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Postscript to the Medical Innovation Bill: Clearing Up Loose Ends

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Abstract: The focus of the debates surrounding the Medical Innovation Bill and Access to Medical Treatments (Innovation) Act 2015 was the negligence provisions. This paper examines the other aspects that were consequently ignored: the proposed database of innovative treatments and the 'effect on the existing law' clause of Lord Saatchi's Bill. The chapter argues that some aspects of the database require rethinking, but that its biggest problem lies in the lack of stakeholder clamour for it.

Keywords: Innovation; Database; Protection for Doctors.

Introduction - A Brief History of the Bills

Lord Saatchi initially introduced his Medical Innovation Bill (MIB) as a private members' bill in the House of Lords in 2014.[1] In its original form, the MIB dealt only with the law relating to negligence, claiming (though not providing any evidence to support the assertion) that a fear of litigation was discouraging medical innovation. Lord Saatchi's bill provided a process that, if followed, precluded courts from finding a doctor liable in negligence. Later, the idea to include a database of innovative procedures was added to the MIB although, as I demonstrate below, this was not an idea conceived by the creators of the Bill, and it was only reluctantly adopted. Nevertheless, it was to become the belated focus of the MIB.

Despite almost unanimous opposition from key stakeholders, it received a smooth ride through the House of Lords and found its way to the House of Commons, where it continued to enjoy support from the Conservative government (though not from either their Liberal Democrat coalition partners, or prominent MPs such as the Conservative chair of the

[1] 'How Can An Act of Parliament Cure Cancer: A Guide to the Medical Innovation Bill', 15th May, 2013, http://www.stopthesaatchibill.co.uk/wp-content/uploads/2014/06/Guide-to-Medical-Innovation-Bill-HL-17-June.pdf.

House's Health Select Committee, Sarah Wollaston –herself a doctor).[2] Had it not been for the timing of the general election in 2015, it is undoubtedly the case that the Bill would have passed and become law.[3] As I and others have argued, this was a very flawed piece of legislation that would have done harm had it come into law.[4] Yet this seemed to be nothing more than a reprieve, as Lord Saatchi did not withdraw his Bill from the House of Lords (thus keeping it dormant) and re-introduced it to the House of Commons as a private members' bill through Chris Heaton-Harris MP. Renamed the Access to Medical Treatments (Innovation) Bill (AMTIB), the House of Commons version maintained the negligence aspects of the MIB almost verbatim, but modified the provisions relating to the database. Following renewed fierce opposition from stakeholders, the negligence aspects were eventually dropped from the Bill, which was eventually passed as the Access to Medical Treatments (Innovation) Act 2016 (AMTIA). The only thing that it now does is allow the Secretary of State to create a database of innovative procedures. The government has yet to create one.

The vast majority of the opposition to the MIB and AMTIB was focussed on the proposed modification to the law of negligence, as this was deemed to be actively dangerous to patients – the Royal College of Paediatrics and Child Health, for example, referred to them as posing "a real danger to the safety of infants, children and young people".[5] For this reason, the vast majority of the literature on the subject has addressed that concern. Nevertheless, this means that other aspects of the MIB/AMTIA have been less considered. It is one of these aspects that is the focus of this piece, which therefore seeks to tie up the loose ends of the

[2] For an example of Sarah Wollaston's opposition to the Bills, see, for example, 'The Medical Anecdote Bill', at http://www.stopthesaatchibill.co.uk/the-medical-anecdote-bill/ (last accessed 14th May 2018), or S. Wollaston, 'Half-Baked and Reheated, the Medical Anecdote Bill Returns to the Commons Today', Huffington Post, 16th October 2015 (last accessed 25th April 2018).

[3] The timing of the election meant that the parliamentary procedure used would have needed only one MP to shout 'objection' at the first reading of the Bill to require it to be debated. There was no time to do so, and it was known that at least two MPs would object (Sarah Wollaston and Julian Huppert had already stated their intention to object). A decision was therefore taken by the Bill team not to read the Bill. See 'The End of the Medical Innovation Bill', http://www.stopthesaatchibill.co.uk/the-end-of-the-medical-innovation-bill/ (last accessed 14th May 2018).

[4] See, for example, J. Miola, 'Bye Bye Bolitho: The Curious Case of the Medical Innovation Bill' (2015) 15(2-3) Med Law Int 124.

[5] N. Modi, 'Access to Medical Treatments – Stop the Bill Now', Royal College of Paediatrics and Child Health, 14th October 2015 https://www.rcpch.ac.uk/news/access-medical-treatments-stop-bill-now (last accessed 24th April 2018).

debates around the MIB in particular, in case the Bill, or a new version of it, returns to parliament in the future - the section relating to the database – that has passed into law. I argue that the treatment of the database demonstrates a failure by the authors of the legislation, despite the way in which the Bills were presented publically, to consider the interests of potential patients.

