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**Falling Between the Gaps Post the Declaration of Helsinki: Innovative
Medical Treatment in England: The Case for Comprehensive Legal
Regulation**

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Falling Between the Gaps Post the Declaration of Helsinki: Innovative Medical Treatment in England: The Case for Comprehensive Legal Regulation

This article explores and contrasts the current legal regulation of innovative treatment and health research in England. First, it explores what actually constitutes “innovative” treatment and considers the piecemeal regulatory structures which exist in relation to innovative treatment in England. Secondly, it contrasts this with the current n of clinical research post Nuremberg and the Declaration of Helsinki. Thirdly, it explores the impact of the Access to Medical Treatments (Innovation) Act 2016 and what this might mean for future regulation in this area. Fourthly, the paper suggests that it is time for a radical reconsideration of new ‘innovative’ or ‘experimental’ procedures and explores alternative approaches which could be utilised. It concludes by arguing that the regulation of innovative treatment in England is currently inadequate and provides insufficient safeguards for patients and that legislative reform is required.

Keywords: Innovative Treatment, Law, Health Research

I. Introduction

While the evolution of science and medicine has always led to innovation in clinical practice and new treatments, the sheer pace of change of scientific discoveries in health care across the developed world over the last century has been truly remarkable.¹ In a relatively short space of time, scientific developments progressed from Watson and Crick’s discovery of the

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¹ See e.g. Andrew Webster (ed), *New Technologies in Health Care* (Palgrave Macmillan, 2006).

DNA helix to the Human Genome project and the sequencing of the human genome at the turn of the millennium, to genetic diagnosis gradually changing the face of medicine.² Today we are moving into an age of personalized health care fueled by the information derived as a consequence of those DNA discoveries.³ Innovation in surgical practice itself can lead to ‘medical miracles’. From the first kidney transplant and heart transplant performed by Christian Barnard in 1967⁴ this is now live in an era of uterine transplants⁵ and face transplants.⁶ Stem cells, the ‘master cells’ of the body, can be used to grow new tissue and even ultimately body parts.⁷ Robotics is increasingly changing the practice of surgery.⁸

Yet, at the same time, rapid medical innovation also brings new challenges and real risks. There are notable examples and also cautionary tales of what can happen if scientific advances are introduced too fast, too soon and without proper scrutiny. Of course, to a certain extent, it is inevitable that the early stages of any scientific innovation will lead to failure as scientists and clinicians struggle to find the right approach/correct technique.⁹ Before the birth of Louise Brown, the first “test tube baby”, there were many unsuccessful

² Though for more scepticism in relation to this issue see Nickolas Rose “The Politics of Life Itself” (2001) 18 *Theory, Culture and Society* 1.

³ See e.g. discussion in Nuffield Council of Bioethics *Medical Profiling and online medicine: The ethics of personal healthcare in a consumer age* London (2010).

⁴ See generally the discussion in David Price, *Human Tissue in Transplantation and Research* (Cambridge University Press, 2009).

⁵ Wafa Fageeh, H, Raffa and Hussain Jabbad, ‘Transplantation of the human uterus’ (2002) 76 *Int J Gynaecol Obstet* 245; Mats Brännströ, et al. “Livebirth after uterus transplantation” (2015) 385 *Lancet* 607.

⁶ Lynn Eaton “First patient to receive complete face transplant can leave hospital” (2010) 341 *BMJ*, 27TH July 2010.

⁷ See e.g. the discussion in Russell Korobkin with Stephen R.Munzwer, *Stem Cell Century: Law and Policy for a Breakthrough Technology* (Yale University Press, 2008).

⁸ See e.g. Zeshaan Maan et al “The use of robotics in otolaryngology – head and neck surgery a systematic review” (2012) 33(1) *American Journal of Otolaryngology* 137.

⁹ See also Tsachi Keren-Paz’s contribution in this special issue at pages TO BE INSERTED AT PROOF STAGE **.

pregnancies.¹⁰ The recipient of the first heart transplant Louis Washkansky lived only for 18 days.¹¹ Nonetheless IVF and heart transplants today represent very successful medical innovations, albeit still raising potential risks. But innovation needs to be accompanied by effective assessment of risks and benefits - and without it there can be devastating consequences. One such example is that of the use of the drug Thalidomide for pregnant women with morning sickness in the 1950's and early 1960's which led to a large number of children being subsequently born with major disabilities.¹² The drug had not been tested as to its effects in pregnancy. Thalidomide led to a huge change in the approach to regulation of research on pharmaceuticals. The more recent case of Paulo Macchiarini provides a terrible cautionary tale of what can happen without effective regulatory controls.¹³ Macchiarini, along with his team, became famous in 2008 after inserting a new trachea into a young woman from a deceased donor in Sweden; the trachea was coated with stem cells from the patients' own bone marrow. The operation was heralded a success and because stem cells were derived from the patient it was claimed that she did not need immunosuppressant drugs. Similar operations on other patients followed. In 2011, Macchiarini developed a plastic windpipe which was then also coated with the stem cells of the intended recipient and implanted, which was followed by the treatment of some other 17 patients. The subsequent revelations of devastating harms and deaths of some recipients, including some treated in the

¹⁰ Remah M. Kamel "Assisted Reproductive Technology after the Birth of Louise Brown" (2013)14(3) *Journal of Reproduction and Infertility* 96.

¹¹ Interestingly Barnard told the patient's wife that there was an 80% chance of the procedure being successful something subsequently described as "wildly optimistic"- see David Lamb "Organ Transplants, Death and Policies for Procurement" (1993) 76(2) *The Monist* 203.

¹² See generally on the Thalidomide disaster *Distillers v Thompson* [1971] AC 458, Harvey Teff and Colin Munro, *Thalidomide: the legal aftermath* (Saxon House Reprint, S.Wales 1979); Pamela Ferguson, *Drug Injuries and the Pursuit of Compensation* (Sweet and Maxwell, 1999).

