Northern Ireland Legal Quarterly

Volume 70 Number 1

Spring 2019

Chief Editor

Dr Mark Flear

Queen's University Belfast

School of Law

NILQ

Contents

Special Issue: Reviewing the boundaries of health law – new directions and dimensions

Guest Editors: John Coggon and Judy Laing

ISSN 2514-4936 (online) 0029-3105 (print)

NILQ 70(1): 1–3

Reviewing the boundaries of health law – new directions and dimensions: editorial

John Coggon and Judy Laing

Centre for Health, Law, and Society, University of Bristol Law School

It is an important and exciting time for scholars working at the intersections between law and health. The scope of our study is expanding in its practical reach, the range of disciplinary approaches that we employ, and in relation to our learning from, collaborations with, and influence on partners, actors, and agencies outside of academia; including those affected by, regulated by, and involved in the production of health law. We were delighted to mark this expansion with the founding, in October 2017, of the University of Bristol's Centre for Health, Law, and Society (CHLS),[1] and, consequent to the Centre's launch event,[2] the production of this special issue of the *Northern Ireland Legal Quarterly*. Our aim with CHLS – which draws together colleagues with wide-ranging interests, expertise, and practical experience in health law – is to push through the traditional boundaries of the field of healthcare ethics and law, and to explore new directions and dimensions; to identify how we should reconfigure the historical, conceptual, and practical reach of the field, and advance its potential to represent the best of rigorous research as a simultaneously theoretical and applied area of study. This special issue is a marker of, and contribution to, that aim.

As identified in Margaret Brazier and Jonathan Montgomery's opening paper ('Whence and whither "modern medical law?"'), which takes a long view on the history of the field, there are currently significant challenges confronting health law, at both an academic and a practical level: some challenges are more pervasive (e.g. the impacts of Brexit, austerity); some are rooted in the healthcare sector (e.g. questions regarding regulation of and in the NHS); some derive from the expansion of health as a concern across sectors, and entailing both the traditional micro- and the less explored macro-level concerns; and some obtain from the continued (relative) neglect of areas of concern (such as mental ill health). With such challenges in mind, the following six papers seek to shine a spotlight on areas of importance, and on critical and practical approaches, that are too easily neglected in health law. For example, our contribution ('Exploring new paradigms in mental health and capacity law: persons, populations, and parity of esteem') focuses on mental health inequalities and the significance of law to a population health approach to achieving better mental health and wellbeing; Albert Sanchez-Graells ('Centralisation of procurement and supply chain management in the

1 See <www.bristol.ac.uk/law/research/centres-themes/chls>.

2 See < www.bristol.ac.uk/law/research/centres-themes/chls/about>.

English NHS: some governance and compliance challenges') explores the impact of the new model for NHS procurement on the delivery of care in the NHS, and key challenges for assuring legal oversight. The collection's aims to push agendas that link interdisciplinary insights with practice are represented, for example, in Oliver Quick and Catherine Kelly's historical analysis applied in the area of patient safety and achieving candour in the NHS ('The legal duty of candour in healthcare: the lessons of history?)'; and in Dave Archard's paper ('"My child, my choice": negotiating disagreement between doctors and parents'), which examines the place of philosophical commitments in health law and public debate. And the special issue's aims to examine and contribute to ensuring the coherent expansion of the field, both in terms of coverage and critical approaches, are illustrated, amongst others, in Keith Syrett's paper ('Healthcare resource allocation in the English courts: a systems theory perspective'), which considers the novel application of systems theory as a tool for explication and evaluation of the relationship between law and allocative decision-making; and the critical feminist perspective, re-enforced through original empirical research and doctrinal legal analysis, in the paper by Louise Austin and Sheelagh McGuinness ('Reproductive loss and disposal of pregnancy remains').

As well as the extended articles, we are delighted to include legal and academic commentaries, which further highlight the expansive nature of health law as an academic and practical agenda. Jane Rooney's case note on extraterritorial corporate liability for environmental harm reinforces the potential to move in new directions, highlighting how human rights can play a much stronger role than traditional tort law mechanisms to protect citizens across the globe from environmental harms which damage their health and wellbeing. Transcending traditional boundaries is a key theme in Peter Dunne's legislative note on the new law to affirm the 'diverse' legal gender of persons who experience intersex variance in Germany. He welcomes the introduction of the new law, but at the same time offers some important critiques on the limitations of the German approach. We are also pleased to include book reviews on topics that push the boundaries of health law. The first, from Paul Skowron, on Charles Foster and Jonathan Herring's *Depression: Law and Ethics*, emphasises the importance of interdisciplinary legal studies regarding mental health; and the second, a review by Louise Hatherall of Benjamin Meier and Lawrence Gostin's latest edited collection on *Human Rights in Global Health: Rights-based Governance for a Globalizing World*, underscores the importance of international legal norms and trans-jurisdictional health challenges.

Our hope is that this rich collection of essays is indicative of some of the challenges and proper directions for the next generation of health law scholarship, and represents well the contributions that we anticipate will be made by scholars across the field, including from within CHLS. We are both honoured to be the founding Co-Directors of the Centre, and proud that it spans such an impressive range of research expertise, as evidenced by the breadth and depth of contributions from 11 of CHLS's members to this collection. We are grateful to the University of Bristol Law School for its support for the establishment of the Centre, for the launch event itself, and in the ongoing work of CHLS. We thank as well Professor John Iredale, Pro Vice-Chancellor (Health) at the University of Bristol, for his support at that event and his subsequent, continued encouragement. We would also wish here to thank the participants and attendees at the CHLS launch for their constructive contributions and comments, as well as to all of the contributors to this collection – both colleagues within and beyond CHLS – for sharing their insights and ideas. In the production of this special issue, many academic colleagues have given generously of their time to assist with the anonymous review process,

for which we give our thanks. Finally, we would like to express our gratitude to Marie Selwood for her editorial assistance and efficiency, and to Mark Flear, the Chief Editor of the *Northern Ireland Legal Quarterly*, and other members of the Editorial Board, for supporting the scholarship in this special issue.

NILQ 70(1): 5–30

Whence and whither 'modern medical law'?

MARGARET BRAZIER*
University of Manchester
and
JONATHAN MONTGOMERY**
University College London

Abstract

Academic study of law relating to healthcare has flourished in the UK. Yet our field of study is often seen as 'new', both as an 'area of importance in legal practice and as an academic discipline'. We argue that practical engagement between English law and medicine has a long history, a history revealing that claims of historic deference from one learned profession (the law) to another (medicine) is a myth. We further contend that 'medical law' as an academic discipline also enjoys a history. We explore these histories by looking back to the late medieval and early modern eras, and then show that crucial developments in more recent history have been overlooked in the emphasis on medical law as 'new'. An appreciation of whence *'medical law' is crucial to assessing how future directions for law and scholarship in relation to the regulation of health may develop* – whither *it may go.*

Keywords: medico-legal history; deference; regulation of health: future.

Introduction

In this paper – a first version of which was delivered by Margaret Brazier at the inspiring conference held to celebrate the inauguration of the University of Bristol's Centre for Health, Law, and Society – we explore the past and speculate on the future of the relationship between English law and health. This paper derives from a series of conversations between the authors, conversations which may pose more questions than answers.

In 2000, Andrew Grubb contended that what he and Ian Kennedy described as 'medical law' was 'still a comparatively young subject', and only late in the twentieth century had it emerged in English law 'as a distinct subject, both as an area of importance in legal practice and as an academic discipline'.[1] Insofar as there was any history of engagement between law and medicine, the assumption was made that judges had from time immemorial deferred to their medical brethren.[2] We argue that practical engagement between English law and medicine has in fact a long history, a history which (inter alia)

* Centre for Social Ethics and Policy, School of Law, University of Manchester, margaret.r.brazier@manchester.ac.uk.

** Faculty of Laws, University College London, jonathan.montgomery@ucl.ac.uk.

1 A Grubb (ed), *Kennedy and Grubb: Medical Law* (3rd edn, Butterworths 2000) 3.

2 H Teff, *Reasonable Care: Legal Perspectives in the Doctor/Patient Relationship* (Clarendon Press 1994) 69.

reveals that the claim of historic deference from one learned profession (the law) to another (medicine) is a myth, and a myth that retarded the development of the law. Slightly more tentatively, we further contend that 'medical law' as an academic discipline also enjoys a history, albeit a neglected one. We first explore these histories by looking back several centuries to the late medieval and early modern eras. We then show that some crucial developments in more recent history (the 1940s–1980s) have been overlooked in the emphasis on medical law as 'new'. Some appreciation of the history of 'medical law' is crucial to assessing how future directions for law and scholarship in relation to the regulation of health may develop, and to prevent us making the same mistakes again and again. We argue that there are enduring themes that enable us both to understand better the continuity between the emergence of medical law as a discrete subject and its antecedents and also to identify key issues for the future. We end by considering possible future directions, informed by our historical analysis, but also recognising that now and in the future there will always be contemporary pressures arising both from developments in biomedical science and social change that we and our ancestors have not yet encountered.

'Modern medical law'

Ian Kennedy's Reith Lectures published in 1981 as *The Unmasking of Medicine*[3] are often cited as marking the birth of medical law in the UK.[4] *The Unmasking of Medicine* and the creation in the mid-1980s of academic centres dedicated to the study of medical ethics and law[5] may rather be seen as marking the beginning of the rebirth, for some a 'renaissance',[6] of medical law, not its birth. We will describe this rebirth as 'modern medical law'.