In relation to whether the MIB will return to parliament, in mid-April 2018, Lord Saatchi gave a speech at the Royal Society of Medicine, where he addressed the MIB.[6] He stated that the AMTIA not just empowered but 'required' the government to set up a database;[7] which is, as I demonstrate below, not correct. He also reiterated his firm, yet similarly mistaken, belief that a doctor who provided the standard treatment, even when she knew that it would not work, was safe from being sued in negligence.[8] This latter belief was the catalyst for the MIB, and indeed the fulcrum of its doctor-centred philosophy. It may well be, then, that we have not yet heard the last of it. If that is the case, we can only hope that the ancillary issues, as well as the negligence provisions, are better thought out than they were last time.

All About That (Data)Base

The only aspect of the legislation to survive and enter into the statute book is the register of innovative treatments as provided for by the AMTIA. This is a different provision to the one that appeared in the MIB, but it is perhaps worthy of note that a database or register was not originally conceived by the MIB's creators, and indeed that they had to be coerced into including it. The more recent claims that it is intrinsic to the MIB can therefore be seen to contain a large element of revisionism.[9] Indeed, the original briefing note to accompany the launch of the MIB did not mention a database at all. Rather, the first mention of a register of innovative treatments appeared at the second reading of the MIB in the House of Lords in

[6] A video of the speech can be seen here: https://videos.rsm.ac.uk/video/access-to-medical-treatments-act (last accessed 14th May 2018).
[7] Ibid, see video from 2m 55s to 3m 10s.
[8] Ibid, see video from 4m 50 to 5m 05.
[9] Indeed, the register became very prominent in the MIB's website, where it was listed as a 'key tenet' – see MIB, 'The Medical Innovation Bill Will Support Evidence-Based Medicine', http://medicalinnovationbill.co.uk/the-medical-innovation-bill-will-support-evidence-based-medicine/ (last accessed 14th May 2018).

June 2014.[10] At this stage Lord Saatchi declared that the University of Oxford had agreed to host a register of innovative treatments, something very much welcomed by other Lords. However, as David Hills has noted, despite the supportive words by Lord Saatchi the register was not included in subsequent drafts of the Bill at either the Report or Committee stage of the legislative process.[11] The reason why this is the case is unclear. It was instead left to Lord Hunt to make it clear that if it were not included then he would force a vote in the House. At this point Lord Saatchi relented, put his name to the amendment and it was passed and became a part of the MIB, seemingly somewhat reluctantly.

What makes this potential resistance to the database even more perplexing is the fact that even with the amendment accepted the MIB did not actually create a register. Indeed, the MIB's provision (s.1(3)(e)), forced by the Lords, states that the doctor must:

> "comply with any professional requirements as to registration of the treatment under the provisions of this Act with a scheme for capturing the results of innovative treatment (including positive and negative results and information about small-scale treatments and patients' experiences)."

This clearly does not establish a register or database, nor does it compel doctors to record their results if one is established. Rather, it demands only that any professional requirements to do so are met. In other words, it relies on the regulator (in this case the GMC) requiring such recording. Yet, as I have noted elsewhere, the GMC made it clear that it would not be establishing such a register or policing it.[12] It is perhaps for this reason that, when he took over the MIB and created the AMTIB, Chris Heaton-Harris MP modified this provision in a way that he did not do with the negligence provisions, which he adopted virtually verbatim. In the final version, the provision relating to the database (s.2(1)) became this:

> The Secretary of State may by regulations make provision conferring functions on the Health and Social Care Information Centre ("the HSCIC") in connection with the

[10] HL Deb, 27th June 2014, 1453 (Lord Saatchi) and 1469 (Lord Ribeiro).
[11] D. Hills, 'Rearranging the Deckchairs', The Wandering Teacake Blog, https://wanderingteacake.wordpress.com/the-saatchi-bill-2/rearranging-deckchairs/ (last accessed 24th April 2018).
[12] See Miola (n4), 137-9.

establishment, maintenance and operation of a database containing information about—

(a) innovative medical treatments carried out by doctors in England, and

(b) the results of such treatments.

Again, it will be noted that this provision – which, let us remember, is the sole legislative effect of the AMTIA – also fails to establish a register of innovative treatments. It merely claims to confer on the Secretary of State the power to do so. However, as pointed out by Heidi Alexander MP (the then Shadow Secretary of State for Health) at the time, not only is there nothing preventing the Secretary of State from establishing such a register, s.254 of the Health and Social Care Act 2012 explicitly confers on the Secretary of State the power to direct the HSCIC to establish databases.[13] In this sense, then the entire AMTIA is redundant and does precisely nothing. To date, the government has given no indication that it intends to set up such a register, raises the suspicion that passing the legislation was a face-saving exercise given that it had supported the Bills. Nevertheless, it does beg the question of whether one might be useful.