¹³ John Rasko and Carl Power, 'Dr Con Man: the rise and fall of a celebrity scientist who fooled almost everyone' *The Guardian*, 1st September 2017. BBC News "Paolo Macchiarini: A surgeon's downfall" (10th September, 2016). See further discussion by Sarah Devaney in this special issue. Also see the discussion of the implications of "innovation" in the context of off-label prescription in the Singapore Devathsan case in Tracey Chan, 'Legal and Regulatory Responses to Innovative Treatment' (2013) 21 *Medical Law Review* 92.

UK, demonstrated the lack of effective oversight of clinical innovation in treatment.¹⁴ Had both these procedures been classified as research, the resultant harm would very likely have been prevented.

While the Macchiarini case throws into sharp relief the need to ensure the safety of patients where the use of innovative treatments and technologies are proposed across jurisdictions, there has been a push back against the drive to regulate. It has been suggested that legal regulation simply serves to inhibit innovation thus reducing the prospect of patients accessing new treatments, rather than safeguarding patients' interests. So for example, in the United States there has been the introduction in some 38 states of what are known as "right to try" laws.¹⁵ Such legislation operates to enable patients who are terminally ill to have access to new drugs and devices which although having gone through early stage "Phase I testing", have not been approved by the US Food and Drug Administration (FDA).¹⁶ This is in addition to existing federal law which enables the doctor of a seriously ill patient to petition an Institutional Review Board that the risks to the patient do not outweigh what are the potential benefits.¹⁷ In addition, in May 2018, a Federal Right to Try Bill was signed by the US President.¹⁸ It gives terminally ill patients the right to seek drug treatments where these

¹⁴ Nigel Hawkes "News "Swedish Government sacks entire Karolinska Institute Board over Macchiarini (2016) 354 *BMJ* i4894; Stephan Wigmore, *Special Inquiry into Regenerative Medicine Research at UCL*, 29th September 2017. https://www.ucl.ac.uk/news/news-articles/0917/Special_Inquiry_Final_Report_605109702_7_.pdf (accessed 18th September 2018).

¹⁵ See discussion of the "Right to Try" Bills in the United States below and Rebecca Dresser "The Right to try Investigational Drugs: Science and Stories in the Access Debate" (2014) 93 *Texas Law Review* 1631; Jonathan Darrow et al., "Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs " (2015) 372 *New England Journal of Medicine* 279; Caitlyn Martin "Questioning the Right in State Right to Try Laws: Assessing the Legality and Effectiveness of These Laws" (2016) 77 *Ohio State Law Journal* 159.

¹⁶ See Colin B.Begg, Kyung M.Lim and James D. Neaton "Right to Try Laws" (2014) 11(5) *Clinical Trials* 519.

¹⁷ US Food and Drug Administration CFR Code of Federal Regulations, Title 21.

¹⁸ Morten Wendelbo and Timothy Callaghan, 'What is "right to try" and will it help terminally ill

have been approved under phase one of the Food and Drug Administration's approval process, but have not received full approval. In England, as we shall see below, the Medical Innovation Bill (referred to below as the “Saatchi Bill”) introduced by Lord Maurice Saatchi in 2011 was predicated upon similar principles to facilitate rapid access to “innovative” treatments because current legal regulation was seen as an inhibitor to clinical practice. But rather than law being an inhibitor, it can be argued that the regulation of innovative treatments simply does not go far enough. Despite the drive post-Nuremberg and Declaration of Helsinki to regulate innovation in the area of health research, innovations in medical treatment remain an outlier and are largely simply reliant on general principles of civil and criminal law.

Before considering the extent to which innovative treatment is and indeed should be regulated in English law, we need to pause and examine what actually is “innovative treatment”? What does it mean to say that there has been innovation? When is something really “new” and distinctly different? There has been considerable discussion in the academic literature as to what actually is a “new technology” and this provides a useful starting point and comparator as we consider what may be regarded as “innovative treatment”.¹⁹ A technology may be entirely “new” or it may simply be a new application which is derivative upon an existing application. As Boise de Chazourne comments, the “new technology of today will no longer be new in the future and more generally all technologies are new when

patients?” CBS News: The Conversation <https://www.cbsnews.com/news/right-to-try-bill-trump-signing-will-it-help-terminally-ill-patients-today-2018-05-30/>

¹⁹ See discussion in Therese Murphy ‘Repetition, Revolution and Resonance’ in Therese Murphy (ed), *New Technologies and Human Rights* (Oxford University Press, 2009) and the discussion in Nayha Sethi’s contribution in this special issue.

introduced into societies”.²⁰ Many health care developments can be seen as part of a continuum from early scientific development to the present day. The “great” scientific innovations may be staging posts along the way but are they necessarily as radical or indeed as “new” as they might at first appear? Innovation in relation to health care may, as Murphy highlights, be even more complex. Rather than a technology inevitably turning from new to old and becoming accepted or even replaced over time, the technology itself or aspects of it may be reinvigorated or even become effectively almost reborn. Murphy suggests that something such as IVF

May come and go from the early days of Louise Brown and the first test tube baby to the technology becoming almost mundane to engagement with fresh dimensions such as pre-implantation genetic diagnosis.²¹

As she suggests, an existing health technology may become “newly controversial”. Thus what constitutes an “innovative” technology or treatment can be seen as relative and a question of time and space.

In relation to treatments - the focus of this paper – ‘innovation’ consists in either being something which is unique to this context and has never been used before in another clinical setting, or something which has been adapted from use in a different clinical setting.²² A better approach is perhaps to consider adaptations as “experimental”. So clinicians are “trailing” the first heart transplant, the first brain surgery operation etc. In so doing they are essentially undertaking an experiment - essentially research, albeit not necessarily classified as such. Such definitional uncertainties can be seen as a practical problem in terms of

²⁰ Laurence Boisson de Chazournes “New Technologies, The Precautionary Principle and Public Participation” in Murphy *ibid*.

