability, is complicated due to: the limited information available at the time clinical decisions are taken about the likely results;[18] the problems of hindsight and optimism biases;[19] physicians' potential conflict of interests between the patient's BI and the prospect of future benefits to future patients (with the potential for

[16] Keren-Paz (n 3) note 31.

[17] Both are needed under a negligence framework. See Montgomery v Lanarkshire Health Board, [2015] UKSC 11 [61], [82]-[83].

[18] Richards and Hutchinson (n 12).

[19] Jeffery Rachlinski, 'A Positive Psychological Theory of Judging in Hindsight' (1998) 65(2) University of Chicago Law Review 571 <https://chicagounbound.uchicago.edu/uclrev/vol65/iss2/4/>; Megan Miller et al., 'Ethical Issues in Surgical Innovation' (2014) 38(7) World J Surg 1638 <www.ncbi.nlm.nih.gov/pubmed/24728580> (discussing optimism bias, conflict of interests and the challenges they create for informed consent).

reputational and financial gain to the physician initiating the IT);[20] and the effect of all of the above on the patient's ability to form informed consent to the treatment.

Clearly, not every adverse result—ex-post failure—is ex-ante unreasonable risk taking (negligence). When the court is faced with an adverse result of an IT, it will be difficult to assess to which of the four categories the treatment belongs. The problem seems to be systemic. By definition, since the treatment is innovative: its results are uncertain; it will take time until sufficient number of case studies/data has accrued to become statistically significant (so reliable to draw conclusions about the treatment's desirability); and specifically, it will take time to ascertain whether a SIROT pattern exists. One might reply that, in England at least, what matters is whether experts back up the IT. This is largely correct but merely pushes the epistemic difficulties to the experts rather than to courts.[21] The responsible body of peers will also be unable to know whether at the time the clinical decision was made (and in all likelihood, at the moment they testify) the IT was BI or not and was likely to be/no-SIROT.

Like any negligence determination about medical treatments, ITs, whose prospect of success is by definition uncertain, are susceptible to hindsight bias. Courts might erroneously conclude—given that it is yet unknown at the time of litigation that the

[20] See eg., Miller ibid; Tracey Chan, 'Legal and Regulatory Responses to Innovative Treatment' (2013) 21(1) Medical Law Review 92 <https://academic.oup.com/medlaw/article/21/1/92/949163>; Wendy Rogers and Jane Johnson, 'Addressing Within-Role Conflicts of Interest in Surgery' (2013) 10(2) Journal of Bioethical Inquiry 219 < https://link.springer.com/article/10.1007%2Fs11673-013-9431-1>.

[21] For the uncertainty whether courts cannot examine, as part of Bolitho's 'illogical' test, the treatment on its own merit see Rachel Mulheron, 'Trumping Bolam: A Critical Legal Analysis of Bolitho's "Gloss"' (2010) 69(3) Cambridge Law Journal 609 <https://www.cambridge.org/core/journals/cambridge-law-journal/article/trumping-bolam-a-critical-legal-analysis-of-bolithos-gloss/12E1A801046FFA958F745BC5E83776DC>.

treatment's benefits outweigh its risks—that a treatment which was in fact BI, though unsuccessful, is inferior (or SIROT[22]) and therefore unreasonable.[23]

A related difficulty is the extent to which the harm or benefit resulting from the ITs are foreseeable.[24] To be sure, unforeseeable risks and benefits should be excluded from negligence determinations. Moreover, whether the IT will prove over time as BI or SIROT is not likely to be known with any degree of certainty before the patient's litigation is over. The IT context might involve, to use Donald Rumsfeld's terminology, known unknowns, and perhaps even unknown unknowns.[25] We might not know the specific risk from the course of action but do know that the nature of innovative treatments involves risks, and probably benefits, that are currently unknown. Whether such known unknown risks (and benefits) should be considered as foreseeable could be disputed;[26] the answer to the question will obviously affect the conclusion whether a failed treatment is negligent or not. In any event, the facts that the treatment is innovative

[22] Whether SIROT not-BI ought to be considered as negligent might be debated, at least in law and economic quarters (see Part 3); doctrinally it clearly is (at least if courts are faithful to their rhetoric). See Walker-Smith v GMC [2012] EWHC 503 (Admin).

[23] Whether, despite self-warning rhetoric, courts substantially find defendants liable, due to hindsight bias, when they should not have, is at the crux of the defensive medicine debate. A common reference to the proposition that English courts, at least, get it right, is Simms (n 9) [48]. But Simms is an exceptional case in which court's oversight was done in foresight and was therefore not subject to hindsight bias.

[24] The problem of hindsight bias is broader then unforeseeable risks. A risk might be foreseeable but small enough (when looked ex-ante) to ignore, but might lead to liability, since, given hindsight bias, is mistakenly assessed ex-post to be more significant than it really was.