Of course, much would depend on what sort of register would be established. This presents us with some difficulty, as neither the MIB nor the AMTIA goes into any significant detail regarding what sort of register they imagined being set up. Indeed, the MIB says nothing at all about the register other than what has been quoted above. The AMTIA, however, does provide a little more information, although it does not shed too much more light on matters. Thus s.2(3)(b) states that it is for the HSCIC to make provisions relating to access, while s.2(4) states that such provision may include disclosing information to (unspecified) persons (s.2(4)(a)(i)), for use for (unspecified) 'specified purposes' (s.2(4)(a)(ii)), and to limit further disclosure by the parties who have been granted access to the information (s.2(4)(b)). No further guidance is given in the actual legislation, including whether the information might be used in disciplinary or indeed in legal proceedings.

Yet, from what we can tell from the public pronouncements regarding the proposed legislation, there is a difference in approach between the two Bills. Lord Saatchi's MIB was

[13] HC Deb, 29th January 2016, Col 565.

clear in its view that the database should be open to the public. This much can be seen in the MIB's official website which, in its section on the register, explicitly states that "[a]n open access register that records novel treatments and is searchable by both patients and doctors does not currently exist in the UK. It will be a significant development in the field of medical practice."[14] On the same page, there is a graphic showing how the MIB was intended to work. The third point on the graphic states that the "[p]atient or doctor researches potential new treatments and checks the open access Medical Innovation Register".[15] The intent is undoubtedly that patients are intended to be able to search the register themselves. Yet this brings with it its own dangers: as patients cannot demand treatments from a doctor, this format risks inundating those willing to perform procedures and could also create an environment that facilitates unscrupulous surgeons (like Ian Patterson or Paolo Macchiarini) making financial gain out of the demand for innovative treatments.

By the time that the legislation has morphed into the AMTIB, however, this has changed. During the debates in the House of Commons, Chris Heaton-Harris stated that any database "will not be available for patients to access".[16] This was echoed by the then Life Sciences Minister, George Freeman MP, who stated that "there is nothing in the Government's plans to make such a database available to the public".[17] Needless to say, this constitutes a significant point of departure from the MIB, although it should be noted that there is nothing in the AMTIA to prevent an open access database. It does mean, however, that some of the issues brought about by the putative existence of the database will have different effects depending on which approach would be adopted. Nevertheless, there are clearly some elements that merit further consideration despite the fact that few, if any, further details exist regarding them.

Cost

The first of these is cost. As mentioned above, Lord Saatchi disclosed that the University of Oxford had agreed to host the database. However, he provided no further details about this. We do not know, for example, who had authorised this, where the database would be hosted,

[14] See http://medicalinnovationbill.co.uk/medical-innovation-register/ (last accessed 28th June 2018). Emphasis added.
[15] Ibid.
[16] HC Deb, 3rd November 2015, Col 928.
[17] HC Deb, 16th October 2015, Col 603.

how it would be accessed and whether it would be maintained by the University as a whole, a single department or a College or even the HSCIC. Questions may also be raised about who would have legal responsibility for the host, and whether this body would be considered the controller or processor of the information for the purposes of the General Data Protection Regulation (and the law preceding it). These had yet to come into force when the AMTIA received Royal Assent, but any register would have to conform to the new law. It is beyond the ambit of this paper to consider such issues, and indeed they should be easily resolved, but there is no evidence in the debates in relation to the AMTIA that they were discussed. We have also not been told who would pay for the establishment and maintenance of the database, or where the money would come from. What information we do have, from the MIB's official website, suggested that these issues had yet to be resolved:

> Oxford University have already offered to host the Medical Innovation Register and the Medical Innovation Bill team is consulting widely on how the register will be set-up, managed and funded.[18]

These are, of course, significant issues, as one of the things that we do know is that such a database would require money. Indeed, in the House of Commons George Freeman stated that an indicative costing for the mere set up of the database had been estimated at between £5 million and £15 million.[19] That does not include the cost of maintenance. Moreover, this is the cost of the database for doctors envisioned by the AMTIA, not the open access version suggested by Lord Saatchi. In relation to the latter, there would presumably be extra costs involved in ensuring that the information was able to be understood by laypersons – indeed the sort of information that would be needed by doctors would be different to that required by patients, and this may well involve extra work and therefore extra cost. If the government were to pay for it, from where would the money come? Would any cuts elsewhere have to be made? If someone other than the government would contribute, would they be asked to do so without any advantage being granted, or would they, for example, be granted special access (that may confer financial advantage) above and beyond that given to others? In any event, it is obvious that the establishment of the database would require a significant amount of money, as would its maintenance. This makes it even more

[18] http://medicalinnovationbill.co.uk/medical-innovation-register/
[19] HC Deb, 3rd November 2015, Col 922.

critical that the database would provide information that is useful to those who are intended to be able to access it.

Effect on Clinical Trials/Effectiveness of the Database

In medical research, clinical trials in the form of randomised controlled trials (RCTs) are considered to be the 'gold standard.[20] Participants are selected on strict criteria, which minimises the chances of factors outside of what is being tested influencing results. Some participants are given the standard treatment or a placebo, while others are provided with the treatment or drug under investigation. The information that is gathered is considered to be as pure as it is possible to be, and it is for this reason that clinical trials form the bedrock of the drug licencing process. They clearly constitute a social good in that they are the most reliable way to test the safety and efficacy of treatments, and thus contribute greatly to the advancement of medical knowledge. The key is the controlled nature of the setting, which in theory provides accurate and full information. In contrast, a database containing details of individual treatments provided to patients in a setting that is uncontrolled when aggregated falls far short of this ideal.