²¹ (n19) xx. PAGE NO TO BE ADDED AT PROOF STAGE

²² For further discussion see Sethi (n 19).

ensuring effective oversight and subsequent accountability. Nonetheless, in 2016 for the first time in English law, a statutory definition of innovative treatment was introduced in the Access to Medical Treatments (Innovation) Act (referred to subsequently as AMTIA 2016). The implications of this are explored below

The paper begins by examining what is very much a patchwork system of legal regulation concerning “innovative treatments” in English law. Secondly, it contrasts this with the current system of health research regulation. It argues that while the existing research regulatory framework is by no means perfect, nonetheless it provides a far better approach for regulating innovation on an evidence basis. Thirdly, it explores the potential impact of the AMTIA 2016 upon the regulation of innovative treatment in the future. While this legislation was initially intended to reduce the “fetters” of legal regulation, it is suggested that in its revised form (and despite its originators’ intentions) it could be used as a means for greater accountability and oversight and ultimately greater control over the use of innovative treatments in the future. Nonetheless, it is argued that this would still not go far enough. The article concludes by arguing that it is wholly time to re-evaluate the regulation of innovative treatments in the UK and it considers possible alternative approaches which could be adopted.

2. Innovative treatment, legal regulation and accountability

Much of the debate around innovative treatment in recent years has been premised upon the claim that existing English law concerning innovative treatment unduly inhibited innovation

by doctors.²³ But is this accurate? There is currently no overarching specific legal regulatory system for innovative treatment. Instead, current regulation is derivative upon existing legal principles which have general application. Healthcare professionals are responsible in law for their actions and any resultant harm caused to patients may lead to criminal prosecutions or civil tort actions.²⁴ Use of the criminal law against a clinician is rare and was not what drove calls for law reform to make it “easier” to undertake innovative treatment; rather, it was the alleged stifling effect of the law of negligence. To bring an action in negligence it is necessary to establish duty, breach and harm caused by that breach. While in the case of the doctor-patient relationship the duty itself is assumed to arise, it is the breach element which can be seen as more problematic. The standard of care to which doctors are subject was set out in the case of *Bolam v Friern Hospital Management Committee*.²⁵

A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.

Although *Bolam* did allow for judicial scrutiny, in practice it was interpreted very restrictively and establishing a successful claim in medical negligence proved very difficult. Even a small number of practitioners would be sufficient to establish a proper body of medical opinion.²⁶ Nonetheless, in the late 1990’s, the House of Lords in *Bolitho* did indicate

²³ See eg David Nutt “Saatchi Bill Will Stifle Explosion of NHS Litigation” (2015) 139(1) *Solicitors Journal*.

²⁴ See for example the recent case of Ian Paterson: Claire Dyer “Breast surgeon is convicted of 20 counts of unlawful wounding and wounding with intent” (2017) 357 *British Medical Journal* online, 2nd May 2017 and see also the Sentencing Remarks of Mr Justice Jeremy Baker, *R v Paterson*, <https://www.judiciary.gov.uk/wp-content/uploads/2017/05/r-v-paterson-sentencing-remarks-mr-justice-jeremy-baker-20170531.pdf> (last accessed 18th September 2018); Claire Dyer “Convicted breast surgeon Paterson has sentence increased to 20 years (2017) 358 *British Medical Journal* online, 4th August 2017. See further Ian Kennedy, *Review of the Response of Heart of England NHS Foundation Trust to Concerns about Mr Ian Paterson’s Surgical Practice; Lessons to be Learned; and Recommendations* (2013), <https://hgs.uhb.nhs.uk/wp-content/uploads/Kennedy-Report-Final.pdf> (last accessed 18th September 2018) and the ongoing inquiry *Independent Inquiry into the Issues raised by Paterson* chaired by the Right Reverend Graham James, Lord Bishop of Norwich <https://www.patersoninquiry.org.uk> (accessed xx).

²⁵ [1957] 1 WLR 582 (McNair J).

²⁶ *De Freitas v O’Brien* [1993] 4 Med LR 281.

that courts would be prepared to scrutinise decisions in clinical negligence cases and if the judgment of the professional was “not capable of withstanding logical analysis” a professional body of opinion could be held to be “not reasonable or responsible.”²⁷ While this was initially hailed as transformative, this was not in reality a radical change. As Brazier and Miola commented:

While the medical experts are to be required in rare cases to justify their opinions on logical grounds there still appears to be a *prima facie* presumption that non-doctors will not be able fully to comprehend the evidence. This leads inexorably to a conclusion that the evidence cannot after all be critically evaluated by a judge.²⁸

Moreover, the manner in which *Bolam* has been interpreted over several decades can be seen as affording a wide professional scope to clinicians. Despite this reality, the view that law was a fetter on clinical innovation continued. Concerns in relation to the stifling effects of the law on innovation in treatment were raised by Lady Butler Sloss in *Simms v Simms* in 2002:

The *Bolam* test ought not to be allowed to inhibit medical progress. And it is clear that if one waited for the *Bolam* test to be complied with to its fullest extent, no innovative work such as the use of penicillin or performing heart transplant surgery would ever be attempted!²⁹

However, as Montgomery notes, in *Simms* itself *Bolam* did *not* inhibit innovation and the treatment sought was authorised.³⁰ Hoppe and Miola argued that it was wrong to say that the current medical negligence system provided an “inappropriate deterrent” to medical

²⁷ *Bolitho v City & Hackney Health Authority* [1998] AC 232.

²⁸ Margaret Brazier & Jose Miola, ‘Bye-Bye Bolam: A Medical Litigation Revolution?’ (2000) 8 *Medical Law Review* 85. See also Rachel Mulheron “Trumping Bolam a critical legal analysis of Bolitho’s gloss” (2010) 69(3) *Cambridge Law Journal* 609.

²⁹ [2002] Fam Div 22.

³⁰ See now also *In the Matter of the Mental Capacity Act 2004 University College London Hospitals NHS Foundation Trust v by his litigation friend the official solicitor* [2018] EWCOP 29 and the discussion by Jonathan Montgomery in this special issue.

innovation.³¹ As they note, in fact the law of negligence gives considerable scope to clinicians with a considerable degree of deference given to professional decision making autonomy.