[25] 'Donald Rumsfeld Unknown Unknowns !' (YouTube, 7 August 2009) <www.youtube.com/watch?v=GiPe1OiKQuk>.

[26] See (outside of ITs context) Justin Pidot, 'Governance and Uncertainty' (2015) 37 Cardozo Law Review 113, 179 <https://digitalcommons.du.edu/cgi/viewcontent.cgi?article=1013&context=law_facpub> (known unknowns are foreseeable); Vicky Chico, 'Known unknowns and unknown unknowns: the potential and the limits of autonomy in non-disclosure of genetic risk' (2012) 3 Journal of Professional Negligence 162, 166 <https://core.ac.uk/download/pdf/42610790.pdf> (same).

and therefore 'known unknowns' are likely should be considered as material, so failure to disclose them should lead to liability.[27]

Both the physician offering the IT and the patient accepting (or pushing for[28]) it might operate under an optimism bias, whose effect is to erroneously overestimate the chances of success and underestimate the chances of adverse result.[29] Again, this is a general problem in (medical) decision making that might be exacerbated in the context of ITs. For example, the prospect of something going wrong due to known unknowns might be especially discounted and the framing of the treatment as innovative (whose connotation is much more positive than experimental, unproven, or untested) might contribute for that. Optimism bias might also cause the physician to erroneously (even if innocently) believe that a SIROT treatment is in the patient's BI, thus ignoring or minimising risks suggesting that only in the long run the treatment will become a superior alternative. The systemic prospect of conflict of interests—that the physician might reap significant benefits in the future from SIROT treatments—might exacerbate this optimism bias (or even cause her to mislead the patient). Optimism bias might also cause the patient to misinterpret the information presenting the IT as category 3 (not in their BI) as a category 2 (BI).[30]

[27] See Cockburn and Fay in this special issue, discussing also whether liability should be in negligence or battery.

[28] That ITs are partially a patients' driven phenomenon was acknowledged by several stakeholders in Nuffield Council on Bioethics' Roundtable 'Novel medical treatments: innovation, hope and headlines', held in London on 19 April 2018. See also Jonathan Montgomery's contribution to this special issue.

[29] Rachlinski (n 19).

[30] Camilla Scanlan, Cameron Stewart & Ian Kerridge, 'Decision Making in the Shadow of Death' (2016) 16(5) The American Journal of Biothethics 23 <https://doi.org/10.1080/15265161.2016.1161404>.

Above all, it should be recalled that real-life prospects are messy and are often in the grey area. Modern quacks aside,[31] the likely scenario for IT is that the physician herself is uncertain whether the IT is likely to be successful, and whether it will prove in the long run to be inferior, SIROT or BI. She hopes it is going to be successful and she naturally believes that what she offers is not merely a SIROT (category 3) but also BI (category 2) treatment. I doubt that there are many physicians out there who cynically realise that the treatment is not in the patient's BI but might become SIROT and try to misrepresent it as BI treatment.[32] Far more likely is the scenario that the physician sincerely believes that the IT is very promising, is very likely to be SIROT and is hopefully also in the patient's BI. It is here, where optimism bias and conflict of interests might operate to push for a treatment which in fact might not be in the patient's BI. Finally, recall that patients' autonomy to decide which risks are acceptable to them might make the same treatment in one patient's BI, but not in another's, and that BI determinations are hard to make, and under negligence, done in retrospect so are prone to hindsight bias. For example, on the statistics mentioned above, reasonable minds could differ on whether the first heart transplants were in the patients' BI—after all most teams attempting them stopped due to the initial poor results—but few would dispute that they became a clear SIROT. The critique that informed consent is unattainable due to patients' limited ability to understand the risks and the power gap with physicians is well known.[33]

---

[31] See Jose Miola, 'Bye Bye Bolitho? The Curious Case of the Medical Innovation Bill' (2015) 15(2-3) Medical Law International 124, 152-3 <http://journals.sagepub.com/doi/pdf/10.1177/0968533215605667>, Sarah Devaney in this special issue documents few scoundrels, suggesting there 'is evidence that these high profile examples are the tip of the iceberg of poor practice in science'. See also the case of Ian Patterson, discussed by Cockburn and Fay and Jean McHale in this issue.

[32] But see Devaney, ibid.

[33] See eg., Onora O'Neill , 'Some Limits of Informed Consent' (2003) 29 Journal of Medical Ethics 4 <http://dx.doi.org/10.1136/jme.29.1.4>; Ann Kelly 'Research and the Subject: The Practice of Informed Consent' (2003) 26(2) Political and Legal Anthropology Review 182 <

In the context of ITs the added problem of 'known unknowns' (and perhaps also of 'unknown unknowns') and the background conditions magnifying optimism bias (conflict of interests, severe underlying condition of candidates to ITs) might cause us to further doubt such feasibility.