It is perhaps for this reason that former doctor, Conservative MP and chair of the Commons Health Select Committee Sarah Wollaston referred to the MIB as the "medical anecdote bill" due to the inclusion of the database.[21] As she noted, a series of vignettes not controlled for important factors would be no replacement for clinical trials:

> If publicly searchable it would make for wonderful free advertising for private clinics but a vast sprawling register of treatments is no substitute for a proper evaluation of evidence and simply fails to understand the science.[22]

This view was echoed by the Academy of Medical Royal Colleges (AMRC), which includes the Royal Colleges, the BMA, Medical Defence Union and the Patients' Association. They wrote a letter to MPs outlining their opposition to the AMTIB, and

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[20] See, for example, D. McGovern, 'Randomized Controlled Trials' in D. McGovern, R. Valori and W. Summerskill, Key Topics in Evidence Based Medicine (BIOS 2001).
[21] See Wollaston (n2).
[22] Ibid.

commented adversely on the database.[23] The letter argues that the proposed register "does not mandate recording of results meaning that lessons would not be learnt, unsuccessful/dangerous treatments may be repeated".[24] Indeed, s.2 is silent on what, if anything, must be registered, instead merely authorising the HSCIC to make such decisions when establishing the register. Clinical trials are governed by strict rules surrounding reporting enshrined in law by the International Council on Harmonisation's Good Clinical Practice rules and the European Clinical Trials Directive (and the Medicines for Human Use (Clinical Trials) Regulations 2004), but both Bills are silent in relation to whether these rules would be adopted in relation to what was frequently emphasised as not being research but treatment. Therefore, and perhaps of even more concern, the AMRC letter also warns about the potential effect on clinical trials, as "[p]atients could risk untested treatments rather than enter the well-regulated clinical trials that are the current route to innovation".[25] This is a point that is echoed by Wollaston, who also argued that the legislation risked 'undermining' clinical trials.[26]

Indeed, the effect on clinical trials is a point worth emphasising. The MIB was advertised as applying to rare diseases – in particular but not exclusively rare cancers (even if this was not the case in the end). Nevertheless, if the majority of entries into the database will be from patients being treated for rare diseases, then two unintended consequences arise. First, patients will receive experimental treatment outside of the protective research ethics and governance infrastructure that is designed to protect research participants.[27] Patients would be receiving a level of oversight that would be far inferior to that had they been involved in a clinical trial. Secondly, and perhaps more importantly for the purposes of this point, if the disease is rare then diverting even a small number of patients away from clinical trials and into the MIB/AMTIB framework may mean that insufficient participants may remain to conduct a trial at all. Ironically, the rarer the disease, the more significant this effect may be. Moreover, there are factors that would push both doctors and patients towards

[23] The letter, from December 2015, can be downloaded from the Royal College of Physicians website: https://www.rcplondon.ac.uk/news/rcp-signs-joint-letter-access-medical-treatments-innovation-bill (last accessed 25th April 2018).
[24] Ibid.
[25] Ibid.
[26] Wollaston (n2).
[27] This is particularly the case given the lack of protection offered by the lax peer review requirements within the negligence provisions of the Bills, which formed a large part of the opposition to them.

the MIB/AMTIB. First, there would be far less administrative burden involved, as the (onerous) research governance rules would not apply. Patients, meanwhile, may well prefer a model where they will definitely receive the treatment rather than risking being placed in the control group, as they might be in a clinical trial.[28] Patients acting in such a way would be justifiable given their own interests, and this is considered below, but what can be said is that these 'push factors' risk making clinical trials for some rare diseases unfeasible, and this formed a part of the objection to the Bills of the research bodies in particular. Such issues were alluded to by the Medical Protection Society, which warned that,

> This Bill could create a mechanism allowing doctors to bypass research and development processes necessary to properly evaluate all treatments. There would be a reluctance to undertake full clinical trials on innovative treatments doctors had used under this Bill that had failed on one, maybe two, occasions – thereby delaying or even preventing the introduction of good treatments.[29]

This was made plain by the Brain Tumour Charity, whose own assessment of the database provisions was withering:

> We are concerned that doctors may choose to prescribe an innovative treatment rather than enrol their patient in a clinical trial where treatment is monitored and data collected but not guaranteed (for example, if the patient is part of the control group that receives a placebo) ... Although we understand that it is not appropriate to outline the fine details of the database in legislation we have a number of reservations about how the database will work in practice. For example, data entry is not mandatory which may undermine data quality. Given that mandatory databases such as the

[28] See A. McConaghie, 'UK Experimental Drugs Bill "Could Hit Clinical Trial Recruitment"', Pharmaforum, 21st October 2014, https://pharmaphorum.com/news/uk-experimental-drugs-bill-could-affect-clinical-trials/ (last accessed 8th May 2018).
[29] MPS Casebook, Medical Innovation Bill, http://www.medicalprotection.org/uk/casebook/casebook-september-2014/medical-innovation-bill (last accessed 30th April 2018).