Nonetheless it is the case that not all clinicians would regard innovation as something which should be a matter for the specific surgeon to personally decide. Thus while in the recent Paterson case there was controversy over his personal decision to make use of a specific controversial clinical procedure - the “cleavage sparing” mastectomy - in other contexts clinicians have worked together to evolve innovative treatments and procedures. So for example, the Royal Brompton and Harefield NHS Foundation Trust London established a multi-professional group which is chaired by the Medical Director of the Trust who is also its responsible officer. The Trust comprises of senior doctors, nurses and managers and a representative from the Patient Advice and Liaison Service³² and it considers applications brought by teams and individual clinicians who are proposing new innovations. These are to be supported by a justification as to rationale, benefit, consent processes and training/equipment needed. In addition, after discussion by the team, data obtained is to be subject to audit and adverse outcomes must be reported. This type of approach enabling evidence-based innovation can itself be seen as good professional governance. The professional practice standard itself can also be seen as affected today by broader professional standards working at national level such as produced by the National Institute for Healthcare and Clinical Excellence (NICE) which is a statutory body. The NICE Medical

³¹ Nils Hoppe and Jose Miola “Innovation in Medicine through degeneration in Law? A critical perspective on the Medical Innovations Bill” (2014) 14(2) *Medical Law International* 266. 'Medical Innovation Laws : an unnecessary innovation' *Aust Health Review* (2015) <http://dx.doi.org/10.1071/AH15081>;

Bernadette Richards et al., “The Medical Innovation Bill: Still more harm than good”, (2015) 10 *Clinical Ethics* 1.

³² Kim Fox et al., “How should the UK pioneer innovative and untested procedures?” (2015) 386 *The Lancet*, October 10th 2015.

Technologies Evaluation Programme facilitates adoption of innovative technologies both diagnostic and therapeutic. Indeed, evidence-based innovation can be seen as something which is fundamentally desirable - a “gold standard” approach to aspire to. NICE also produces guidance on interventional procedures and their safety and efficacy. Procedures included here are “making a cut or a hole to gain access to the inside of a patient's body” and use of electromagnetic radiation.³³ In addition there is a NICE Interventional Procedures Advisory Committee advising NICE on developing guidance on a range of interventional procedures.³⁴ Where such guidance exists, it would inevitably be a factor to take into consideration if a subsequent negligence action was brought. But as Fovargue notes, while there is an expectation that such guidance would be followed, it is not legally binding as such.³⁵

But these developments at individual Trust level and via NICE, while potentially very valuable, are by no means comprehensive. At present, the general principles of criminal and civil law outlined above remain the legal framework for the regulation of innovative treatment, and they are retrospective. This regulatory framework is in stark contrast with the regulation of innovation in clinical research post the Declaration of Helsinki and the regulation of reproductive technology treatment and research considered in the next section.

3. Regulating innovation in clinical research post Nuremberg and Helsinki

³³ <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedures-guidance>, accessed 7th November 2018.

³⁴ <https://www.nice.org.uk/get-involved/meetings-in-public/interventional-procedures-advisory-committee>, accessed 7th November 2018.

³⁵ Sarah Fovargue, ‘Oh Pick Me, Pick Me-Selecting Participants For Xenotransplant Clinical Trials’ (2007)15 *Medical Law Review* 176.

The greater discretion clinicians have with respect to innovative *treatments* is in stark contrast to the ever increasing international and domestic regulation, post WWII, of innovation in clinical research. Nuremberg cast a long shadow upon the regulation of clinical research.³⁶ The Nuremberg Code was produced in 1949 and was later followed by the Declaration of Helsinki 1964 setting out fundamental ethical principles for undertaking research which provide the basis of research regulation internationally and nationally today.³⁷ It took some time before clinical research regulation was introduced in the UK, initially through developments from the Royal Colleges and the establishment of research ethics committees at local level. It was only in the 1990's that finally major government guidelines for Research Ethics Committees were published - the so-called 'Red Book' and a gradual proliferation of non-statutory guidance followed.³⁸ It was though from the 2000's onwards where the regulation of research in England started to develop apace. The first trigger for reform was the major scandal of the unauthorised retention of human material across the country leading to the Alder Hey Report.³⁹ The Human Tissue Act 2004 set in place a regulatory system for the use of human material both in relation to treatment and research which is rooted in the fundamental - and still not comprehensively defined - principle of "appropriate consent".⁴⁰ Secondly, reform was introduced as a consequence of the EU Clinical Trials Directive - agreed in 2001 and eventually implemented into domestic law in

³⁶ Aurora Plomer, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* (Cavendish Publishing, 2005); Hazel Biggs, *Healthcare research ethics and law: regulation, review and responsibility* (Routledge, 2009).

³⁷ Adopted by the 18th World Medical Assembly, Helsinki, Finland 1964.

³⁸ Department of Health, *Local Research Ethics Committees* (DoH, 1991) and see discussion in Jean McHale 'Medical Research: Some Ethical and Legal Dilemmas' (1993) 1 *Medical Law Rev* 160–186

³⁹ Bristol Inquiry Interim Report, *Removal and Retention of Human Material* (2000) <<http://www.bristol-inquiry.org.uk>>. *Report of the Inquiry into the Royal Liverpool Children's Hospital* (Alder Hey) (2001) <<http://www.rclinquiry.org.uk>>.

⁴⁰ See generally on the Act, David Price, 'The Human Tissue Act 2004' (2005) 68 *MLR* 798; Kathleen Liddell and Alison Hall 'Beyond Bristol and Alder Hey: The Future Regulation of Human Tissue' (2005) 13 *Medical Law Review* 170.

2004. This provided a legislative framework for clinical trials undertaken on medicinal products. It sets out requirements on matters such as consent and ethical approval and led to research ethics committees approving clinical trials concerning medicinal products on a statutory basis.⁴¹ A new Clinical Trials Regulation is due to come into force in later 2019 across the EU. Whether it comes into force in the UK is dependent upon whether at that point we remain under a transitional period following our formal exit from the EU in March 2019.⁴² This Regulation aims to facilitate cross-border trials through more streamlined processes including a new cross-border EU database on which details of all clinical trials concerning medicinal products would have to be entered. The third area was that of mental capacity. The Mental Capacity Act 2005 provides that intrusive research involving adults lacking mental capacity over the age of 16 in England and Wales is deemed to be unlawful unless subject to research ethics approval and authorised under the processes set out under related statutory instruments produced under the legislation.