We do not question the evidence that this rebirth has witnessed the rise of a sub-discipline of scholarship to be variously named 'medical law', 'healthcare law' or 'health law'. The nomenclature of the subject of study has provoked sharp differences of opinion among scholars.[7] What may be more readily agreed is that, as the sub-discipline grew up, its adherents sought to research and critique the relationship between law and the practice of medicine, the provision and regulation of healthcare and the amazing developments in biomedical science. The debate over the naming of the subject area will continue, but we have concluded that it can be a distraction, and that understanding where this burgeoning area of legal practice and academic enquiry came from is an important guide to where it might go to in the next three decades. In this paper, we concentrate on this issue rather than seeking to defend a particular label.

The development of scholarly study of 'modern medical law' in the past 30 years cannot be divorced from at least three other key developments affecting the law as it applied to health matters. (1) At the same time that academic enquiry developed in this field in the last quarter of the twentieth century, English judges began to abandon their apparent prior deference to 'medical men', patients became less patient, and the courts as well as academe became much more engaged with questions of healthcare practice.

3 I Kennedy, *The Unmasking of Medicine* (Allen & Unwin 1981).

4 D Wilson, *The Making of British Bioethics* (Manchester University Press 2014) 105–39.

5 Ibid 196–209.

6 See J Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship* (Hart 2001) 33–54, on a medical ethics 'renaissance'.

7 See J Montgomery, *Health Care Law* (Oxford University Press 1997) 1–4; J Coggon, *What Makes Health Public* (Cambridge University Press 2012) 86–91; T Hervey and J McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015) 10–29.

Medical law swiftly became an area of importance in legal practice. (2) Closely linked, if not conjoined to the growth of law in relation to healthcare, are profound changes in the older tradition of medical ethics, first in Gillon's emphasis on 'critical ethics'[8] and then in the evolution of bioethics,[9] culminating in a sometimes uneasy sibling relationship between law and bioethics.[10] (3) Finally, the development of research in law, ethics and healthcare was swiftly mirrored by a proliferation of undergraduate courses in UK law schools on medical or healthcare law and ethics and the creation of specialist Masters' and PhD programmes focused on law, ethics, medical science and healthcare.

The pace and extent of these developments might be seen as proof that claims of something 'new', in academe in particular, were right. Travel back in time to the 1960s and tell the Dean of a Faculty of Law that his undergraduates and postgraduates should study medical law or law and healthcare, whatever name you chose for your proposal, and the likelihood is he would respond with a derisory laugh. Announce an intention to research law and healthcare and you might well meet the puzzled question: 'Surely this isn't legal scholarship?'. Legal scholars addressed the development of the common law, fundamental questions of obligations, contract and tort, property law, jurisprudence, international law. The study of Roman law marked a scholar out as a true intellectual, and legal history was respectable.

Family law was only barely respectable. In 1957, when Peter Bromley wrote a textbook on family law,[11] eyebrows were raised. What on earth was a good Oxford man like Bromley about? Applying, analysing, how law related to particular domains of human life was likely to be dismissed as quasi-sociology. It is not surprising that Kennedy and Grubb, doyens of 'modern medical law', described the field of academic study as 'comparatively new'. That claim must, however, be considered in the light of evidence that before the 1970s not only was research carried out in law faculties in the UK limited in scope, but not much research as we would understand it today was done at all.[12] Many law teachers combined teaching with professional practice. Publications tended to be textbooks and contributions to works designed to assist practitioners. So, if there was little research into healthcare law it is unsurprising, as there was little research at all.

What of practice? When Kennedy and Grubb first applauded the novelty of medical law there were relatively few twentieth-century cases troubling the law courts. As Kennedy put it later:

> Medical law used to be fun. All you had to do was read a lot of strange American cases, the odd Commonwealth decision and maybe some English nineteenth-century cases on crime then you could reflect that none of these was relevant and get on with the fun of inventing answers. Suddenly, in the last few years, the courts have got into the act. Cases have come rattling along. Medical law is beginning to get a corpus of law. Medical lawyers are having to do homework.[13]

For a legal scholar coming to medical law in that era, it felt new.

8 R Gillon, *Philosophical Medical Ethics* (John Wiley & Sons 1986).

9 Oxford University Press launched a Studies in Bioethics series in 1984 with the first volume, P Singer and D Wells, *The Reproduction Revolution*.

10 Wilson (n 4); and see D Wilson and R Chadwick; 'The Emergence and Development of Bioethics in the UK' (2018) 26 Medical Law Review 183; A Grubb, 'The Emergence and Rise of Medical Law and Ethics' (1987) 50 Modern Law Review 241.

11 P M Bromley, *Family Law* (Butterworths 1957).

12 G Wilson, 'English Legal Scholarship' (1987) 50 Modern Law Review 818.

13 I Kennedy, 'The Patient on the Clapham Omnibus' in *Treat Me Right* (Oxford University Press 1988) 175; originally (1984) 47 Modern Law Review 454.

Insights from history: the past is not so foreign a country[14]

In the absence of evidence of much late nineteenth to late twentieth-century engagement between law and medicine, seeking to go further back in time to Tudor England and before might seem pointless. One might assume that there was little healthcare available to most people, few doctors, and that what medical remedies there were, such as blood-letting and leeches, have little relevance today. If there was no pertinent healthcare then it would follow there was not much to take to the law courts or to trouble the legislature. Add to these factors the myth of deference suggesting that if a patient went to court a judge would just back the doctor and the case for the existence of robust medico-legal history looks thin.

The premises on which the case looks thin are simply wrong. The medical historian Margaret Pelling[15] has demonstrated that the assumption made by older historians that 'most of the population before the nineteenth century had no access to medical services worthy of the name' and that 'medical care was necessarily confined to the rich'[16] was plain wrong. Nor was access to healthcare limited to residents of London alone.[17] In common with their descendants, Pelling declares 'early modern people were obsessed with health, with its fragility and with the means of preserving it'.[18] The very importance of health to people well before the nineteenth century created a space for law and lawyers. And as today, there is evidence that laypeople, the consumers of healthcare, have long sought 'rights over their own lives and bodies'.[19] Moreover rather than there being very few 'doctors' in Tudor and Stuart England, there were too many healers, many men and some women, who fought over their share of the healthcare market. Courts were regularly resorted to in disputes between patients and doctors and between the different sorts of doctors.[20] Legislation relating to medical practice was common. The law engaged with medicine on a regular basis.

For much of the last quarter of the twentieth century it may be argued that, with some exceptions, judges distorting the direction of McNair J in *Bolam*[21] allowed the medical profession to dominate the legal framework of medical practice and to define medical ethics.[22] As the twentieth century gave way to a new millennium, 'modern medical law' might be characterised as a battle against *Bolam*. The dominance of the medical profession in defining what constituted ethical and lawful practice was challenged.

Area of importance in legal practice?

In seeking out a forgotten history, let us take first the question of legal practice. Engage with the primary sources and guided by the work of medical historians and there will be discovered a rich history of the relationship of law and healthcare in England stretching

14 We allude to the opening of *The Go-Between* by L P Hartley (Hamish Hamilton 1953): 'The past is a foreign country; they do things differently there.'

15 M Pelling, *The Common Lot: Sickness, Medical Occupations and the Urban Poor in Early Modern England* (Routledge 1998).

16 Ibid 5.

17 R S Roberts, 'The Personnel and Practice of Medicine in Tudor and Stuart England: Part I The Provinces' (1962) 6 Medical History 363.

18 Pelling (n 15) 5.

19 Ibid 8.

20 Roberts (n 17) 363–4.

21 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

22 Miola (n 6).

back to the medieval era.[23] Until the Reformation, the canon law of the Roman Catholic Church promulgated laws across Western Europe governing many matters that constitute healthcare law today.[24] Successive Councils of the Church addressed (inter alia) the ethics of medical practice, consent to treatment, questions of reproduction (including but not only abortion), the limits of what we may do to and with our living bodies, the care of the dead and much more. The Church also delivered much of the healthcare available to the sick and played a major role in the control of communicable diseases, such as leprosy and the plague.[25] Medieval canon law can be characterised as 'Western European health law' long before the European Union was ever thought of. Questions we struggle with today, canon law considered centuries ago.

In the sixteenth century and in particular post the Reformation, the legislature and secular courts began to play a larger role in relation to medicine and healthcare.[26] It should be noted though that the reformed Church of England continued to be responsible for licensing surgeons and midwives outside London until well into the eighteenth century.[27] The reign of Henry VIII saw a series of Acts of Parliament and Royal Charters addressing the regulation of medicine, legislation often claimed to be for the protection of the people.[28] The creation of the College of Physicians in 1518 signalled the start of a vicious war between the three sorts of medical practitioners who saw themselves as 'orthodox professionals': the physicians, the surgeons and the apothecaries.[29] The College sought domination over the 'lower' orders. Its members perceived themselves to be educated gentlemen, while the surgeons and the apothecaries regulated in Tudor England within the craft Guilds (the Barber-Surgeons[30] and the Grocers Companies)[31] were mere tradesmen. It was a war often fought in the courts. The power of the College was challenged in a range of court battles in the Courts of King's Bench,[32] Common Pleas[33] and even Star Chamber.[34] The physicians fought with the surgeons and the apothecaries, suffering a significant defeat in 1703 in *Rose v College* of Physicians.[35] All three 'orthodox' groups of licensed medical practitioners agreed on one

23 See generally C Rawcliffe, *Medicine and Society in Later Medieval England* (Sandpiper Books 1999); O Grell, 'Medicine and Religion in Sixteenth Century Europe' in P Elmer (ed), T*he Healing Arts: Health, Disease and Society in Europe 1500–1800* (Manchester University Press 2004) 85.