Systemic Anti-Cancer Therapy (SACT) Dataset are incomplete it is unlikely that this database will be properly populated.[30]

These are important points, and there are several that are worthy of elaboration. The main problem is the incompleteness of such databases. For rare diseases, as the quote above makes clear, even mandatory databases are either incomplete or insufficiently populated and controlled to provide evidence that can be used by researchers to a degree comparable to clinical trial results. They can provide vignettes, but the lack of identical environments, patient characteristics and a control group means that the information is certainly less valuable than that obtained through a proper clinical trial. In clinical trials, however, the ethical framework includes a positive duty to report adverse events, and would be guaranteed as a part of the research ethics committees' examination of the proposal.

Furthermore, it must be remembered that RCTs also involve a controlled environment, while a register of innovative treatments would not do so: even patients with the same condition given the same drug would not necessarily receive them under the same circumstances, and they may have other underlying conditions that may also serve to skew the results. It is for this reason that Wollaston referred to the register as providing a series of 'anecdotes' that do not compare to clinical trials. That is not to say that such databases cannot be valuable in themselves – and this is particularly the case where there is a choice between the information being recorded and it not being recorded at all. However, the danger comes when, as imagined by the MIB (though not the AMTIA), such a register of treatments is made available to patients. Here there are two principle dangers. The first is that the register will almost certainly be literally incomplete. There is no requirement in either the MIB or the AMTIA for mandatory reporting, and therefore it is inevitable that some results will not be registered. We can also surmise that there will be greater temptation not to register unsuccessful treatments. The picture will therefore be incomplete.

This was identified as a danger by the BMA:

[30] The Brain Tumour Charity, Position Paper: Innovation in Treatment, https://assets.thebraintumourcharity.org/live/media/filer_public/17/0c/170c8b9d-1a07-4d2a-8a19-43ee2db49657/innovation_in_treatments_-_policy_position_statement.pdf (last accessed 25th April 2018). The same point is made by the Association of Medical Research Charities (of which The Brain Tumour Society is a member) in their briefing on the AMTIB: https://acmedsci.ac.uk/file-download/38141-5628ad61619e1.pdf (last accessed 25th April 2018).

> It is unclear whose responsibility it would be to record information on innovative treatments, and whether this task would be voluntary or not. It has also not been stipulated that records included in the proposed database would be quality assessed or peer reviewed. Without this rigour, the inclusion of instances of innovative practice in a database may give the impression that they are approved or have been given some form of endorsement for use again, and the seriousness of the consequences must be fully considered. This could represent a serious risk to patient safety.[31]

Secondly, the idea – as expressed in the graphic on the MIB's website on how the Bill was intended to work – imagines that patients will request the treatments that they find on the register from their doctors.[32] This can be seen as part of a libertarian, consumerist mindset that is the basis of US 'right to try' laws, something that the MIB team tried to link itself too – such as by using the hashtags 'saatchibill' and 'righttotry' together in tweets.[33] Patients would thus be encouraged, with incomplete information, to pressurise doctors into providing treatments that are untested. As Rebecca Dresser has noted in the context of 'right to try' laws, this patient population is already vulnerable; and more willing to hear voices that point at successful treatment and less cautionary tales.[34] In other words, truly informed decision-making would be made far less likely due to the distortion of information caused by a combination of objective factors (the incompleteness of the information available) and a natural desire to accept positive information while rejecting negative results. Clinical trial recruitment might be hampered in some cases and its replacement would be far less effective.

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[31] BMA, 'Parliamentary Brief: Access to Medical Treatments (Innovation) Bill', 29th January 2016. It can be downloaded from here: https://www.google.com/search?client=safari&rls=en&q=medical+innovation+bill+database&ie=UTF-8&oe=UTF-8 (last accessed 25th April 2018).

[32] This is certainly the subtext of the view that patients would search the register as put forward in the MIB website's own graphic describing how the Bill would work: http://medicalinnovationbill.co.uk/about-the-medical-innovation-bill/supporters-medical-innovation-bill/ (last accessed 25th July 2018)

[33] See here: https://twitter.com/search?f=tweets&q=%40saatchibill%20righttotry&src=typd (last accessed 25th July 2018).

[34] R. Dresser, 'The "Right to Try" Investigational Drugs: Science and Stories in the Access Debate' (2015) 93 Texas LR 1631.