These developments by themselves were, however, in distinct areas. It was not until 2009 that a general regulatory body the Health Research Authority was established in the UK first by statutory instrument then under primary legislation in the Care Act 2014. This Act is particularly significant as it provides the first statutory definition of health research. Section 110(3) of the Act provides

Health research is research into matters relating to people’s physical or mental health; but a reference to health research does not include a reference to anything authorized under the Animals (Scientific Procedures) Act 1986

⁴¹ As implemented in Pt 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031. See further discussion in Jean McHale, ‘Clinical Research’ in Judy Laing and Jean McHale (eds), *Principles of Medical Law* (4th ed) (Oxford University Press, 2017).

⁴² EU Clinical Trials Regulation 536/ 2014 and see further Emma Cave “EU Clinical Trials Regulation 2014: Fetter or Facilitator?” (2018) *Medical Law International* online first September, <https://doi.org/10.1177/0968533218799535>

The Health Research Authority's roles include coordinating and standardizing practice in relation to health and social care research along with functions to establish and provide oversight of research ethics committees.⁴³ Section 110(2) of the Care Act 2014 sets out the main objectives of the HRA in undertaking its role to protect participants in health or social care research and also the general public through the encouragement and facilitation of research which is "safe and ethical."

Even if procedures are in place to regulate research problems may arise. So for example, there was a major incident at an independent research unit at Northwick Park hospital in London in 2006, where six healthy male volunteers suffered a sudden violent reaction during a trial involving an anti-inflammatory drug, which was being developed for the treatment of arthritis and leukemia.⁴⁴ All six men suffered multiple organ failure, with two in particular suffering serious complications.⁴⁵ Thankfully, this case remains exceptional in the UK, which is a testimony both to enhanced regulation (the establishment of the HRA was several years after this incident) including ethics scrutiny, but also to an enhanced awareness by researchers of their own professional obligations and duty of care to research participants.

Clinical research regulation post Nuremberg and Helsinki is predicated on the regulation of risk of harm to others and the concern to safeguard fundamental human rights. But despite an increased use of statutory regulation of research at domestic level the existing legal framework is by however no means complete. So for example, consent to involvement in research on medicinal products remains to be determined by a mixture of both common law and statutory principles- the specifics of informed consent being left to the common law- an

⁴³ S.110 Care Act 2014.

⁴⁴ 'BBC News 'Six Taken Ill After Drug Trial' 6 March 2006 <<http://news.bbc.co.uk/1/hi/england/london/4807042.stm>>.

⁴⁵ See the special report established by the Secretary of State AUTHOR, *The Expert Group on Phase One Clinical Trials: Final Report* (2006).

area which in turn has never been tested in the courts.⁴⁶ To date there has been no attempt to seek to comprehensively codify the legal principles which apply in relation to health research such as in the areas of consent and confidentiality. Nonetheless being subject to regulatory norms is seen as a given – one which is in various areas subject to specific statutory regulation. In sharp contrast once something is classed as innovative treatment it falls outside such structures. There were, however, proposals made some 17 years ago which could have led to alignment of the processes. The Bristol Royal Infirmary Report in 2001 recommended that where a doctor was intending to undertake a ‘new and hitherto untried invasive clinical procedure’ this should be subject to a local research ethics committee determining that such a procedure was justified in the patient’s best interests.⁴⁷

There is, however, a notable example of an area where there is a statutory structure and related Codes of Practice which impacts on the development of both new treatments and research: IVF, driven by the birth of Louise Brown. This led to the establishment of the Warnock Committee⁴⁸ and eventually following the establishment of Voluntary and Interim Regulatory bodies of the passage of the Human Fertilisation and Embryology Act 1990.⁴⁹ The Act (as amended in 2008) provides for regulation of a range of reproductive treatments and also of embryo research. There is a statutory regulator in the form of the Human Fertilisation and Embryology Authority (HFEA). There are express statutory limitations on what research and treatment procedures can be undertaken and persons and premises

⁴⁶ Jean McHale “Innovation, informed consent, health research and the Supreme Court: *Montgomery v Lanarkshire* – a brave new world?” (2017) 12(4) *Health Economics Policy and Law* 435.

⁴⁷ See Bristol Royal Infirmary Inquiry, Final Report Recommendations (2001), paras 100-1.

⁴⁸ Dame Mary Warnock, *Report of the Committee of Inquiry into Human Fertilisation and Embryology* Cmnd 9314, (1983).

⁴⁹ E. Jackson, *Regulating Reproduction; Law, Technology and Autonomy* (Hart, 2001); Kirsty Horsey, *Human Fertilisation and Embryology: Reproducing Regulation* (Routledge 2007).

undertaking those procedures are subject to licence by the HFEA.⁵⁰ The HFEA proved generally responsive to new scientific and treatment developments in this area over the decades while at the same time recognizing the sensitive ethical and moral challenges which arise.⁵¹ This legislation is not totally comprehensive, as some requirements of informed consent also depend upon common law interpretations, such as those contained in the Mental Capacity Act 2005. Criticisms have also been made in relation to the speed of responsiveness to developments in technology, something which can be a problem where a statute is too . The need to respond to scientific as well as to social change led to the Act being reframed in 2008 to take forward a revised regulatory structure.⁵² Despite the criticisms, overall the 1990 Act has provided a framework through which innovative treatments and research - eg in relation to pre-implantation genetic diagnosis - have been able to develop in a considered and responsible manner.

4. Innovative treatment and the impact of the Access to Medical Treatments (Innovation) Act 2016.

To date, the current legal regulation of innovative treatments can be sharply contrasted with the regulation of activities deemed as being health research. However, as this section will argue that despite its problematic conception, the AMTIA 2016 may provide for the first time a pivotal moment such that innovative treatment could potentially be subject to specific

⁵⁰ Ss 12-5 Human Fertilisation and Embryology Act 1990.

⁵¹, *Review of the Human Fertilisation and Embryology Act 1990: Proposals for Revised Legislation* CM 6989 (Department of Health, 2006).