2. Fairness

2.1 The case for strict liability

In the paradigmatic case of SIROT (category 3, but applicable also to 2), the restitutionary/fairness case for SL is based on what Stoljar called unjust sacrifice: the inextricable link between the loss to the patient and the benefit to future patients.[34] There is no way to confer the benefits to future patients, to move, in the heart transplant example, to the improved 10% long run mortality, without incurring the short term 67% (or higher) mortality. The case for SL for ITs is even stronger than that for injury from unforeseeable risks, since in the latter, there was a need for only one person to be injured to change the state of the art, so arguably only one future alternative patient was saved, while with ITs, clearly many will benefit but some have to suffer the loss. So while with regards to conventional treatments, one can doubt whether the intervention is indeed beneficial/successful (and as such justifies restitution despite absence of altruistic motive),[35] no such doubts exist with regards to IT cases.

All SIROT treatments, whether initially superior to alternative treatments (and therefore in the patient's BI) or not, present a strong case for SL. This proposition is most

https://anthrosource.onlinelibrary.wiley.com/doi/full/10.1525/pol.2003.26.2.182>. Cf in the context of high risk medical procedures: Scanlan et al., (n 30).

[34] Samuel Stoljar, 'Negotiorum Gestio', in: Ernst von Caemmerer and Peter Schlechtriem (eds), International Encyclopedia of Comparative Law, Volume X (Brill, 2007), chapter 17.

[35] See Keren-Paz (n 2) 290-92, for the challenge and an explanation why it is unconvincing.

intuitive in category 3 cases (SIROT, not-BI). It is easy to see the link between the patient's loss and future patients' benefit when at the time the treatment is attempted it is inferior to existing treatments. In such cases, whether consciously or not, the claimant is a Guinea Pig of sorts: by submitting to a treatment which is inferior to existing alternatives but that with time, and due to (knowledge gained from) her injury, she confers a significant and incontrovertible benefit on future patients. Unless her costs are reimbursed, this amounts to unjust sacrifice. The justification for no-fault compensation exists whether the claimant was aware of the SIROT not-BI pattern (as in clinical trials, or where informed of that pattern and agreed to partake, notwithstanding the fact the treatment should not have been offered) and whether she was misled to believe that it was in her BI while it was not.

Perhaps less intuitively, the argument works also in category 2 cases (BI, SIROT), which currently, under negligence (and unlike category 3) do not lead to liability. Under the assumption that the harm suffered by the patient is what advances the state of the art and allows for improved results to future patients, the claimant still provides a benefit inextricably linked with the harm she suffered and is still exposed to disproportionate high risk, and not only to the misfortune of suffering a random harm by a member in the same community of risk.[36] Indeed, similar to injuries from unforeseeable risks, the patient acts to advance her own BI but deserves compensation to avoid an unjust sacrifice. Only here, if a SIROT pattern is foreseeable, she might act with a partial altruistic motive (to be discussed below).

[36] Ibid, 300-303.

2.2 Causation

The ethics of undue sacrifice is based on the necessary link between the claimant's injury and the benefit to future patients (for example, in the heart transplants example, between the initial 67% mortality within a three months to the subsequent 90% survival rate). As explained elsewhere, even if this knowledge could have been achieved by alternative means, the first patients' injury was still the actual (rather than hypothetical, or pre-empted) cause of the conferral of the benefit so justifies reimbursing them the costs of producing the benefit.[37] Jose Miola argues that ITs might be socially undesirable since and to the extent that they undermine clinical trial recruitment and provide incomplete and potentially distorted information.[38] I cannot tackle the broader issue here but few comments are in order: (1) to the extent that the benefit was not the actual result of the injury (since it was produced independently) the theory defended here cannot support SL; (2) in theory, the costs of reduced knowledge from medical research due to availability of ITs might be properly offset against ITs' benefits to examine whether a net benefit exists; if so, reimbursing the costs involved in producing that net benefit is justified. I suspect, however, that the case for such set-off might be limited due to evidentiary and practical considerations.[39] (3) if the knowledge (benefit) could have been produced by participants of clinical trials, my argument would strongly support compensating these participants for their injuries, a point acknowledged in the literature.[40] From the

[37] Ibid, 303.

[38] See Jose Miola's contribution in the special issue.

[39] Ariel Porat and Eric Posner, 'Offsetting Benefits' (2014) 100(6) Virginia Law Review, 1201 <www.virginialawreview.org/volumes/content/offsetting-benefits>. Arguably, such set-off is still problematic since it conflates hypothetical alternative benefits with actual benefits. See Keren-Paz (n 37).

[40] See eg., Joanna Manning, 'Does the law on compensation for research-related injury in the UK, Australia, and New Zealand meet ethical requirements?' (2017) 25(3) Medical Law Review 397 <https://doi.org/10.1093/medlaw/fwx019>.

beneficiaries' perspective—future patients—it is immaterial whether the beneficial knowledge was produced by patients injured from ITs, by participants who would have been injured in clinical trials conducted in lieu of ITs, or by research participants who were in fact injured. However the knowledge was produced, fairness demands that the costs of producing it (=the injuries) will be shared by the beneficiaries.