Perhaps ironically, the MIB's official website recognised the issue of the difficulty of finding enough participants to enrol on clinical trials for very rare diseases, without stopping to think whether their database would make matters better or worse.[35] However, it should be remembered that the proposed database does not require either the MIB or the AMTIA to be set up. The Bills, in turn, do not require such a database to be established. There has also been no information regarding how it might be funded, and its potential benefits are, at best, questioned by key stakeholders. What is more, research charities feel that, if anything, it might serve to undermine clinical trial recruitment – something that can render them unviable for rarer diseases. This would, needless to say, cause us to question its social utility. Indeed, this is perhaps the reason that the government has taken no steps to set up the database at the time of writing. Nevertheless, the proposals for a database within the Bills do serve to pose some uncomfortable questions for us traditionalists.

Responding to Counter-Arguments

The first of these is the desirability for patients of participating in a clinical trial rather than receiving innovative treatment. There are several reasons why patients may prefer the latter. The first of these is that, while the aim of a clinical trial is to gather information about the safety and efficacy of the treatment, the provision of experimental treatment is designed to directly benefit the patient. Indeed, it is not coincidence that in RCTs those receiving the investigational drug or procedure are participants. It would be well within the realms of acceptable self-interest for people with chronic conditions and no other hope to wish to receive interventions that are designed to cure them rather than to test the drug.

Secondly, as mentioned above, in RCTs the participants have an equal chance of being in the control group, while all patients being treated will receive the experimental treatment. Again, it is well within the bounds of acceptable self-interest for a person to wish to choose the option that would guarantee them treatment. Put bluntly, the choice is between possibly receiving the experimental therapy or definitely doing so. If a database can help in this endeavour, it is difficult to regard it as a negative thing. Finally, any argument based on the idea that patients should want to be protected by the research infrastructure is based on the paternalist notion that a person should seek a clinical trial rather than experimental

[35] 'Ebola and the Medical Innovation Bill', http://medicalinnovationbill.co.uk/ebola-and-the-medical-innovation-bill/ (last accessed 14th May 2018).

treatment so that they can be afforded all of the protections inherent in the research process – such as ethical oversight from RECs and the compulsory insurance and compensation provisions. Again, the fact that the treatment's route guarantees treatment may well make experimental treatment a preferable option to many despite any increased risks.

There are, though, arguments against these objections. First, we have to be honest and say that clinical trials provide a more substantial social good, in particular to future patients. It is also still true that clinical trials also, by their very nature, provide a safer environment for patients, as well as more accurate information gathered due to the controlled conditions not present when providing innovative treatment on an individual basis. It is perhaps for this reason that even the libertarians behind 'right to try' (RtT) laws in the US specified that RtT should only apply when no clinical trial is available.[36] In other words, the provision of innovative treatment was meant to complement, rather than compete with, the clinical trial regime. The key, is honesty about what we are doing: we are protecting RCTs because they offer the best route to scientific progress in treating diseases for all patients in the long run. This may in some cases justify not encouraging individualised treatment if it harms the provision of RCTs.

Confidentiality

It will be remembered that the MIB and AMTIA envision different levels of access to the database. Under the MIB, it would be accessible to both doctors and the public, while the AMTIA framework appears to imagine that only doctors would be able to access it – although this is not made clear in the wording of the Act. It will also be remembered that the MIB was sold (although this was not the case in practice) as being designed for rare cancers and other rare diseases. Both of these present problems in relation to confidentiality, and each will be dealt with in turn.

Beginning with the latter, a good example of the problem would be treatment for Ebola. I use this example deliberately, since not only is it a rare disease, but it is also an

[36] Right to Try Act 2017 s.561(B), which explicitly limits eligibility to patients who are "unable to participate in a clinical trial".

example that was used on more than one occasion by the MIB team: on its official website,[37] by Lord Saatchi himself in the Daily Telegraph,[38] and indeed by supporters of the Bill in the House of Lords.[39] It cannot, therefore, be considered to be an unfair example, as the very architects of the legislation had it in mind themselves. Yet in the UK Ebola is as rare as it is possible to be: there is only one person in the UK who has received the experimental treatment. The case was widely publicised and we even know the patient's name: Pauline Cafferkey.[40] In the case of Ebola, then, we simply have to accept that any information on a database will not be confidential – we will know precisely who it pertains to. This is the case due to two factors: the rarity of the condition and the media attention that the case generated. With respect to the latter, this will clearly not eventuate in every such case. However, in relation to the rare nature of the disease, we can extrapolate that there is a higher chance of identifying information being available in exactly the types of disease that the MIB and AMTIA were sold as applying to. This is because the type of information that will be needed if the database is to be more than a collection of anecdotes, as critics claim – such as age and gender – may well also serve to identify the individuals concerned. In other words, not only can we not trust the database to be confidential, we can expect that in at least some cases we shall be able to identify at least one or more patients. Ironically, those conditions for which there are the most patients (and thus a higher chance of recruitment on to a clinical trial and therefore less need for the database) are the ones for whom anonymity is more likely.