⁵² See generally Margot Brazier “Regulating the Reproduction Business” (1999) 7 *Medical Law Review* 166; Danielle Griffiths and Amel Alghrani “ Revisiting the regulation of the reproduction business” in Catherine Stanton et al., (eds) *Pioneering Healthcare Law: Essays in Honour of Margaret Brazier* (Routledge, 2015) and Amel Alghrani, *Regulating Assisted Reproductive Technologies* (Cambridge University Press, 2018).

legal regulation in the future. As mentioned above, until recently, there was no definition in English law as to what actually constituted an “innovative treatment” as such, but in 2016 the situation changed. AMTIA now for the first time enshrines in statute the words “innovative medical treatment”.⁵³ What could be the impact of this Act on the regulation of innovative treatment in the future?⁵⁴

AMTIA originally began with a private members bill, the Medical Innovation Bill (MIB) aimed at protecting clinicians who undertook some forms of innovative treatment from negligence liability.⁵⁵ The MIB was introduced by Lord Maurice Saatchi into the House of Lords in the 2013-4 parliamentary session.⁵⁶ The backdrop to the Bill was very much Saatchi’s frustrations as what he saw as existing legal structures inhibiting effective innovation in medical treatment following the death of his wife, the novelist Josephine Hart, from ovarian cancer in 2011. Saatchi was concerned that the law of negligence deterred clinicians from acting and created an inherent bias against innovation. Thus the law in his view should provide certain safeguards for innovating clinicians.

The original Saatchi Bill differed considerably from that which eventually received Royal Assent. From the perspective of the proponents of the original Bill, negligence was seen as the ultimate deterrent. As a result, the Saatchi Bill initially provided immunity in negligence for a doctor who departed from “the existing range of medical conditions for a treatment for a condition if the decision is taken responsibly”.⁵⁷ In ascertaining this, it sets out criteria

⁵³ S. 2(1) Access to Medical Treatment (Innovation) Act 2016.

⁵⁴ See further Jose Miola’s contribution in this special issue.

⁵⁵ See further Jose Miola “Bye-Bye Bolitho? The curious case of the Medical Innovation Bill” (2015) 15(2) *Medical Law International* 124.

⁵⁶ Maurice Saatchi “How can an act of Parliament cure cancer?” (2013) 106 *Journal of the Royal Society of Medicine* 189.

⁵⁷ S. 1(2).

including obtaining the views of one or more doctors who were ‘appropriately qualified’⁵⁸ and taking these views into account and obtaining any consent as required by law.⁵⁹ There should also be consideration of the patients’ opinions/requests or those expressed in relation to them, whether the risks/benefits of the treatments are those which can/not reasonably be expected to fall within the range of “accepted medical treatments” for the condition, and other factors relevant for a clinical judgement. Finally, the doctor was to “take such other steps as was necessary to secure that the decision is made in a way which is accountable and transparent.”⁶⁰ While the Bill provided for consultation by the treating doctor of other clinicians, there was no requirement that the treating doctor actually had to take into account the views of those consulted.⁶¹

The potential impact of the Saatchi Bill on the law of negligence was the source of acute controversy. Major concerns were advanced, by many in the medical and legal community, as to the impact of the Bill. Miola argued that there were various myths around its nature and scope.⁶² Assertions that the Bill was limited to rare cancers and other diseases were inaccurate. There was no specific evidence establishing that the increase in the number of NHS negligence claims concerned innovative treatment.⁶³ Furthermore, claims that the Bill had received wide support were also a myth. Despite suggestions that there had been overwhelming interest in the Bill, the Department of Health received only some 170 responses to its Consultation on the Bill, a large number of which were very critical,

⁵⁸ S.1(3)(a)

⁵⁹ S 1(3)(b) and(c).

⁶⁰ S. 1(3) (f).

⁶¹ Hoppe and Miola (n31) 271.

⁶² See Miola (n 55) 129.

⁶³ Ibid 131.

including those from medical bodies such as the GMC and BMA.⁶⁴ The Bill was amended during its passage to include a data registry which would enable information regarding innovations to be recorded with the aim that this information would be accessible to doctors. The Bill eventually passed through the Lords in January 2015 but fell before consideration in the House of Commons due to the 2015 General Election. It was subsequently introduced into the House of Commons by the MP Chris Heaton- Harris, renamed as the Access to Medical Treatments (Innovation) Bill, and built upon the original Saatchi Bill. It initially also contained provisions concerning clinical negligence and a proposed database. The provisions concerning the law of negligence were removed at Report stage after amendments were tabled by Mr Heaton-Harris and the eventual Bill was simply concerned with the establishment of the database.

On its face, the 2016 Act seems a pale shadow of its predecessor Bills. It is, however, significant in several respects. Section 2(1) provides for the establishment of a database by the Health and Social Care Information Centre (HSCIC) through regulations enacted by the Secretary of States which will contain information regarding:

- a) innovative medical treatments carried out by doctors in England, and
- (b) the results of such treatments.⁶⁵

The HSCIC is now known as NHS Digital. The database is to be located within NHS Digital because this body is concerned with the establishment and maintenance of information systems within the NHS itself. The regulations will enable NHS Digital to state what information is to be recorded in the database, what procedures will be undertaken in relation to recording of such information and how there will be access to information contained in the

⁶⁴ Ibid 134, 136.

⁶⁵ S.2 (1).

database.⁶⁶ The regulations can also authorise NHS Digital to disclose information to specified persons or for specified purposes or to impose conditions as to how information could be used. The original Saatchi Bill included provision for an open access register for innovative treatments. This was criticised by some professional bodies such as the Association of Medical Charities who thought it could undermine clinical trials.⁶⁷ Miola suggests that the new legislation is effectively redundant as section 254 of the Health and Social Care Act 2012 already gives the power to the Secretary of State to establish databases.⁶⁸ It can be argued, however, that the register as set out in the 2016 legislation may be seen as a positive move. The provision in the 2016 Act arguably goes beyond the scope of section 254 as the latter applies to the obligations of the Secretary of State in relation to the NHS but the 2016 Act is not limited in that way and could be arguably used to require information disclosure by clinicians used in private practice. Secondly, the Saatchi Bill took the approach that a register would be seen as a professional obligation although, as Miola commented, the GMC itself had indicated that it had no intention of establish or police such a register.⁶⁹ In contrast, the final provisions in AMTIA 2016 have the advantage of placing the register within NHS Digital for its operation thus making it a responsibility of the NHS itself. The intention is that the database will be established after consultation with doctors. Information concerning innovative treatments will be transferred through the NHS via coding undertaken in the notes of patients.⁷⁰ The best approach would be to require entry of information to be a mandatory professional requirement of clinicians with specific criminal penalties attached for failure to comply with these requirements. This then could be linked to

⁶⁶ S.2 (3).