24 C Rawcliffe, *Leprosy in Medieval England* (Boydell Press 2006) 9.

25 Ibid.

26 T Gelfland, 'The History of the Medical Profession' in W F Bynum and R Porter (eds), *Companion Encyclopaedia of the History of Medicine* (Routledge 1993) 1119.

27 J R Guy, 'The Episcopal Licensing of Physicians, Surgeons and Midwives' (1982) 56 Bulletin of the History of Medicine 582.

28 See T Cunningham, *Physicians, Surgeons and Apothecaries containing All the Statutes, Cases at Large, Arguments, Resolutions and Judgments against them compiled at the Desire of a Great Personage* (W Griffin of Catharine Street in the Strand 1767).

29 M Brazier, 'The Age of Deference – A Historical Anomaly' in M Freeman (ed), *Law and Bioethics* (Oxford University Press 2008) 465.

30 The surgeons gained independence from the Barbers in 1745 becoming the Company of Surgeons, and in 1800 received a Royal Charter to become the Royal College of Surgeons.

31 In 1607, apothecaries were granted a discrete status within the Grocers Company and in 1617 the Society of Apothecaries was established by Royal Charter.

32 It is known that there were proceedings in *Bonham's Case* in the Court of Kings Bench, but to our knowledge no full records have as yet been found: see H J Cook 'Against Common Right or Reason: The College of Physicians Versus Dr Thomas Bonham' (1985) 29 American Journal of Legal History 301.

33 *Dr Bonham's Case* (1609) 77 ER 646.

34 See the account of the criminal libel case of *Edwards v Woolton* STAC/8/130/12 (1607) in Roberts (n 17) 371.

35 *William Rose (Plaintiff in Error) v the College of Physicians* (1703) ER 857.

question and joined together in one enterprise – to drive out other healers, the empirics, later more often styled as 'quacks'.

How to regulate medical practice was not the only medical law issue to engage the courts. Disputes between doctors and patients were common but, at first glance, look unlike the clinical negligence claims of today. What would now be a clinical negligence claim, might well in the sixteenth century be brought as a complaint by a patient to the Censors of the College of Physicians, which could result in a criminal prosecution for *mala praxis*.[36] Occasionally, aggrieved patients and competing healers sought indictments for witchcraft.[37] Clinical negligence suits hide in the Law Reports, often beginning as actions for debt brought by the doctor for breach of contract, i.e. non-payment of fees.[38] The defendant counterclaimed stating that no payment was due, rather that the doctor ought to compensate them. In the eighteenth and nineteenth centuries there was a series of prosecutions of unlicensed practitioners for gross negligence manslaughter – initiated by the orthodox professionals using the law in what proved to be a vain attempt to drive out other sorts of healer.[39]

Discovering whence healthcare law is fun, but as one former Secretary of State for Education, Charles Clarke, said of any study of medieval history, should the taxpayer pay for it? Our first response would be that the pursuit of knowledge and scholarship is a good in itself. History helps us understand who we are and how our society evolved. The medical historians, led by Roy Porter,[40] use the focus of medicine to tell us much more about the society of the times. The sociology of health provision shows how societies organised themselves (creating categories of private and public care provision, paid and unpaid health labour) and managed their understanding of the world (developing the uses of concepts such as health and illness to transition from a theological to scientific understanding of the natural world).[41] Developing research into medico-legal history adds to that picture.

We would go further and suggest that medico-legal history has lessons for law and medicine today. By neglecting history we waste time and effort and repeat the same mistakes. If we have only a vague notion of history, a notion unsupported by evidence. we may make bad laws today. Researching the history of medical law unearths enduring themes and some dangerous myths.

Enduring themes

Biomedical science has altered radically over time; human nature and desires have altered less. Many of our concerns about healthcare and science can be found to have been addressed by our forebears, giving rise to themes that permeate history. Perhaps the first and central theme is the enduring importance of health itself as both a private and public concern. Health was ascribed a value of high importance, justifying the engagement of the Crown and the legislature, both to protect the subject's 'right' to healthcare and manifest the Crown's responsibility for the health of the public.

36 See *Dr Groenvelt's Case* (1697) 9 Will 3 BR.

37 See B Woolley, *The Herbalist* (Harper Perennial 2005) 213–15.

38 *Slater v Baker and Stapleton* (1797) 95 ER 860.

39 M Brazier, 'The Criminal Process and Medical Practitioners: Shield and Sword' in M Henaghan and J Wall (eds), *Law, Ethics and Medicine: Essays in Honour of Peter Skegg* (Wellington, Thomson Reuters 2016) 7.

40 R Porter, *The Greatest Benefit to Mankind: A Medical History of Humanity from Antiquity to the Present* (Harper Collins 1997).

41 M Stacey, *The Sociology of Health and Healing* (Unwin Hyman 1988).

Our ancestors perceived healthcare, if not as a right, as a powerful claim generating obligations on others. Consider monastic healthcare in the medieval era. The Rule of St Benedict stated:

> The care of the sick is to be placed above and before any other duty, as if indeed Christ himself were being directly served by waiting on them.[42]

The monks were obliged to offer care to anyone in need who came to their doors. They were forbidden to act for gain. The 'Monastic Health Service' was in theory not free to pick and choose – not permitted to treat their guests as the common sort of persons who should be condescended to and patronised. They must be served as the monks or nuns would serve Christ. When the monks were driven out and the battling kinds of 'doctors' fought for their share of the market, all sought to claim that they would treat the poor for free.[43]

Once healthcare was disaggregated from the rules of religious life, and no longer free save for the indigent poor, then a different and complex regulatory context emerged. Within London and its environs, the Crown, Parliament and the secular courts came to play a major role in regulation, albeit one that often entailed judging the claims of the respective kinds of practitioner. Outside London, the craft guilds undertook the task of regulating surgeons and apothecaries.[44] Regulation governing surgery might differ between London and Norwich or Norwich and York. Devolution of healthcare regulation is not new. Regulation, as it always has, determined disputes in ways that reflected the context, parties, and the fora that are empowered to resolve them. The diverse forms of regulation of medical practice in Tudor and Stuart England are a fertile field for scholars of regulatory theory.

Developments in medical science, even when that 'science' was rudimentary, also have common and ancient themes in legal debate. The several uses of the human body and human material have generated much academic debate and public controversy in 'modern medical law'.[45] How the dead are treated has given rise to bitter controversies, most recently in relation to organ retention. In 2000–2001, when the retained organs controversy hit the headlines, the medical historian Ruth Richardson could have said: 'I told you so'. In *Death, Dissection and Destitute*[46] she outlined the several attempts by the Crown, Parliament, and the anatomists in the fifteenth to nineteenth centuries to gain a sufficient supply of corpses to engage in dissection and research. She describes the huge public opposition and a chasm of misunderstanding between 'scientists' and much of the populace.[47] Crowds, who had cheered the executions, sought to snatch the bodies of executed criminals from the scaffold to save them from the surgeons. Battles over the Anatomy Act 1832 led to riots and the burning down of the anatomy school in Sheffield.[48] Above all, the nature of the debates and the language used by the elite to condemn those lower classes who stood in the way of science as superstitious and ignorant are echoed in the more modern controversy around organ retention.

Controversy around bodies highlights two further enduring themes: first, those surfacing when scientific developments appear to seek to change attributes of humanity. Thus, the actions of the anatomists in the sixteenth and seventeenth centuries embarking

42 Porter (n 40) 111.

43 *Rose v College of Physicians* (n 35); Brazier (n 29).

44 Roberts (n 17).

45 M Brazier, 'Retained Organs: Ethics and Humanity' (2002) 22 Legal Studies 550.

46 R Richardson, *Death Dissection and the Destitute* (2nd edn, University of Chicago Press 2000).

47 Ibid 3–29.

48 Ibid 263.

on research and unpicking some of the mysteries of the human body were received by many people with scepticism and fear.[49] A similar popular reaction can be seen again in the early years of artificial reproductive technologies (ARTS). Medical science even in its crude early forms was feared when it appeared to take control of human life; fears well evoked in Mary Shelley's horror novel, *Frankenstein*.[50] Those concerns are exacerbated when evidence of 'scandal' emerges. So, while there were many people who thought that dissecting dead bodies was wrong per se, opposition to dissection was further inflamed by the evidence of body-snatching and murder,[51] 'crimes' in which the medical professions were complicit.[52]

We have identified five enduring themes: the social organisation of healing; the sphere of regulation; the significance of human bodies; fear of science; and the impact of scandal. Analysis of the history of law and medicine based on these (and no doubt others) reduces the risk that contemporary developments are seen as more significant than they really are. We should be wary of overestimating discontinuity with the history of interactions between the law and health provision. We use these five dimensions to help us understand better the roles that legal engagement plays.