The causation requirement has also bearing on the timing in which the cause of action crystalizes. In theory, this happens when the benefit is received by future patients, which is subsequent to the claimant's injury.[41] However, since SIROT is so endemic to ITs and for reasons explained in the next two sections, compensation is justified when the injury is suffered, before the benefit is captured by future patients.

2.3 Altruism

In necessitous interventions/private necessity cases ('rescue')—which I argue include injuries from ITs—the success of the intervention is a substitute for acting out of an altruistic motive as a condition for reimbursement of the rescuer's costs. So while altruistic interventions will entitle the rescuer for reimbursement of costs, provided the intervention was necessary and reasonable (in the sense of being ex-ante cost-justified), successful rescues will entitle reimbursement of costs—for example of the person whose property was used by the defendant or a third party to rescue the defendant—even when the claimant lacked an altruistic motive, or was not even aware of such use.[42] In SIROT categories 2 and 3, the 'rescue' is successful so an altruistic motive can only strengthen further the claim but is unnecessary.

[41] Keren-Paz (n 2) 304.

[42] Ibid 286-89.

In the case of an unforeseeable injury from routine treatments, there is clearly no altruistic motive by the patient. In the context of ITs, this is more debated. On the one hand, usually the patient will decide to try IT, since she hopes it will be in her BI. On the other hand, the patient, if informed at all that the treatment is innovative,[43] might operate under a mixed motive to partially advance science and assist future patients.[44] Such motive is absent in cases of unforeseeable injury. On a spectrum, participants in clinical trials (and especially in Phase 1) are the most altruistic,[45] those consenting to IT in the middle, and those injured from unforeseeable risks lack altruistic motivation. In a corresponding manner, there is an increased need for successful rescue in order to justify SL for claimants in these categories.[46]

Moreover, the treating physician might be in a position of conflict of interests, and consciously or not might recommend a treatment which is doubtful BI out of the hope it might become SIROT. This strengthens the case for compensation both because under such circumstances the claimant is passively used by a third party with a motive to benefit the defendant (beneficiary) so she deserves (and is often entitled to) reimbursement of the

[43] Clinicians often fail to inform their patients that the treatment is innovative, that it amounts to variation, or that they are inexperienced in conducting it. Nuffield Roundtable (n 28); Richards and Hutchison (n 12). This will often, and justly so, establish liability based on failure to disclose a material fact. See eg., Hall v Petros [2004] WADC 87 [348] (West Australia) and in general Cockburn and Fay (n 27).

[44] Granted, this is somewhat contentious and assumes a lot. For sure, we have little reason to assume that clinicians will highlight benefit to future patients as a selling point. But a realization that IT is likely to benefit science and future patients might be intuitively grasped by many patients. Indeed, some comments in Nuffield's Roundtable (n 28) suggested that patients might be altruistically motivated in deciding to undergo IT. Finally, at best, most patients who are aware of all the above, operate under mixed motives which might not be sufficient to justify SL in cases an altruistic motive is a condition for restitution.

[45] However, in many jurisdictions Phase 1 participants are paid – allegedly for out of pocket and inconvenience expenses - but sometimes quite a big sum, which at time is a motivation to participate. Another qualification has to do with patients' therapeutic misconception of research trials.

[46] For clinical trials see Manning (n 40).

cost she incurred,[47] and since obfuscation of the ulterior motive to offer IT undermines the claimant's informed consent to the treatment. In other words, either the patient is fully aware that one motivation to offer the IT is to benefit future patients, and in such a case she could be said to have an altruistic (although mixed) motive; or the patient is unaware of such motivation so her consent is undermined and therefore deserves to be compensated.[48] From a policy perspective, then, SL could be a response to the built-in conflict of interests between the treating physician and the patient.[49] Such conflict exists precisely due to the prospect of developing a treatment which is long term superior but disproportionately risks early patients. Related to this is the widely acknowledged phenomenon of passing research and experimentation as IT, under the banner of compassionate or humanitarian use, in order to avoid the elaborated regulation of clinical research.[50]

2.4 Physician as proxy to beneficiaries

Both ITs and injuries from unforeseeable risks raise the question whether the treating physician is the correct defendant who should reimburse the injured patient for the benefit conferred on future patients. I have answered 'yes' to this question in the non-IT context, as the physician is a good proxy to the benefit received by the patients.[51] The argument and its caveats (eg., the case for public necessity analogy and the relevance of the way

[47] See Keren-Paz (n 42).

[48] See Cockburn and Fay (n 27).

[49] See Keren-Paz (n 20).