In relation to whether the database is only open to doctors or whether it is open access, it is obvious that this will have a large effect on how likely it is that the patient may feel that her privacy is violated by the legislation. Equally obviously, this is exacerbated by the fact that the rare nature of the (claimed) conditions being registered make confidentiality impossible to guarantee. Again, the sort of detailed information that is needed to make the database useful to doctors and patients causes the problems, as it will have to be personal in nature. Patients, even those who wish to use their experiences to help others, may feel that this is an intrusion too far. Indeed, in the case of Source Informatics the Court of Appeal

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[37] (n 35).
[38] M. Saatchi, 'If it Works for Ebola, It Can Work for Cancer', Daily Telegraph, 20th October 2014.
[39] Such as Lord Cormack; see HL Deb, 24th October 2014, Col 877.
[40] The BBC have referred to her as 'the Ebola nurse' – see M. Cacciottolo, 'Ebola Nurse Pauline Cafferkey to Return to Sierra Leone', BBC News, 12 April 2017, http://www.bbc.co.uk/news/uk-39553391 (last accessed 14th May 2018).

considered the issue of aggregated medical information and identified the protection of personal privacy as the philosophy that should drive the law.[41] It is difficult to argue that such a breach of privacy would not occur in relation to Pauline Cafferkey, particularly if the information was open to the public. Yet this therefore begs the question of what, precisely, would be the effect of the patient therefore refusing to have their information included in the database?

Indeed, this brings up a central tension within the whole of the MIB/AMTIA framework: that since its authors had in mind a desire to 'free' doctors from the shackles of the law,[42] patients tend to be forgotten and their interests sometimes conflict with the ethos of the legislation. This is evident in the negligence provisions, where the key theme was putting doctors' minds at rest and allaying any fear of litigation. The unintended consequence was the consequent weakening of patient protection that this made inevitable, and this clash of interests was the focus of the criticism of the MIB/AMTIB's modifications to the law of negligence.[43] Yet a similar lack of consideration of patients can be seen in relation to the database.

That this is the case can be seen in the idea mooted by the architects of the Bills to require doctors to register innovative treatments – of course, it should again be made clear that neither the MIB nor the AMTIA actually does this. But there is nothing in either version of the legislation that provides patients with a right of choice, or for that matter provides them with a protected right to refuse. This is despite the fact that such information would clearly be confidential (if the patient is identifiable) under both English common law and the European Convention of Human Rights, and thus prima facie requiring a justification to disclose it.[44] See, for example, the explanatory notes that accompany the AMTIA:

> The Act provides a regulation-making power for the establishment of a database of innovative medical treatments by the Health and Social Care Information Centre ("the

[41] R v Department of Health, ex parte Source Informatics [1999] EWCA Civ 3011, [34] (per Simon Brown LJ).
[42] See M. Saatchi, 'Saatchi Bill: People Power Drives the Fight to Cure Cancer', Daily Telegraph, 1 May 2014.
[43] See generally Miola (n4).
[44] See X v Y [1988] 2 All ER 648 and Campbell v Mirror Group Newspapers [2004] 2 AC 457.

> HSCIC"). It is intended that information relating to innovative medical treatments, and the outcomes of those treatments, carried out by doctors in England will be passed to the HSCIC through the use of coding in patient notes. The detailed design of the database would be consulted upon with professional bodies and organisations. It is envisaged that the patient's right to privacy would be respected and the data securely managed. The database would be searchable by other doctors to use as a knowledge base of innovation. Again it is intended that the exact detail of how the access to the database would be granted would be consulted upon with professional bodies and organisations. The database would support the Government's emphasis on increased transparency and sharing of innovation and learning.[45]

As can be seen, while there is a reference to patient privacy, this seems to be aligned more with an attempt at anonymisation of the information through coding and the fact that it will only be searchable by doctors rather than any control by patients. The MIB was even more direct on this point. In a briefing note accompanying a new version of the Bill following the government consultation (before the results were known, and also containing no provision for a database), it was made clear that unless doctors registered their innovative treatments into the database they would not obtain the protection afforded by the MIB:

> we are committed to including an obligation on doctors that they must register innovative interventions in order to be protected by the Bill.[46]

As can be seen, not only are patients not given the choice regarding whether to allow their information to be used, but doctors are under an obligation to do so – with a threat of removing the legal protection offered by the MIB if they do not. As mentioned above, this is very much indicative of the way in which the MIB and AMTIA are focussed on doctors, with patients treated as something of an afterthought. It could certainly be argued that this would

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[45] Access to Medical Treatments (Innovation) Act 2016, Explanatory Notes para 7 http://www.legislation.gov.uk/ukpga/2016/9/notes/division/3/index.htm (last accessed 1st May 2018), emphasis added.

[46] Medical Innovation Bill Briefing Note, Session 2014-5, 10th June 2014, at 14. The note cane be found at: http://medicalinnovationbill.co.uk/wp-content/uploads/2014/05/Medical-Innovation-Bill-Briefing-Note-10th-June-2014.pdf (last accessed 1st May 2018). Emphasis added.

breach the law relating to privacy in England, unless the doctor first obtained the patient's permission. Yet this would mean that a patient who refused permission to have her information included in the database would risk being refused treatment unless the doctor was willing to sacrifice her legal protections. While it might be argued that the situation is the same in clinical trials, the difference here is that this would be a refusal of medical treatment rather than the research framework. The purpose of research is to gain knowledge, while the purpose of treatment is to benefit the patient. This is surely undesirable and yet another unintended consequence of the legislation's framework.