Dangerous myths

Another reason why we should consider whence 'modern medical law' derives from the importance of myth-busting. Coupled with the belief that medical law was new was the assumption that, when doctors did end up in court or the regulation of doctors was under consideration, English judges and the legislature had always endorsed a paternalistic tradition[53] and been unwilling to question medical practice. The evidence, at least until late in the nineteenth century, is to the contrary. Prior to the later decades of the nineteenth century, judges declined to offer any sort of privilege to a medical man of any persuasion, be they physician, surgeon or apothecary.

Given the competing groups of 'orthodox' professionals, not to speak of the many other sorts of healers, to whom would you defer? Until the creation of the General Medical Council in 1858[54] and the Medical Register any uncritical *Bolam* approach would have encountered difficulty. How would one identify the responsible 'medical man'?[55] It was only the organisational demarcations that the 1858 Act introduced which made 'responsible professional practice' a coherent and ascertainable concept.

One answer to the question of identifying the responsible medical man prior to 1858 might have been to defer to the licensed practitioners dismissing other groups of healers as 'quacks', and/or accept the College of Physicians' claim that it was the ultimate authority ruling over 'the whole domain of medicine'. Before 1858 and even later, judges showed little inclination to favour the licensed doctor be he physician, surgeon or

49 J Sawday, *The Body Emblazoned* (Routledge 1995).

50 Mary Shelley, *Frankenstein: or; The Modern Prometheus* (Lackington, Hughes, Harding, Mayor & Jones 1818).

51 Richardson (n 46) 52–72.

52 Ibid 55–57.

53 Teff (n 2) 69–93. And see I Goldrein, '*Bolam*: Problems Arising out of "Ancestor" Worship' (1994) 144 New Law Journal 144.

54 M Davies, *Medical Self-regulation* (Ashgate 2007) 15–17.

55 The popular belief that there were only medical 'men' who had ever practised medicine in England is another myth. Elizabeth Garrett Anderson was not the first woman to practise medicine in England. In the 1500s to 1700s there were women surgeons and apothecaries benefiting from Guild laws that allowed widows and even daughters to take over the family business: See M Green, 'Women's Medical Practice and Health Care in Medieval England' (1989) 14 Signs 434.

apothecary. In *Bonham's Case* in 1610, finding in favour of Dr Thomas Bonham's challenge to the College of Physicians, Sir Edward Coke CJ was unimpressed by the College's claim to determine who practised 'physic' and what constituted good practice. Harold Cook, in a masterly analysis of the complex litigation now known simply as *Bonham's Case,*[56] commented that Coke removed from the College the unfettered power it claimed to judge what constituted good or bad practice:

> The College was not to be the only expert judge of medical practice – or rather any judge with a university education could find whether a medical case had been handled correctly or not.[57]

Two centuries later the founder of *The Lancet*, Dr Thomas Wakley, led a campaign by the licensed practitioners to drive out the quacks by instigating prosecutions for manslaughter whenever a patient in the care of an unlicensed healer died within three days of receiving treatment.[58] Ironically, they invoked a dictum from Coke[59] that there was a presumption that if an unlicensed practitioner treated a patient and she died within three days he was guilty of manslaughter. The judges rejected such arguments saying that whether the practitioner was licensed or unlicensed, to be convicted of homicide it must be shown that he acted with gross negligence, out of grossest ignorance, or the most criminal inattention. What is notable is that the language of the judgments dismissing the arguments put forward at the instigation of the licensed medical professionals resonated with undeferential scorn. To give just one example, Park J said that it mattered not:

> [W]hether the individual consulted the president of the College of Physicians, the president of the College of Surgeons or the humblest bone-setter in the village.[60]

Claims to deference based on medical professional status cut little ice with sceptical judges. Lack of deference to doctors before the late nineteenth century should not perhaps surprise us. Medicine did not share the mantle of a learned profession suitable for a gentleman until well into the nineteenth century. Medicine was an occupation, a business, not much different to the trade of the master baker or farrier.

Bolam is not the only dangerous myth. Another example relates to leprosy and communicable diseases and illustrates the dangers of a 'little knowledge'. In the nineteenth century, colonial administrators who were dealing with leprosy in the British empire and public health doctors drafting public health legislation on communicable diseases in England believed that it was draconian laws imposing a stringent regime of isolation of and quarantine which brought about the decline in leprosy in medieval England. Thus, Victorian laws were drafted which were thought to be based on sound medieval precedent. In *Leprosy in Medieval England*[61] Rawcliffe provides conclusive evidence that the 'laws' on which the nineteenth-century lawmakers relied were of as dubious provenance as the medical 'evidence' relating to the decline of leprosy. Rawcliffe warns of:

56 Albeit it involved at least three sets of related proceedings,

57 Cook (n 32) 317.

58 Brazier (n 39).

59 *Coke's Institutes* 4 Inst 251 (1644).

60 *R v John St John Long* (1831) 172 ER 172; and see *R v Van Butchell* (1829) 172 ER 576.

61 Rawcliffe (n 24).

> [F]antasies and misapprehensions about 'the medieval leper' propagated during a period when microbiologists, colonial administrators and evangelicals turned to the past for evidence to support their own campaign for mandatory segregation.[62]

The 'leprosy' myth still affects public health law today in that (although heavily amended) modern legislation on communicable diseases remains modelled on the old Victorian laws.[63] Moreover, the initial response to the HIV epidemic was again influenced by the enduring myths around the law and leprosy.[64] Knowing a very little about history is as dangerous as knowing nothing.

An academic discipline?

While we can claim that law's engagement with medicine has a long history as an important area of legal practice, the question of its longevity as an academic discipline cannot be answered without bearing in mind the way in which it has been manifest. The emergence of 'modern medical law' scholarship needs to be considered alongside the ways in which academic legal writing in England developed more generally in the latter parts of the twentieth century. The explosion of activity relating to law and medicine in the past 30 years is as much a change in the form of legal scholarship generally as a discovery of a new area of legal scholarship.

There is evidence from at least three centuries ago of legal writing, what might be described as legal scholarship, addressing issues that count as medical/health law today. The 'fathers' of the common law, including Bracton, Coke and Hale, all addressed matters of law and medicine. In 1768, Blackstone gave as an example of a private wrong: 'the unskilful management of his physician, surgeon, or apothecary . . . *Mala praxis* is a great misdemesnor [*sic*] and offence at common law, whether it be for curiosity and experiment, or by neglect; because it breaks the trust which the party has placed in his physician'.[65]

The commentaries of the legal giants of the past were comprehensive analyses of the laws of England in their entirety. It could be argued that they no more identified an area of study relating to medicine than they did blacksmiths' law. Doctors were just one illustrative example of the application of criminal law and/or the law of torts. Yet it is clear that the judges made some allowance for the special nature of the doctor–patient relationship exemplified by what Blackstone says about trust. The commentaries were written predominantly by legal practitioners and judges, not academics. Such was the tradition of the times. Blackstone was, prior to his appointment to the Bench, the first Vinerian professor of English law at the University of Oxford. Legal scholars of the kind we know today did not exist.

In addition to the inclusion of analyses relating to medical practice in the writings of iconic judges, a number of books from the eighteenth and nineteenth centuries focus expressly on laws relating to medicine. We note two examples. (1) In 1767, Timothy Cunningham, a barrister, published *Physicians, Surgeons and Apothecaries containing All the Statutes, Cases at Large, Arguments, Resolutions and Judgments against them compiled at the Desire of*

62 Ibid 5.

63 Public Health (Control of Diseases) Act 1984, despite the amendments made by the Health and Social Care Act 2008.

64 Rawcliffe (n 24) 17, 90.

65 *Commentaries on the Laws of England* vol 3 (1768), ch 8, s 4, 122, in the facsimile edition published by University of Chicago Press 1979. He goes on to observe that the civil law (as well as the common law) recognised an action for 'neglect or want of skill in physicians and surgeons'.

a Great Personage.[66] (2) In 1814, Robert Masters Kerrison[67] published *An Inquiry into the Present State of the Medical Profession in England containing an Abstract of all the Acts and Charters granted to Physicians, Surgeons and Apothecaries and a Comparative View of the Profession including the Need for Reform and an Analysis of Medicine in Classical Times*. Both books attest to the existence of a discrete focus on the medical professions and healing.

Cunningham's book if assessed by today's classification of legal writing might resemble a text and materials book; Kerrison is much more a critical work – a monograph on the regulation of medical practice. However, Kerrison was neither a lawyer nor an academic but practised as a surgeon–apothecary, later becoming a licentiate of the College of Physicians. Both works have an additional mission over and above critiquing the law. Cunningham argued for the importance of laws that prevent and punish 'quackery'. Kerrison's work seeks to advance the case for the Bill before Parliament which became the Apothecaries' Act 1815. Neither the medical authorship of the work nor the campaigning role of both books disqualifies them from being seen as proto-medical law scholarship. J K Mason's work is not ruled out of the canon because Mason was a medical professional. Much of modern scholarship in our field is campaigning too.

No exact analogy can be made with modern scholarship. Rather, the history of medical or health law scholarship is as 'ancient' and persistent as many other fields of legal scholarship. It is only relatively recently that anything resembling legal scholarship today has existed at all. The infrastructure did not exist. The first law journal in England allowing ready dissemination of legal scholarship, the *Law Quarterly Review*, was first published in 1885. The first volume included an article on lunacy laws. In the third was a piece on 'moral mania' in which the views of Dr Maudsley (founder of the famous London hospital) were discussed. Academics were writing on mental health law as early as on other areas of scholarly inquiry. For the most part, however, until the 1970s or so legal research of any kind going beyond fundamental common law, legal history, jurisprudence and international law was rare. Work assessing how the law applied to human life, such as the family or the environment, began to flower only a little earlier than 'modern medical law'.[68] It may be true that 'modern medical law' lacks an extensive history as a conventional academic sub-discipline, but this is in common with many of the categories we use to organise legal scholarship today.