[50] This featured quite strongly in both Seminar 6 of the series and in Nuffield's Roundtable (n 28). See eg., Special Inquiry, Kjell Asplund, 'The Macchiarini Case, English Summary' (Citizens For Responsible Care and Research, 31 August 2016) <www.circare.org/info/pm/fallet-macch-google-20160903.pdf>; Tamra Lysaght et al., 'The Deadly Business of an Unregulated Global Stem Cell Industry' (2017) 43(11) Journal of Medical Ethics 744 < http://dx.doi.org/10.1136/medethics-2016-104046>.

[51] See Keren-Paz (n 2) 295-300.

the health system is funded) are largely the same in the context of ITs so would not be repeated here. In ITs, physicians are more likely to reap a benefit from the treatment if ultimately successful, than they are where a routine treatment causes unforeseeable injury;[52] they are more likely to operate out of a motivation (and certainly awareness) that the IT is likely to benefit future patients; this both puts them in a potential conflict of interests and might affect their judgment whether the treatment is in the patient's BI. For these reasons, the case for holding them strictly liable is even stronger than in the case of unforeseeable risks. While I still think that private necessity, and consequently, liability of the treating physician is defensible, I would not oppose a state-based compensation. This relates also to the dual terminology of 'strict liability' and 'no-fault'. The former relates to a tort action in which a defendant is liable to the claimant based on their interaction, but does not require a proof of fault as a constitutive element of the cause of action.[53] A claim of (or by analogy to) private necessity against the treating physician/institution is a form of SL. Those (like Keating[54]), who accept the case from fairness for compensation but disagree that the treating physician is a good proxy for future patients, could support a no-fault scheme. Such schemes are typically publicly administrated, alternative to traditional tort litigation, so take the injurer out of the picture, and compensate the injured patient, often at lower rates than tort law would, from public funds (which in a medical injuries context could be a healthcare budget or beyond).[55]

[52] As discussed by Devaney in this issue, and illustrated by the case of Paolo Macchiarini, the prospect of successful innovation is much behind (sound or otherwise) ITs. But this of course depends on health care systems' market structure.

[53] Edwin Peel & James Goudkamp, Winfeld & Jolowicz Tort, 19th ed. (Sweet & Maxwell, 2014) 27-8.

[54] Gregory Keating in this special issue, while ultimately supportive of no-fault compensation, believes that the fairness case for sharing the risks of ITs is less compelling than I think. In a previous draft, I aimed to explain why I am not convinced by Keating's main misgivings; but space limitations prevent me from discussing this here.

[55] Michael Jones, Medical Negligence (Sweet & Maxwell, 2003) 20-52.

3. Efficiency

3.1 A framework: a solution in search of a problem?

Efficiency in the law of accidents aims to minimise the sum of accidents, precautions taken to prevent or minimise their effect and the costs of litigating them.[56] A framework for answering whether efficiency requires/justifies SL for injuries from ITs presents the following questions:

(1) Is there a problem of under supply of ITs (due to liability rules)? If current liability rules do not unduly stifle innovation, there is no need to adopt SL to solve an incentive problem, although SL could still be supported on fairness grounds. If SL does not affect at all incentives to offer (and accept) ITs, the fairness argument, if sound, should lead us to adopt SL. If it decreases such incentives, a trade-off presents itself between decreased efficiency and increased fairness. The answer to this question (and the broader question around defensive medicine) is disputed. So for example, Parchomovsky and Stein in the US context offer a theoretical model, and cite some empirical evidence suggesting that the tort liability stifles innovation,[57] but Miola found more recently in the UK Medical Innovation Bill context that there is no evidence that the problem exists.[58]

[56] For two examples in the medical context see Ariel Porat, 'Offsetting Risks' (2007) 106 Michigan Law Review 243 <http://repository.law.umich.edu/mlr/vol106/iss2/2>; Gideon Parchomovsky and Alex Stein, 'Torts and innovation' (2008) 107 Michigan Law Review 285 <http://repository.law.umich.edu/mlr/vol107/iss2/2>.

[57] Ibid. As I have argued elsewhere, the empirical evidence is weak. Tsachi Keren-Paz and Alicia El Haj, 'Liability versus Innovation: The Legal Case for Regenerative Medicine' (2014) Tissue Engineering DOI: 10.1089/ten.tea.2013.0324 < http://ssrn.com/abstract=2487942>.

[58] See Miola (n 31).

(2) An important policy issue, neglected by Parchomovsky and Stein,[59] is that bad ITs should be discouraged – we want more good ITs, not more ITs per se. Therefore, even if it is true that current rules stifle innovation, there is a need to conclude whether the loss of useful innovations outweighs the gain from deterring harmful innovations. Recall also Miola's argument that ITs might be socially undesirable since and to the extent that they undermine clinical trial recruitment. If this is true—a species of 'the good is the enemy of the best' problem—the evaluation of the social value of ITs should take into account the forgone social value of medical research.[60]

(3) Next, if we do not have enough ITs, is this because there are not enough physicians willing to offer treatments (due to the fear of liability) or because there are not enough patients willing to submit to ITs due to fear of not being compensated under a negligence regime? This goes back to the problem central to economic analysis of private law of the inability to provide adequate incentives to both interacting parties.[61] To answer the efficiency (and fairness) inquiry adequately, it is also crucial to know whether the costs of damages are passed on to patients or borne by physicians.[62] If the costs are passed on to patients,

[59] See Parchomovsky and Stein (n 56).