⁶⁷ See (n55) at page 138.

⁶⁸ See Miola in this special issue.

⁶⁹ See Miola (n 55) 137-9.

⁷⁰ See Explanatory Notes, para 7.

annual detailed and effective audit of “innovative” clinical practice. Outcomes could be assessed. In addition, the legislation could be expanded to require that information regarding innovative clinical practice be included in an annual report required to be submitted by the Secretary of State for Health to Parliament for scrutiny. Such an approach would be in line with the recent introduction of the statutory duty of candour placed on health care professionals.⁷¹ Some concerns have been raised as to the extent to which such a register can be aligned with issues of confidentiality. It is almost certain that such information would be anonymised. It is true that if the database was open and included identifiable information, aspects of successful high profile cases would inevitably and problematically be in the public domain.⁷² In addition, it has to be recognised that privacy and confidentiality are inevitably a spectrum and indeed section 254 as with its predecessor provision can themselves be seen as effectively “driving a coach and horses” through patient confidentiality given the number of exceptions they enable.⁷³

One particularly notable aspect of AMTIA 2016 is that section 2(1) sets out for the first time in English law a definition of what actually constitutes “innovative treatment”. Given the definitional complexities and uncertainties of this term highlighted above, this may be thought to be welcome. The statute provides as follows:

S.2 (2) In this section, “innovative medical treatment” means medical treatment for a condition that involves a departure from the existing range of medical treatments for the condition.

⁷¹ See further Jean McHale, ‘Patient safety, the “safe space” and the duty of candour: reconciling the irreconcilable?’ in John Tingle, Clayton O’Neill, and Morgan Shimwell (eds), *Global Patient Safety, Law, Policy and Practice* (Routledge, 2018).

⁷² See discussion by Miola in this special issue.

⁷³ See further Health Services (Control of Patient Information) Regulations 2002, SI 2002/1438, reg 4; Paula Case, ‘Confidence Matters: The Rise and Fall of Informational Autonomy in Medical Law’ (2003) 11 *Medical L Rev* 208.

At first glance this might seem straight forward and indeed obvious. The kernel of ‘innovation’ is doing things differently. But a closer look renders the definition more than a little perplexing. A treatment may be a departure from existing medical treatments but still not ‘innovative’, in that it fails to be very new. So for instance it might not be seen as “innovative” in the form of advancing new science because it has been used previously but is currently seen as outdated or discredited.⁷⁴ The Act does give some examples as to the type of procedures which may be included under legislation. Section 3(2) provides that

For the purposes of section 2(2), the kinds of medical treatments include (amongst other things) -

- (a) the off-label use of an authorised medicinal product, and
- (b) the use of a medicinal product in respect of which no marketing authorisation is in force

Section 3(3) states that ‘off-label’ concerns its use

- (a) for a purpose other than the one for which its use is specified,
- (b) in relation to a person who is not within a description of persons for whom its use is specified or
- (c) in any other way in which its use is not specified.

The rationale for this inclusion can be seen as linked to the history of the legislation itself. It makes it easier for off-label use of drugs. But again closer examination reveals that a further element of complexity is introduced. As the Explanatory Notes make clear, use of “off label” drugs “are not necessarily always innovative. “Off label uses of medicines in particular may

⁷⁴ See further in relation to what constitutes innovation Nayha Sethi’s contribution in this special issue.

be part of standard care for some conditions”.⁷⁵ A further interesting exception included in the legislation is that of section 3 (6) which provides that

Nothing in section 2 applies in relation to treatment which is carried out solely for cosmetic purposes

Clearly, cosmetic purposes are not seen as a priority in this regard. Very confusingly there is no further definition of what constitutes “solely for cosmetic purposes.” Given that this term is not defined in a statute elsewhere, it could be potentially very broad indeed.⁷⁶ Does this mean that the draftsmen of the legislation regarded “cosmetic procedures” as fundamentally different from other treatments? But what precisely is a procedure which is solely for “cosmetic” purposes? Some cosmetic procedures may very well be seen to be at least to some extent therapeutic in nature, for example, ear pinning in children and breast reconstruction in the case of patients who have had a mastectomy as part of cancer treatment. Secondly, this assumes that such procedures are not to be seen as “special” for recording innovation. It could be argued that the performance of cosmetic procedures is precisely an area where any innovation needs recording. It may be far more difficult in the private sector to ensure the accountability of a particular physician working in the private sector on a day to day basis. Moreover, the lack of comprehensive regulation of cosmetic procedures and concerns regarding their ethical dimension have been the subject of considerable debate in

⁷⁵ Explanatory Notes to the Access to Medical Treatments (Innovation) Act 2016, para 20.

⁷⁶ Cf Nuffield Council on Bioethics which defines cosmetic procedures in their (2017) report “*Cosmetic Procedures: Ethical Issues*” as being “the definition contained in invasive, non-reconstructive procedures that: aim to change a person’s appearance primarily for aesthetic, rather than functional, reasons; are carried out by third parties in a medical environment, or in an environment that ‘feels’ medical (such as a medi-spa); and are not ordinarily publicly funded through public health systems such as the NHS.’ See also the Queensland Public Health Act 2005 which criminalises cosmetic procedures performed on persons under 18 and defines these as being including abdominoplasty, foreheadplasty, liposuction or liposculpture, resurfacing of the skin by removal of the epidermis, and penetration of the papillary dermas, insertion of facial contour implants, mammoplasty, genioplasty, insertion of permanent injectable fillers, rhinoplasty, and porcelain veneer of teeth.

recent years.⁷⁷ Thus this is an area which should not be excluded from the scope of data collection.