Labour pains in the birth of 'modern medical law'

And so to the rebirth, renaissance, of modern engagement between law medicine and healthcare and whither tomorrow. We noted at the start of this paper that Kennedy's Reith Lectures may be seen as marking this rebirth and triggering the public emergence of 'modern medical law'. In practice, however, events before the 1980s demonstrate that, at the very least, matters of 'modern medical law' and healthcare were being gestated some years before any announcement of a 'birth'. One factor may have been that a focus on judicial activity obscured important legislative interventions (a blinkered view that reflected a widespread belief in law schools that only the common law was really worthy

66 Cunningham (n 28).

67 Robert Masters Kerrison, *An Inquiry into the Present State of the Medical Profession in England containing an Abstract of all the Acts and Charters granted to Physicians, Surgeons and Apothecaries and a Comparative View of the Profession including the Need for Reform and an Analysis of Medicine in Classical Times* (Longman, Hurst, Rees Orme and Brown 1814).

68 See W Twining, 'Professionalism in Legal Education' (2011) 18 International Journal of Legal Education 165. And for an account of English law schools more generally, see W Twining, *Blackstone's Tower: The English Law School* (Stevens & Sons 1984).

of attention). Another may have been that the connections that most early medical law scholars made between their new subject and bioethical concerns. An early critic of these developments, Joe Jacob of the London School of Economics, suggested that this concern with the 'untoward' obscured the realities of most clinician work.[69] It is necessary to assess these issues in order to characterise more accurately where the birth of medical law belongs in the historical succession of scholarly reflection.

The National Health Service Act 1946 and the creation of the National Health Services (separately for England and Wales, Scotland and Northern Ireland) in 1948 radically altered the way in which health services were provided and regulated, opening them up to the growing potential for public law scrutiny. The Act, however, also consolidated medical power in decision-making,[70] creating perhaps a context in which the medical profession was or could be seen as the dominant voice as to what constituted good practice. The relief and gratitude with which many patients greeted healthcare free for all may have contributed to a culture of deference to doctors providing that care. The withdrawal of healthcare for the most part from the market changed expectations from a degree of scepticism about what your doctor was 'selling' to one of 'trust' in what patients were being given.

The creation of a publicly funded and publicly managed service took medical law into the framework of public law.[71] Legal writing on 'NHS law' was also to be found in Speller's *Law relating to Hospitals and Kindred Institutions*,[72] although it was said that this was 'not intended to be a reference book for members of the legal profession'.[73] The NHS legislation represented both an affirmation of the value placed on health and access to healthcare and a further episode in the relationship of regulation and healthcare. A newly constituted sphere of regulation – NHS law – came into being. Its potential to trigger critical scholarship and place 'modern medical law' more firmly in the domain of public law took a number of years to realise,[74] but it showed how changes to the social organisation of healthcare prompted new forms of legal engagement.

What of other legislation before 1981? Primary legislation on matters of medical ethics was scant and rarely the subject of much academic debate at the time of enactment, but our enduring themes of embodiment, scientific advance and scandal brought some issues into the legal arena. The 1960s saw the passing of the Human Tissue Act 1961 and the Abortion Act 1967. In part, both legislation[75] and its avoidance[76] was the product of the manipulation of law-making by campaigners, with the medical profession constituting a major stakeholder in the legislative process.[77] As was the case in relation to judge-made law and the dominance of *Bolam*, from 1957 to the 1980s, so the legislature seemed

69 J Jacob, *Doctors and Rules: A Sociology of Professional Values* (Routledge 1988) 166; see the review article J Montgomery, 'Medical Law in the Shadow of Hippocrates' (1989) 52 Modern Law Review 566.

70 R Klein, *The New Politics of the NHS* (3rd edn, Longman 1995) esp 49–52.

71 Or perhaps, better, back to the sphere of public law, given the long tradition of the poor laws in public provisions of care. See K Price, *Medical Negligence in Victorian Britain: The Crisis of Care under the English Poor Law c 1834–1900* (Bloomsbury Academic 2015).

72 S R Speller, *Law relating to Hospitals and Kindred Institutions* (HK Lewis 1947); and see *The National Health Service Act 1946 Annotated* (HK Lewis 1947).

73 Review in the [1948] Cambridge Law Journal 161.

74 D Longley, *Public Law and Health Service Accountability* (Open University Press 1992).

75 S McGuinness and M Thomson, 'Medicine and Abortion Law: Complicating the Reforming Profession' (2015) 23(2) Medical Law Review 177.

76 P Lewis, 'Legal Change on Contraceptive Sterilisation' (2011) 32 Journal of Legal History 295.

77 M Latham, *Regulating Reproduction: A Century of Conflict in Britain and France* (Manchester University Press 2002).

content to regard the medical profession as the principal arbiter of good practice in matters of ethics, as well as clinical practice.

The picture was different, however, in mental health law. Here both legal involvement and lack of deference to medicine began much earlier. Legalism was said to have 'triumphed' in the late nineteenth century and a series of statutory reforms followed, including those based on human rights litigation during the 1980s.[78] Some thought the law was being too assertive, not deferential.[79] This view was largely neglected in the general acceptance in the academy of the 'Bolamisation' thesis and the less deferential approach seemed anomalous.

There were some significant developments in twentieth-century malpractice law and associated scholarship before 1981 too. In 1957, Lord Nathan published the first modern textbook in the field, *Medical Negligence*, addressing the phenomenon of apparently increasing litigation following the creation of the NHS, which he attributed to three factors.[80] First, 'a subtle change in the relationship between the medical man [sic] or institution and the patient' that he suspected had arisen because healthcare had become a matter of right rather than beneficence, or in return for a voluntary contribution to an association. Second, legal aid reforms made it possible for impecunious patients to sue. Third, developments of legal doctrine in relation to vicarious liability assisted plaintiffs[81] to sue the hospital.

Nathan's book is little known today, despite the fact that his analysis was prescient. The issues he identified resurfaced later. Litigation to enforce rights to healthcare began to be explored in the 1980s in relation to kidney dialysis and access to fertility services.[82] The availability and subsequent withdrawal of legal aid funding, apart from that relating to children, was said to have played a significant factor in changes to clinical negligence litigation rates.[83] The shift from vicarious to direct liability has played a further important role in litigation, something that is currently being worked out in the Supreme Court.[84]

Nathan espoused much the same critical assessment of liability for medical negligence as did later legal academics condemning *Bolam*.[85] He thought that health practitioners were more vulnerable to litigation than lawyers; counsel were then by law immune from the consequences of their negligence, and solicitors could in practice secure such immunity by seeking counsel's opinion.[86] In contrast, the physician, surgeon, nurse or

78 C Unsworth, *The Politics of Mental Health Legislation* (Oxford University Press 1987). Few of the pioneers of 'modern medical law' covered this area, although see B Hoggett (now Lady Hale P), *Mental Health Law* (1st edn, Sweet & Maxwell 1975). Practitioners were better served, see the loose-leaf text, *Mental Health Services, Law and Practice* (Shaw & Sons 1986).

79 N Rose, 'Unreasonable Rights: Mental Illness and the Limits of the Law' (1985) Journal of Law and Society 199.

80 Lord Nathan PC (in collaboration with A R Barrowclough), *Medical Negligence: Being the Law of Negligence in Relation to the Medical Profession and Hospitals* (Butterworth & Co 1957) 5.

81 As claimants were then styled.

82 G Morris, 'Enforcing a Duty to Care: The Kidney Patient and the NHS' [1983] Law Society Gazette 3150; R Singh, 'Infertility Treatment and the Courts' [1988] Family Law 299.

83 P Fenn and C Whelan, 'Medical Litigation: Trends, Causes, Consequences' in R Dingwall (ed), *Socio-legal Aspects of Medical Practice* (Royal College of Physicians 1989); P Fenn, A Gray, N Rickman and D Vencappa, *Funding Clinical Negligence Cases: Access to Justice at Reasonable Cost?* (Nuffield Foundation 2016).

84 *Darnley v Croydon Health Services NHST* [2018] UKSC 50, [14]–[21]. See also P*oole BC v GN* UKSC 2018/0012 which was argued in July 2018.

85 See e.g. M Jones *Medical Negligence* (5th edn, Sweet & Maxwell 2017)

86 Nathan (n 80) v.

hospital was required by the law to 'stand or fall by what they do, or fail to do'.[87] Most pertinently, Nathan suggested that there was no special law of negligence for medicine, only the application of the general principles. He noted that there would inevitably be cases in which:

> . . . the standard of skill and care exacted by the judges may appear to the medical profession to be excessively high; but isolated cases of that sort ought not to blind the profession to the fact that the standard of measurement always used is the reasonably careful and skilful practitioner.[88]

On his analysis, there was respect for professional skill, but little deference. It is ironic that Lord Nathan signed off his 'Preface' in October 1956, slightly more than four months before the direction of McNair J and decision of the jury in *Bolam v Friern Hospital Management Committee*[89] instituted a period of the very deference to which Nathan was opposed. In the long arc of history, Nathan's analysis is the orthodox one, and *Bolam* looks to be an anomaly.