[60] In surgery, lots of ITs come in to practice without proper evaluation and it can take years before the harms are visible. Vaginal mesh for example was introduced without relevant research and many patients were harmed before products were withdrawn. See Hannah Devlin, 'Johnson & Johnson's 'irresponsible' actions over vaginal mesh implant' The Guardian, 29 September 2017. Cf the IDEAL Framework (n 14).

[61] For a recent relevant application see Oren Bar-Gill and Ariel Porat, 'Harm-Benefit Interactions', (2014) 16(1) American Law and Economics Review 86 <https://doi.org/10.1093/aler/aht016>.

[62] See Keren-Paz (n 51).

increased liability is not only fair, but is also likely to be efficient since it reduces the extent of positive externalities, which are a source of inefficiency.[63]

3.2 *Patients' incentives*

Unlike in cases of unforeseeable injuries, there is a potential incentive issue here. From the patient's perspective, the crucial question is whether currently the IT is in her best interest. If this is the case, ie., if IT's expected benefits-to-risk portfolio is currently superior to existing alternatives, she is likely to pursue it; the fact that in the future the results are likely to be even more favourable to future patients is unlikely to cause her to wait, since receiving the treatment now is still in her best interest.

SIROT not-BI ITs (category 3) seem to involve a holdout (or free riding) cooperation problem:[64] all patients prefer that others will volunteer first. The first volunteers will be statistically worse off in comparison to those who wait, but after the appropriate lessons are learnt, patients who waited will receive a superior treatment to the one currently existing. Therefore, patients will prefer to wait, with the result that everyone is worse off, since the superior result—the mainstreaming of the treatment after it was tweaked to solve the adverse effects on initial patients—is delayed. It might be the case that SL for injuries will increase willingness to participate in ITs by providing some pooling of the risks of being first in line to be treated.[65]

For the following reasons it is doubtful whether in the context of ITs a cooperation problem exists, and consequently, that SL will solve such a problem. First, as discussed,

---

[63] Porat and Posner (n 39).

[64] Thomas Miceli, 'Free Riders, Holdouts, and Public Use: A Tale of Two Externalities' (2011) 148 Public Choice 105.

[65] Cf Hanoch Dagan and Michael Heller, 'The Liberal Commons' (2001) 110(4) Yale Law Journal 549 <http://digitalcommons.law.yale.edu/ylj/vol110/iss4/1> in the context of sub-optimal investments in co-owned land.

insufficient information and optimism bias would steer a patient away from a conclusion that the IT is SIROT not-BI (which is a pre-condition for a cooperation problem). Secondly, even if the IT is correctly perceived to be SIROT not- BI, it is doubtful whether ensuring compensation is what would convince patients to undergo a treatment which is otherwise not in their BI. After all, the result of a failed IT would usually involve a premature death or a serious bodily injury for which money is a poor substitute. Moreover, given the severity of the underlying condition which is likely to trigger the patient's consent to the IT, the size of the damages award in a case of an adverse effect is likely to be small so the absence of a right to be compensated is not likely to significantly affect patients' participation in IT (or clinical trials).[66] There is no clear evidence that currently, in the absence of SL, there is shortage in patients consenting to ITs or volunteering to clinical trials.[67] Having said this, a move to SL is unlikely to decrease incentives to participate in ITs. If at all (and this is a big if indeed) it might convince otherwise reluctant patients who estimate the treatment is currently too dangerous but might become SIROT with time, to take their chance with the knowledge that the financial consequences of an adverse effect will be mitigated (to the extent possible, which is admittedly limited) by a damages award. Due to its novelty, whether the IT offered is in the patient's BI is likely to be in dispute; this also means that it is uncertain whether following an adverse result, courts will rule that it was negligent. SL ensures

[66] Economic analysis of law suggests that a proper incentive might be an award exceeding patients' loss that captures some of the surplus benefit their injury produces. See Bar-Gill and Porat (n 61). See also (n 45).

[67] Some trials struggle to recruit participants but it is hard to assess how endemic the problem is (and there is less available data on ITs recruitment). See Lisa Newington and Alison Metcalfe, 'Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams' (2014) 14(10) BMC Medical Research Methodology 1 <https://doi.org/10.1186/1471-2288-14-10> It is even harder to assess whether introducing no-fault compensation would make a difference.

compensation and by this might marginally improve patients' incentive to undergo the IT.