Innovative treatment may be “new” treatment. It may be the first time that this has ever been used. But of course, what constitutes “new”, as we have already seen, is very much a question which operates within a particular paradigm of time and of “space”. Something may be innovative because it is new and thus extraordinary and unusual but remains so for only a limited period of time before it becomes routine. AMTIA 2016 is interesting in that it classes innovation in terms of doing something differently. A treatment may be innovative because it is using something, whether a drug or a surgical technique, which is already in existence but for a different purpose, such as Botox.

The Saatchi Bill was ultimately neutered in Parliament. It remains to be seen how the proposed database will operate. At the time of writing there have been no statutory instruments drafted or implemented consequent upon AMTIA 2016. Certainly, the law of negligence remains intact. The Government has also not moved forward to attempt to put into place effective regulation of clinical innovative treatments in general. The process remains fractured and complex. The whole area is ripe for reform - but how? The final section of this paper considers what alternative approaches could be adopted.

⁷⁷ Sir Bruce Keogh , *Expert Group on the Regulation of Cosmetic Surgery: report to the Chief Medical Officer* (2005); Department of Health, *Poly Implant Prosthèse (PIP) breast implants: final report of the expert group* (2012); Department of Health, *Review of the Regulation of Cosmetic Interventions* (2013) and Melanie Latham, ‘The shape of things to come: feminism, regulation and cosmetic surgery’ (2008) 16(3) *Medical*

Law Review 437.

5. Conclusions: Stopping Innovative Medical Treatments Falling Between the Gaps

Today in the UK, there are very clear routes of approval and scrutiny for health research, including the role played by research ethics committees. In contrast, as has been outlined above, any form of specific effective legal regulation of innovative medical treatments has been absent. This inevitably leaves patients vulnerable. While transgressions may of course bring to light problems with innovation and this can lead to prosecutions or to litigation, the obvious limitation here is the retrospective nature of the criminal and civil responses. For all the controversy around its inception, AMTIA 2016 did raise awareness of some of the problems of the regulation of innovation in treatment. However, as noted above, much of the public discourse and debate concerning the original Saatchi Bill distorted reality by viewing existing English negligence law as significantly inhibiting innovation.

Nonetheless, AMTIA 2016 does potentially provide the start of a change in approach. The very existence of the new statutory register, despite the definitional challenges as to what is included, may prove in hindsight to be a significant breakthrough. The need for evidence-based medicine is effectively inherent in the creation of such a register. For example, the departure from “accepted practice” will have to be documented. This in turn could ultimately lead to enhanced transparency of decision making and enhanced data regarding innovation being available. But by itself, this is simply not sufficient. Further detailed audit and empirical evidence are needed as to how this has been undertaken at local level and what the challenges have been in practice. The next step should be for the UK Government to undertake a comprehensive retrospective analysis of the conduct of innovative medical procedures nationally taking initially a sample of a two year period. This would provide

much needed information for researchers, patients and the wider public and would assist in informing new regulatory structures.

Secondly, Government and stakeholders should consider whether we should move away entirely in the clinical context from the term “innovative” to “experimental”. “Experimental” may provide a more realistic description of what is actually being undertaken in such a situation. As has been argued in the context of innovation in reproductive technologies, responsible innovation should require such technologies to be the subject of research.⁷⁸ Experimental procedures need evidence and oversight. There is currently no effective international comparator for comprehensive regulation of innovative treatments, thus here the UK Government has real opportunity to innovate in its regulatory approach. One possible option would be that of incorporating this role within the scope of the HRA, while enhancing the HRA’s role and clarifying the legal position concerning consent to involvement in research etc. Such a regulatory structure would need to include proportionate regulation recognising that there is a range in innovative procedures and practices which inevitably poses different degrees of risk to the individual patient but also potentially to future patients or the wider community. Such an initiative would of course need the Government to commit the appropriate financial resources and staffing to undertake this task. It would have the advantage of providing experimental procedures and undertaking ethical analysis under a body with existing experience of oversight in this area. However, this would also involve a considerable extension of the HRA’s role. In addition, if the HRA were to undertake this task this would need to be linked to enhanced statutory powers. The new medical innovations database should be subject to HRA operation and oversight. In addition, there would need to

⁷⁸ See Wybo Dondorp and Guido de Wert “Innovative reproductive technologies: risks and responsibilities” (2016) 7 *Human Reproduction* 1604.

be greater detail of the specific provisions of the law relating to research. The structure of the Human Fertilisation and Embryology Act 1990 and the Human Tissue Act 2004 could be followed. This would involve clear informed consent provisions supported by specific criminal provisions to ensure their enforcement in practice. Codes of practice could be drawn up to provide guidance as to the ethical and legal requirements of obtaining consent in such a situation. New proposed innovative treatment/techniques could be subject to approval by the new HRA.

Such a development would constitute a huge departure from the debates over the “right to try” legislation. It would recognise that we are dealing with risky and potentially very dangerous innovations which require appropriate oversight and regulation from experienced experts. Of course, some might argue that such regulatory frameworks would stifle innovation, but this should not be the case. There has been regulation of pharmaceuticals for many years since Thalidomide and yet this has by no means stopped scientific progress in medicinal products.⁷⁹ Aligning clinical research and innovative medical procedures under the same legal regime would have the further advantage of ensuring that as a society we recognise that innovative treatments are essentially experimental and raise fundamental questions of safety and human rights. Post Nuremberg and the Declaration of Helsinki we do have fundamental principles which underpin the regulation of research practice. In relation to innovative treatment, these are glaringly absent. While innovative treatments are effectively experimental, they fall through the gaps and are outside the regulatory structure. The events of the last few years should prompt the Government to look again at the legal regulation of

⁷⁹ cf Richard Epstein, *Overdose: How Excessive Government Regulation Stifles Pharmaceutical Innovation* (Yale University Press, 2006).

innovative medical treatments in England to pre-empt the prospect of further risk of harm to patients.