Conclusions on the Database

In conclusion, then, it is possible to identify several problems with the database that both remain outstanding or that no effort has been made to identify or resolve. This is perhaps unsurprising since, as noted above, there is at least a suspicion that the focus on the database was entered into with some reluctance by the MIB team, and became something of a way of saving face when the negligence aspects of the Bill were opposed so vehemently by key stakeholders. It could be argued that the fact that no effort has been made since the passing of the AMTIA to actually construct the database adds to the evidence for this view. Moreover, this would also explain why there are so many unexplored issues surrounding it. As I have noted above, there have never been any details provided about key questions such as funding, where exactly it would be hosted and how access would be obtained. There is not even any clarity provided on exactly what information would be included in the database. These are, unfortunately, the least of the unresolved issues. The prospective database has been criticised by research charities for providing an ineffective series of anecdotes that will fail to help in the way that the authors of the legislation claim. Even more seriously, it has been argued by researchers that it may well have an adverse effect on clinical trial recruitment, potentially rendering trials for very rare diseases unviable – precisely the sort sold by supporters of the MIB as those that the Bill was supposed to help. All of this is before we consider the issue of confidentiality, which cannot be guaranteed given the aim of providing information on the rarest of conditions and, in the case of the MIB, making the database open to the public. Finally, if we believe the claim that doctors will be obliged to register treatments on the database, there is the question of how to treat patients who do not

want their information to be included. This is a very real issue due to the problems regarding confidentiality identified above.[47]

Yet there is also a slightly different, more general point to make about the database. That is that its problems tie in with the general approach of the MIB/AMTIA, which is almost exclusively doctor-centric. The negligence provisions were a good example of this, in that they provided, at best, 'trickle-down' benefits to patients: the MIB did not seek to benefit patients directly, but instead hoped that by removing the fear of litigation that it claimed doctors had patients would (indirectly) obtain more innovative and better treatments. This focus on doctors caused, inadvertently, a weakening of patient protection and led to the criticisms of the negligence provisions. The same can be said about the database: little thought has been given to patients and what they might feel in relation to the sharing of their information. This would explain why confidentiality is not adequately addressed. It would also explain why there seems to be no thought at all given to the question of what happens to patients who refuse to agree to having their information included – or, indeed, any acknowledgment that such consent might be required at all.

But does this mean that no database would be worthwhile? Certainly, the open access version envisioned in the MIB is too problematic to be viable. The potential for the distortion of information and false expectations highlighted above is also troubling. The AMTIA's version, however, protects patient privacy more effectively by being available to researchers rather than the public, and as some information is better than no information it might be worth adopting. The greatest argument against it would appear to be the lack of clamour for it. Indeed, as pointed out in parliament, the AMTIA was not needed to create such a database: the Health and Social Care Act 2012 already does this. Moreover, since the AMTIA passed into law neither the government nor the medical and research organisations – so vocal during the debates about the Bills – have sought the establishment of the register. In other words, while this author would have no objection to the AMTIA's version being created, there seems to be little appetite amongst stakeholders for this to occur.

[47] We might argue that some form of social contract may apply here, in that such a database is in the pubic interest and therefore the right to confidentiality may be waived. However, it would certainly be controversial, as was seen through the attempt to use information already held by the NHS through the 'care.data' initiative.

Conclusion

The MIB, and then the AMTIA that followed it, sold themselves on the basis that they were granting rights to patients. This was never the case, as was repeatedly made clear by those of us who opposed the legislation. Rather, the intent was to create a culture change that, through a form of osmosis, would indirectly benefit patients as doctors felt unencumbered by the threat of litigation. The focus, then, was on doctors rather than patients. This attitude permeated the entirety of both Bills, and helps to explain many of the problems that this paper has argued persist. The less frequently discussed issue of the database – which after all is the only part of the enterprise to enter the statute book – contains several unresolved problems that are absolutely crucial to its viability: Who would be able to access it? How might privacy be protected when confidentiality cannot be guaranteed? If registration of treatments is compulsory, what happens to patients who refuse to consent to having their information included in it? These questions need to be answered, and that is before we get to the issue of whether such a database would be of clinical value at all. That is not to say that such a database could never have any value at all, as argued above, but it would need to be the AMTIA version.

The same can be said of the 'effect on the existing law' clause, although space limitaitons prevent me from developing this point. All in all, then, the less explored areas of the MIB/AMTIA can be said to be no less problematic than the dropped negligence provisions. This will not come as a surprise to many. What might do, however, is that no lessons appear to have been learned, as can be seen from Lord Saatchi's speech at the Royal Society of Medicine mentioned in the introduction to this paper.