The above analysis serves as a correction to Bar-Gill and Porat's model of harm-benefit interactions in which the harm to the victim (as distinct from the underlying defendant's activity) is what produces the benefit to the defendant or third parties (as in the case of IT). According to their analysis, it is important to impose liability in cases in which the benefit outweighs the victim's harm (so the interaction has net positive social value) to remove the victim's incentive to avoid the interaction.[68] Seemingly, in SIROT not-BI cases (category 3) liability is imposed where the benefit outweighs the harms, so SL maintains patients' appropriate incentive to seek an interaction which is socially desirable and is preferable to no liability.

The following comments are in order. First, note the similarity between the incentive argument and the fairness rationale underlying the private necessity and negociarum gestio doctrines. In both cases liability undoes the harm to the claimant, therefore makes him financially indifferent in circumstances in which her harm produces more significant benefits to others. Secondly, the desirability of liability according to their model is limited to interactions which create positive social value. Therefore, irresponsible innovation cases (category 4) require, counter intuitively, withholding of compensation in order to deter the victim from seeking the socially undesirable treatment. This, of course, begs the question whether the victim, in the context of ITs, is well placed to evaluate whether the IT is likely to be category 4 or any of the other categories in which seeking treatment (and hence receiving compensation for an injury) is unproblematic (categories 1,2) or even desirable (category 3); and we have good reasons to doubt such

[68] Bar-Gill and Porat (n 61).

ability.[69] Finally, their model (which did not focus on medical treatments) does not distinguish between injuries sustained under categories 2 (BI, SIROT) and 3 (SIROT, not-BI). From efficiency (but not fairness) perspective, there is no need to give patients incentive to consent to category 2 ITs, since they are already in the patient's BI and no cooperation problem exists; however, compensation is necessary in category 3 (subject to the doubts expressed above about the limits of incentives in this context and patients likely believing that the treatment is in their BI).[70] Importantly, category 3 cases, which require compensation under Bar-Gill and Porar's model, already entitle claimants to recover under the law of negligence, since the treatment was not in the patient's BI (and despite having net social value). This suggests that from patients' incentive perspective, a move to SL is not absolutely required.

To conclude, given patients' likely treatment of some, if not most categories 3 and 4 treatments (which are not in their BI) as BI treatments, there is little to gain, but even less so to lose, from compensating injuries from ITs under a SL rule. In terms of litigation costs, a move to SL will give injured patients an ex-post incentive to argue that the treatment was innovative. How wasteful this incentive is, is unclear, and depends on the ability to develop clear rules demarcating non/innovative treatments. It is possible that a move to SL will produce pressure on defendants to create, or better follow, protocols demarcating the distinction between non/innovative treatments before offering them, in order to reduce their exposure to liability, which seems to be desirable.

[69] See Part 1.2.

[70] See Scanlan et al. (n 30).

3.3 *Physicians' incentives*

Moving to physicians' incentives, seemingly SL is problematic for ignoring positive externalities. According to orthodox economic analysis of law, when the defendant's activity creates net benefits—so that the benefits to third parties outweigh the harm to the claimant—there should be no liability.[71] However, benefits to third parties from medical treatment are ignored for purposes of determining both standard of care towards the patient (given the insistence on BI) and quantum of damages.[72] This is true for all medical treatments, but is especially pertinent to treatments with SIROT pattern (categories 2 and 3), in which the injury is what brings about the benefit to the third parties. While the problem exists under negligence, it is seemingly worse under SL which increases the scope of liability: under negligence, there would be no liability in category 2 (BI, SIROT) since the treatment was in the patient's BI. Under SL, there would be liability which is undesirable in terms of physicians' incentives.

In category 3 as well, liability deters physicians from offering treatments with net social value (a result which is presumably inefficient). However, liability (which arguably improvs *patients'* incentives) is already imposed under negligence. Therefore, a move to SL will not decrease the incentive to provide them; in fact, it might increase it. As I have explained elsewhere, under SL the reputation loss from any single finding of liability is smaller, than under negligence.[73] Therefore, a move to SL might improve physicians' incentives to provide ITs. In category 3, the same amount of damages will be paid under

[71] See Porat (n 56) 256 and Porat and Posner (n 39) 1205. But contrast with Chan (n 20) who views positive externalities as a reason to heighten the required standard of disclosure due to the risk of conflict of interests.

[72] See Walker-Smith (n 22) Outside of the medical context, tort law takes into account positive externalities in setting the standard of care, but not for quantum. Cf Porat ibid.

[73] See Keren-Paz (n 3) which also discusses reputation loss's effect on incentive to settle under the two regimes and reputation loss from settlements (at times confidential) under both regimes.

both regimes, but the physician will suffer a lower reputation loss, since a finding of liability under SL connotes less clearly a finding that the defendant was negligent.