We have noted the claim that there was relatively little academic debate on medical law before the 1980s. Yet in 1958 Glanville Williams published *The Sanctity of Life and the Criminal Law*, covering legal and ethical issues in reproductive medicine (including control of conception, sterilisation, artificial insemination, abortion, suicide and euthanasia).[90] Norman St John-Stevas wrote his Life, *Death and the Law* as he ended his career as a law lecturer (prior to entering journalism and then Parliament).[91] Like Williams, he concentrated on the control of fertility and on the ending of life. These were matters with which the Church of England had also engaged during the middle of the twentieth century. The Archbishop of Canterbury had commissioned a report on *Artificial Insemination* in 1948.[92] A working party on euthanasia reported in 1975, following on from earlier work in the 1960s, considering the case for law reform (which it concluded was not justified).[93] Laws relating to abortion and euthanasia were noted by H L A Hart and Lord Devlin in their celebrated debate on the enforcement of morals[94] and explored by the Oxford theologian Basil Mitchell in his consideration of their positions (described by J R Lucas in the *Dictionary of National Biography* entry on Mitchell as 'a counter-blast to H L A Hart's influential' book).[95]

It is evident that the twentieth century before 1981 was not wholly free of case law, legislation and commentary touching on the law, medicine and health. Well before 1980, new if sparse legal literature emerged to reflect changes in the organisation and doctrinal context in which healthcare was being delivered, much as it always had. Should we adjust the date for rebirth, taking it back to 1946 or forward perhaps to 1998 and the decision

87 Ibid.

88 Ibid 5.

89 *Bolam* (n 21).

90 (Faber & Faber 1958).

91 *Life, Death and the Law: A Study of the Relationship between Law and Christian Morals in the English and American Legal Systems* (Eyre & Spottiswoode 1961).

92 Discussed in Glanville Williams (n 90) ch 4 and St John-Stevas (n 91) ch 3.

93 *On Dying Well: A Contribution to the Euthanasia Debate* (Central Board of Finance for the Church of England 1975; 2nd edn with revisions 2000); Church Information Office, *Decisions about Life and Death* (Church Information Office 1965).

94 H L A Hart, *Law, Liberty and Morality* (Oxford University Press 1963) 25; P Devlin, *The Enforcement of Morals* (Oxford University Press 1965) 125, 139.

95 Basil Mitchell, *Law, Morality and Religion in a Secular Society* (Oxford University Press 1967) 80–2, 108–10.

in *Bolitho*?[96] This would be a mistake. Starting in the 1980s, the pace of and diversity of litigation and the intrusion of legislation were to pick up speed in the following decades; recall Kennedy's quip in 1988 about medical lawyers having to do their homework.[97] The Human Fertilisation and Embryology Act 1990, derived from the Warnock Report of 1984,[98] was the first of a new type of regulatory intervention that could not have been conceived without the explosion of bioethical and legal concern.[99]

What was 'new' in the 1980s was not so much medical law in practice, although its importance within legal practice did grow. Nor was it new to see academics writing about medical law and ethics. What was more clearly 'new' was the way in which scholars (and to some extent practitioners) came to define their activity as a discipline – a specialism – 'medical law', a unified area of law, not just the application of conventional principles of tort, public law, criminal law, family law etc. to medical practice and ethics.

In its emergence as an academic discipline, 'modern medical law' soon to be rechristened 'healthcare law' by many of its scholars, echoed what had happened earlier with family law.[100] Writing on the law relating to husband and wife became organised around the label 'family law', something that seemed obviously wise as divorce became more widely available at the end of the 1960s and the law was democratised. It was reshaped again in the 1970s as child law developed and divorce procedures were simplified. Student interest promoted the creation of textbooks in the modern form. A programme of socio-legal studies emerged, attracting increasing numbers of doctoral students. The burgeoning scholarship focused on the relationship between law and medicine developing contemporaneously with greater judicial and legislative activity in the 1980s makes 1981 a useful marker for the rebirth of medical law. The 'child' may have been gestated in the sea changes of the NHS Act and the writings of Nathan, Williams and others. 1981 welcomed the 'child' on the public stage. The failure to recall much of either the 'ancient' or more modern history impeded the development of practice and discipline.

These processes of demarcation and definition of the 'new' academic discipline were not neat and tidy, but it is clear that something significant occurred. In terms of quantity, academic healthcare law has generated a vast scholarly literature. In terms of textbooks designed for students published in England, we can identify at least 12 substantive books on the market compared to four in 1987. The first edition of Mason and McCall Smith's *Law and Medical Ethics* (now in its 10th edition) published in 1983 comprised 275 pages, including appendices. The first edition of *Medicine Patients and the Law* (now in its sixth edition) published in 1987 was 375 pages. The latest editions are respectively 740 and 617 pages. In terms of research, we estimate that around a hundred books a year published in the UK relate to healthcare law and ethics (excluding books which are primarily ethics-focused). Articles in the field are regularly to be found in generalist legal journals, and there are now at least three specialist law journals dedicated to our domestic law, the *Medical Law Review*, *Medical Law International* and the *Journal of Medical Law and Ethics*. These have somewhat eclipsed the older titles that were generated more by interested doctors

96 *Bolitho v City and Hackney Health Authority* [1998] AC 232 HL.

97 Kennedy (n 13).

98 *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (Department of Health and Social Security, Cmnd 9314 1984).

99 J Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54 Modern Law Review 524.

100 S Cretney, *Family Law in the Twentieth Century* (Oxford University Press 2005); C Bridge, *Family Law towards the Millennium: Essays in Honour of Peter Bromley* (Butterworths, 1997); M Freeman, 'Towards a Critical Theory of Family Law' (1985) 38 Current Legal Problems 153.

than legal scholars – the *Medico-Legal Journal and Medicine*, *Science and the Law*. Academic centres devoted to the study of law and healthcare are now established at many leading universities.

Rapid expansion of judicial and legislative activity in relation to healthcare and biomedical science and the rebirth of a broad scholarly and popular interest in the subject paid little attention to the area's history. Medical law in the courts in the 1980s was typified by the process of Bolamisation. With rare exceptions,[101] judges abdicated responsibility for scrutiny of medical decisions.[102] For the senior judiciary in the 1980s, in the context of medical negligence[103] and consent,[104] ceding 'jurisdiction' to the medical profession seemed to be driven by a combination of seeking to resist what they perceived as the American nightmare of excessive litigation and defensive practice and a settled belief that doctors were better placed to judge the interests of their patients than the patients themselves,[105] or the courts. In the context of the many other areas of healthcare which gradually became *Bolamised*, such as decision-making on behalf of mentally incapacitated patients[106] and withdrawing artificial life support,[107] judges conflated clinical and other interests and again determined that doctors 'knew best'. For academics engaging in this purportedly 'new' arena of legal practice and scholarship, Bolamisation exemplified what was wrong with the law.

The early years of 'modern medical law' in the academy might be summed up as 'the battle against *Bolam*'. What all parties seemed to take for granted was that the judges, even if wrong in their deference to the medical profession, based their judgments on longstanding tradition. Yet what was taken to be a tradition of judicial deference was an aberration based on myth, one that the sturdy advocate of the common law, Edward Coke, would have deplored.[108] The rebirth of medical law initially marked a revival of engagement between the law and medical practice and biomedical science. It failed to rediscover 'ancient' learning, or fully appreciate the tradition in which it sat. 1981 might mark renewed focus on law and medicine but not at that point a renaissance.

As the old millennium drew to a close and in the early years of the 2000s, judges gradually pulled back from Bolamisation, reasserting (inter alia) that the courts, not doctors, are the ultimate arbiters of the standard of care, that competent patients have the right to make their own choices and that, when the law requires that the best interests of an incapacitated person be assessed, those interests encompass much more than medical judgment. Culminating in the decision of the Supreme Court in *Montgomery v Lanarkshire Health Board*,[109] the judiciary now endorses the view that patients should be regarded as 'persons' holding rights rather than the 'passive recipients of the care of the medical profession.'[110] At least in the courts, the battle against *Bolam* appears to have been largely won.[111] Bolamisation should be seen as an instructive episode in the history of

101 *Hucks v Cole* (1968) reported in [1993] 4 Medical Law Review 393.

102 Miola (n 6) 10–15.

103 *Maynard v West Midlands Regional Health Authority* [1985] 1 All ER 635, HL.

104 *Sidaway v Royal Bethlem Hospital* [1985] AC 871, HL.

105 See in particular the speech of Lord Diplock in *Sidaway*, ibid.

106 *F v West Berkshire HA* [1989] 2 All ER 545, HL.

107 *Airedale NHS Trust v Bland* [1993] AC 789, HL

108 See *Bonham's Case* (n 33).

109 [2015] UKSC 11.

110 Ibid [75].

111 Although this does not mean that the implications are yet clear, see J Montgomery, 'Patient No Longer? What's Next in Health Care Law?' (2017) 70 Current Legal Problems 73.

law's engagement with healthcare, an episode that marked the rise and fall of a very short age of deference.[112]

W(h)ither this area of law?

We have identified earlier five enduring themes: the social organisation of healing; regulation; the significance of human bodies; fears of science; and the impact of scandal. Reflecting on the current context, in the light of those themes (and we have by no means identified all such themes), sheds light on how the law, and legal scholarship, might be expected to adapt its concerns in the next phase of its history. We therefore turn our consideration to how medical law should now be examined in the light of those themes and bearing in mind the context of a much broader conception of law, health and biomedical science.