Of course, SL will increase the amount of damages payable overall by compensating category 2 (BI, SIROT) cases. In the context of ITs it is hard to guess by how much a move to SL will increase total payout.[74] It is worthwhile recalling, however, that from the perspective of the treating physician, reputation loss is much more damaging than an obligation to pay damages which is neither borne by herself nor affecting insurance premiums, which are seldom (if ever) experience-based.[75] For this reason, a move to SL seems to improve overall physicians' incentives to engage in IT.[76] Whether this is desirable depends on whether we need more innovation. The question, therefore, is whether the social value from increased numbers of responsible innovations occurring under SL outweighs the social costs of the harms from increased numbers of irresponsible innovations under SL.

Furthermore, the institution (employer/hospital/trust) which pays the bill for the medical injury will care much about the size of damages paid, so SL might create an institutional pressure on physicians to avoid offering ITs, if the rise in damages paid under SL for ITs is significant.[77] This would depend on the way in which the institution's budget is affected by a finding of liability[78] and on the extent to which oversight of the clinician's

[74] For estimations in the context of a general move to strict liability (not limited to ITs) see Stoljar (n 34).

[75] Ibid 376.

[76] For a fuller analysis in the broader context of defensive medicine see ibid 375-87. There might also be a difference between no-fault scheme, which typically removes the physician as a litigant, and SL which still imposes liability on the physician, and might be mistaken as fault-based.

[77] The conflict of interests between the institution and the employee in terms of settling claims, noted in Keren-Paz (n 3), recently came to the fore in James-Bowen v Commissioner of Police of the Metropolis [2018] UKSC 40 (no duty to protect employee's reputation).

[78] In England, given the pooling of damages by NHS Resolution, the effect on the institution's budget might not be significant. A trust annual contribution reflects only partially the

decision to innovate is effective. There is at least some anecdotal evidence suggesting that the oversight of ITs, for example, by way of hospitals' new procedures committee is very loose, where in some hospitals such committees do not even exist.[79] (Of course, SL exposure might increase oversight, which is arguably desirable). Finally, the institution (and not only the physician) has strong non-legal incentives to encourage (responsible) innovation, and under SL, might reduce its own reputation loss; this might offset some of the increased damages payouts. The account offered here adds a nuance to Bar-Gill and Porat's model, which correctly focuses on both physicians' and patients' incentives, but ignores reputation loss and the different extent negligence and SL produce it, does not distinguish between SIROT BI (category 2) and not-BI (category 3), and implicitly does not acknowledge the physician as a co-producer of the benefit to future patients.[80]

Essentially, we revert to the question—the answer to which is disputed and might be contingent on the way the health care system is structured[81]—whether the future benefit (which is co-produced by the patient and physician) can be captured by the physician (in other words, whether the physician is a good proxy for the benefit received by future patients). If so, SL will not deter the physician from offering the treatment, and is efficient, since there are no positive externalities. If physicians cannot capture the benefit, liability will deter them from offering ITs. In that case, the effect of a move to SL is mixed, since reduced reputation loss for physicians (and possibly hospitals) under

institution's claims history. See NHSLA, Clinical Negligence Scheme for Trusts (CNST) Consultation (2016) 12.

[79] See eg., Stephan Wigmore, 'Special Inquiry into Regenerative Medicine at UCL' (UCL, 29 September 2017), at 17 <www.ucl.ac.uk/news/news-articles/0917/Special_Inquiry_Final_Report_605109702_7_.pdf>, A similar sentiment was expressed in Nuffield's Roundtable (n 28).

[80] Bar-Gill and Porat (n 61) 113 (third-party harm that is prevented by victim's harm is not a benefit created by the injurer).

[81] See Keren-Paz (n 51).

SL partially compensates for increased exposure to pay damages in categories 1,2 (borne mainly by hospitals). It might also be that both physicians and institutions have sufficiently strong non-legal incentives to offer ITs which outweigh the putative increased deterrent effect of SL. Finally, a no-fault administrative scheme might be more desirable than SL, since it compensates injured patients, by this attenuating the disincentive to partake in ITs, without deterring physicians from offering them.

The potential deterrent effect of disciplinary proceedings (in England, 'fitness to practice') is often neglected in discussions of tort law, defensive medicine and innovation. If I am correct that a move to SL might under-deter irresponsible innovations,[82] the problem might be mitigated due to availability of disciplinary proceedings as a response to truly irresponsible ITs.[83] Finally, it is cheaper to litigate under SL, since there is no need to litigate the question of fault (and also since the stakes for defendants are lower, given the lower reputation loss produced by a finding of liability). Moreover, ITs are (relatively) well-demarcated and small category of cases, so SL for ITs is more affordable, in comparison to a general shift to SL or no-fault schemes for medical injuries, which are clearly considered as unaffordable.

[82] By decreasing reputation loss from a finding of liability, strict liability provides an incentive to engage in more, including irresponsible, ITs.

[83] See eg., Bill Madden, 'Innovative / Experimental Use of Ketamine' (Medical + health law blog, Australia, 17 May 2018) <https://billmaddens.wordpress.com/2018/05/17/innovative-experimental-use-of-ketamine/>.