The social organisation of healthcare played a role in fostering what we say is the myth of medical dominance. Bolamisation enjoyed a degree of coherence while health services were delivered by a centrally organised NHS and a homogeneous medical profession, which in turn dominated the delivery of healthcare. It implied that accepted and proper practice could be integrated into the fabric of services if law, ethics and medicine worked in partnership.[113] This picture is now far more fragmented. The Health and Social Care Act 2012 disaggregated the NHS into a deliberately unmanageable system of independent entities. Health provision is a mixed economy of public and private (sometimes, but not always for profit). In key sectors of health law concern, such as abortion provision and assisted reproductive services, non-NHS providers are the norm rather than the exception. Boundary work is underway in relation to practices such as aesthetic surgery and the sale of health supplements that sit uneasily between consumer law and health law. The importance of social care, as well as health services, is increasing and restores a holistic approach that was integral to the monastic health service that we have noted from earlier centuries.[114] Public participation in service planning and also the creation of 'soft law' guidance has been substantially integrated in the work of the professions.[115] When courts or the legislature address legal questions in the proto-market, regard must be had to this ever-changing picture of the way healthcare is organised, bringing issues of public law more to the fore.

Spheres of regulation are shifting too. The role of the Care Quality Commission (CQC) as the regulator of the right to provide services (through registration) and quality assurance has become more significant. Thus, the concerns expressed long ago by Lord Donaldson about the need for honesty about medical mistakes,[116] and reiterated by Sir Robert Francis QC in the mid-Staffordshire Inquiry,[117] have been addressed by the creation of duties of candour within the regulatory requirements policed by the CQC.[118] The role of market regulation, including that achieved through EU law, has become more

112 Brazier (n 29).

113 J Montgomery, 'Law and the Demoralisation of Medicine' (2006) Legal Studies 185, 199–206, explores judicial assumptions of such integration as the hold of *Bolam* began to loosen.

114 Exemplified by the scope of the jurisdiction of the Court of Protection.

115 General Medical Council, *The Development of Treatment and Care towards the End of Life: Good Practice in Decision Making* (General Medical Council 2010).

116 *Lee v South West Thames Regional Health Authority* [1985] 1 All ER 385, CA.

117 *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry* (The Stationery Office, HC 898 2013).

118 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, SI 2014/2936, reg 20.

important.[119] Even after Brexit, the pressure to respect principles of harmonisation to facilitate the global health markets will remain. International bodies are also increasingly significant in relation to tobacco control, public health, the migration of health professionals, bioethics norms and individual health rights. Transnational health activities are increasing too, so-called 'health tourism', demanding regulatory responses.[120] The centrality of the doctor–patient relationship that dominated post-1981 'modern medical law' will diminish.[121]

Fascination and fears relating to human bodies, dating back to the popular concerns about anatomical dissection, are unlikely to diminish. One current example of the challenge of transnational regulation is the international market in body parts for transplantation.[122] A failure to dispose of clinical waste (including some human anatomical waste) respectfully and in a timely manner remains a matter of public scandal.[123] Debates about the enhancement of humans, even the possibility of a new 'transhuman' race are heated.[124] On a micro-level, human genome editing is raising concerns across the world, drawing attention to the mobility of science and demanding that traditional bioethics norms are revisited. In different ways, these illustrate the continuing centrality of human embodiment to our sense of what is proper, and the need to respect biological identities. There is little doubt that legal regulation will be required in these areas. However, it is less obvious that increased legal regulation necessarily allays fears,[125] or that the vehicle will be a discrete subject area of medical or health law.

There remains considerable anxiety about scientific advance, with the language of 'unnatural' interventions remaining powerful in public discourse.[126] While it is incoherent and unhelpful as an analytical tool, it reminds us of the importance of recognising public fears and the need to reflect upon and address the 'wisdom of repugnance'.[127] However, there are differences as well as similarities between these modern concerns and the ones we have seen in the past. The increasing importance of data (including genomic data) in addressing health needs has raised concerns about privacy and led to recognition of the importance of improved public deliberation if confidence is to be maintained.[128] Developments in data science have been driven outside health and led to plans for

119 T Hervey and J McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press 2015); G Bache, M Flear and T Hervey, 'The Defining Features of the European Union's Approach to Regulating New Health Technologies' in M Flear, A-M Farrell and T Hervey (eds), *European Law and New Health Technologies* (Oxford University Press 2013) 745.

120 D McMahon, *Medical Tourism and Cross-border Care* (Nuffield Council on Bioethics 2013) <http://nuffieldbioethics.org/wp-content/uploads/Forward_look_background_paper_on_medical_tourism_and_cross-border_care.pdf>.

121 J Montgomery, 'Time for a Paradigm Shift? Medical Law in Transition' (2000) 53 Current Legal Problems 363.

122 S McGuinness and J McHale, 'Transnational Crimes Related to Health: How Should the Law Respond to the Illicit Organ Tourism? (2014) 34(4) Legal Studies 682.

123 'Human Body Parts "Pile up" in NHS Waste Backlog' (*BBC News*, 4 October 2018) <www.bbc.co.uk/news/health-45750389>.

124 D Lawrence and M Brazier, 'Legally Human: "Novel Beings" and English Law' (2018) 26 Medical Law Review 309.

125 O O'Neill, *A Question of Trust?* (Cambridge University Press 2002).

126 Nuffield Council on Bioethics, *Ideas about Naturalness in Public and Political Debates about Science, Technology and Medicine* (Nuffield Council on Bioethics 2015).

127 L Kass, 'The Wisdom of Repugnance' (1997) 216 (22) New Republic, 2 June, 17.

128 O Leyser, *Data Management and Use: Governance in the 21st Century* (British Academy and Royal Society 2017).

enhanced regulation (another new sphere) that will encompass health uses but will not be driven or limited by them.[129]

Scientific advance provokes excitement as well as fear, and scholarship will need to show how regulation can avoid being either too restrictive or failing to protect against abuse. Legal intervention is not automatically popular with the public. The drive for innovation has brought campaigners for the 'right to try' into conflict with the pharmaceutical regulation that emerged in the 1960s to address the thalidomide scandal.[130] The rise of citizen science and bio-hacking challenge regulatory norms.[131]

Scandal remains an important theme too in informing the development of law and regulation. The emergence of mitochondrial replacement therapies has seen scientists flout regulation by taking their work abroad to countries where it is either unregulated or regulation is poorly enforced.[132] The continuing need for robust research regulation has been exposed by abuses in regenerative medicine, including the Paulo Macchiarini scandal[133] that spanned countries and institutions (again drawing attention to the need for health law to work across jurisdictions). Concerns about conflicts of interests and research integrity (or the lack of it) have attracted public, academic and parliamentary attention.[134] There is no lack of scandalous prompts for health law scholarship, to which we will need to respond without distorting our priorities.

The themes that we have identified over several centuries endure, but, as in earlier phases of the history of medico-legal engagement, the response that is now needed should have regard for history but also develop a particular shape that reflects the specific context of the times in which we find ourselves. History can warn us of dangers but cannot prescribe how problems in today's and tomorrow's world should be resolved. In looking forward, we consider that there are a number of features that are salient to the development of the law and that will need to be taken into account in legal practice and the academy.

We flag for attention three areas that we anticipate will characterise the next phase of scholarly work: doctrinal development; jurisdictional matters; and the impact of transnational activity. We shall see that there appears to be a rich feast of new directions in health law for scholars to enjoy. However, we also have concerns about the challenges that the current environment presents. We therefore draw attention to the need to take steps to preserve a vigorous scholarly community if we are going to maintain the

129 Ada Lovelace Institute <www.adalovelaceinstitute.org>; Department for Digital, Culture, Media and Sport, Data Ethics Framework <www.gov.uk/government/publications/data-ethics-framework/data-ethics-framework>.

130 D Meyerson, 'Medical Negligence Determinations, the "Right to Try," and Expanded Access to ITs' (2017) 14(3) Journal of Bioethical Inquiry 385; D Carrieri, F Paeccatori and G Boniolo, 'The Ethical Plausibility of the "Right to Try" Laws' (2018) 122 Critical Reviews in Oncology/Hematology 64–71; J Miola, 'Bye-bye Bolitho? The Curious Case of the Medical Innovation Bill' (2015) 15(2) Medical Law International doi: 10.1177/0968533215605667.

131 E Vayena et al, 'Research Led by Participants: A New Social Contract for a New Kind of Research' (2016) 42 Journal of Medical Ethics 216.

132 S Chan, C Palacios-González and M Medina-Arellano, 'Mitochondrial Replacement Techniques, Scientific Tourism, and the Global Politics of Science' (2017) 47(5) Hastings Center Report 7.

133 *Karolinska Institutet and the Macchiarini Case: Summary in English and Swedish* <https://ki.se/sites/default/files/karolinska_institutet_and_the_macchiarini_case_summary_in_english_and_swedish.pdf>; S Wigmore, *Special Inquiry into Regenerative Medicine Research at UCL* (University College London 2017).

134 See <www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2017/research-integrity-17–19>.

symbiotic relationship between legal practice and academic reflection that we have identified throughout the legal history that we have presented.

Legal doctrine: the roles of the courts and scholars

First, there is a resurgence of the importance of judicial oversight and the recrafting by the senior judiciary of the constitutional foundations of health law. In the same way as the period of Bolamisation was ushered in by a cluster of House of Lords' decisions, so the new phase of the law has been inaugurated by the Supreme Court in a series of important cases. The courts have exhibited greater confidence in the value of judicial scrutiny of clinical judgments, exemplified in the *Montgomery* decision,[135] and also a reminder of the constitutional constraints that are placed by the law on policy-making, illustrated in *Nicklinson*.[136]

As the judges leave *Bolam* behind, they will need to develop common law doctrine, either by applying more general principles to health cases or as a specific field with its own coherence. The more attractive option seems to be to promote the integrity of the common law. During the period of deference, clinical negligence became unduly detached from developments in tort law. We can already see examples of how a more orthodox approach is being applied to determining the standard of care in hospitals. The Supreme Court has recently pointed out that inaccurate statements that cause harm are as much an actionable misstatement when they occur in an accident and emergency unit as they would be in any other setting.[137]

One of us has argued that the common ground of these recent Supreme Court decisions lies in the application of human rights thinking.[138] This can illustrate the point we are making, which is essentially about rigour.[139] Developing a doctrine underpinning the law relating to health founded on 'human rights' will require intellectual discipline. Early pronouncements on human rights and medicine were too often unclear about the differences between human rights law and human rights as a political slogan.[140] Scholarship needs to address both the health-specific rights in international law[141] and also the implications of general human rights in the health context.[142] The impact of positive rights under Article 8 of the European Convention on Human Rights seems particularly important in crafting a mature account of the power of human rights to reshape the relationship between citizens and the state to enable human capabilities to be realised.[143]

135 [2015] UKSC 11.

136 *R (Nicklinson) v Min Justice; R (AM) v the Director of Public Prosecutions* [2014] UKSC 38.

137 *Darnley* (n 84).

138 Montgomery (n 111).

139 For concern about the lack of rigour in the *Montgomery* Supreme Court decision, see J Montgomery and E Montgomery, 'Montgomery on Informed Consent: An Inexpert Decision?' (2016) 42(2) Journal of Medical Ethics 89.

140 Representative examples of discussion at this stage would include: I Kennedy, *Treat Me Right* (Oxford University Press 1988) ch 20; and S Lee, 'Judges, Human Rights and the Sources of Medical Law' in P Byrne (ed), *Health, Rights and Resources* (King Edwards Hospital Fund for London 1987) esp 36–7. S Maclean, *Old Law, New Medicine: Medical Ethics and Human Rights* (Pandora 1999) recognises the programmatic nature of the human rights agenda.

141 J Tobin, *The Right to Health in International Law* (Oxford University Press 2011); T Murphy, *Health and Human Rights* (Hart 2013).

142 European Court of Human Rights, *Research Report: Bioethics and the Case-law of the Court* (Council of Europe 2016) <www.echr.coe.int/Documents/Research_report_bioethics_ENG.pdf>.

143 R Scott, 'Risks, Reasons and Rights: The European Convention on Human Rights and English Abortion Law', (2016) 24 Medical Law Review 1; I Black, 'Refusing Life-prolonging Medical Treatment and the ECHR' (2018) 38(2) Oxford Journal of Legal Studies 299.

As the UK (probably) disentangles itself from the EU, the human rights tradition is likely to become even more significant. This might be as part of the redefined framework of solidarity with the continent's value tradition, as Prime Minister Theresa May promised in her letter invoking Article 50 of the Treaty,[144] or as a result of the senior judiciary taking on a more assertive role as guardians of the rights protected under the Human Rights Act 1998. We anticipate that this is particularly likely in the face of perceived reductions in government commitment to its international human rights obligations and concerns that Parliament is unduly distracted with Brexit-related matters. High quality scholarship will have an important role to play. A focus on rights should not obscure the importance of addressing responsibilities.[145]

Taking forward the promise of human rights will require some important partnerships to be cultivated outside academia too. Test case litigation has already played a significant role in developing the law in some key areas of medical law and bioethics.[146] This has brought together activists, practising lawyers and academics to bring issues before the courts in relation to mental health law,[147] end of life care,[148] assisted conception[149] and abortion.[150] There is scope for this to go well, but also to be an abuse of legal processes as the judicial criticisms of the role of the Christian Legal Centre in the Alfie Evans case highlighted.[151]

Amongst the duties of legal scholars is stewardship of the rule of law. Its principles must be articulated, defended and the risks to them exposed to enable scrutiny. These include important values such as accessibility, due process, precision and clarity, due regard for the separation of powers, the disciplined recognition of fundamental human rights and equality of arms before the law. As Nathan identified, the availability of public funding for litigation is a crucial piece of the jigsaw, and the withdrawal of legal aid needs to be a continuing focus of scholarly attention. The *Purdy* case drew attention to the importance of legal clarity,[152] but also the complexity of enforcement mechanisms in its examination of the role of prosecutorial discretion, and raised concerns about the proper separation of powers.

Professionalism and activism need to be complementary and consistent. There may also be a need to explore the sort of rule of law concerns that relate to the 'inner morality' law – the conditions for effective and stable law to govern activity and the characteristics of effective law-based governance.[153] The time when it was thought unnecessary to

144 J Montgomery, 'Bioethics after Brexit' (2018) 18 Medical Law International 135.

145 M Brazier, 'Do No Harm: Do Patients Have Responsibilities Too?' (2006) 65 Cambridge Law Journal 397; J Coggon, 'Would Responsible Medical Lawyers Lose their Patients?'(2012) 20(1) Medical Law Review 130.

146 J Montgomery, C Jones and H Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence' (2014) 77(3) Modern Law Review 343.

147 L Gostin, *A Human Condition: The Mental Health Act from 1959 to 1975 – Observations, Analysis and Proposals for Reform* (Mind 1975), see also the discussion in Rose (n 79).

148 *Nicklinson* (n 136) saw a number of interventions including from Dignity and Choice in Dying and Care Not Killing.

149 See, for example, *R (Quintavalle) v Sec State for Health* [2003] 2 AC 687; *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28; *R (Quintavalle on behalf of Pro-Life Alliance) v Sec State for Health* [2001] EWHC Admin 918; *(On the application of Quintavalle and CLC) v HFEA* [2008] EWHC 3395 (Admin).

150 *Jepson v Chief Constable of West Mercia Constabulary* [2003] EWHC 3318 (Admin); *British Pregnancy Advisory Service v Secretary of State for Health* [2011] EWHC 235 (Admin).

151 *Evans v Alder Hey Children's NHSFT* [2018] EWCA Civ 805, [42]–[45].

152 *R (Purdy) v DPP* [2009] UKHL 45.

153 L Fuller, *The Morality of Law* (Yale University Press 1969) articulated this in his parable of Rex the failed law-maker.

consider the sanctions for non-compliance with legal norms, as seen in the Human Tissue Act 1961, is long gone. Consideration of the assumptions on which laws are based can demonstrate whether they continue to justify their provisions in the contemporary context.[154] A sound sense of history is vital to this process. It avoids repeating the mistakes of the past and also ensures that ill-informed perceptions of legal history do not lead to anachronistic revivals whose consequences leave considerable difficulties in their wake. We have seen this in relation to the inadequately reflective resurrection of the prerogative jurisdiction to deal with incapacitated patients, only corrected when the Law Commission brought about reform in the law relating to mental capacity.[155] Scholars have a crucial role in supporting lawmakers to be effective in their work. They are unconstrained by the limits that judges have of needing to wait for cases to be brought before them,[156] or the challenges of securing time for parliamentary debate.

Jurisdiction and the regulatory state

A second dimension that we see becoming more significant as medical/health law reshapes itself concerns the careful analysis of jurisdiction and its legitimacy.[157] The form of regulation will be a cause of concern, as well as its substance. It will be important to describe and justify the demarcation of the proper roles of Parliament, the courts and professional expertise. Both analytical and empirical work will be needed to understand better the interfaces between legal and administrative norms and structure. The context for the law is now less the care provided by individual health professionals or a particular hospital clinic than the complex health system in which patients will encounter many different service providers (not all within the NHS) as they receive their treatment.

The demarcations between health and consumer regulation will be of growing importance; including where practices such as body modification, the marketing of health supplements, and fertility services belong. Although consideration of a consumerist future has long been a characteristic of academic healthcare law discussion in the UK,[158] it has usually assumed the continuation of almost monopolistic public provision of services and that health professions remain centrally involved. The Lansley reforms of 2012 inscribed into law an expectation of an unmanaged NHS, with the extension of a much more mixed provider market. This increases the significance of market regulation for the future of health law.

The increasing plurality of health provision and the availability of services and products in non-health markets mean that health regulation and NHS law will increasingly diverge. The scope of regulated services under the CQC goes beyond public provision. The significance of this can be seen in the oversight of abortion services, now usually provided outside the NHS in England (even though mainly paid for from public funds). It was the CQC which was called in by Andrew Lansley in the 'moral panic' over suspected lax regulation by independent providers in 2012 (although it was NHS services

154 S Sheldon, 'British Abortion Law: Speaking from the Past to Govern the Future' (2016) 79 Modern Law Review 283.

155 B M Hoggett 'The Royal Prerogative in Relation to the Mentally Disordered: Resurrection, Resuscitation or Rejection' in M Freeman (ed), *Medical Ethics and the Law* (Stevens 1988) 85.

156 I Kennedy and J Stone, 'Making Public Policy on Moral Issues' in P Byrne (ed), *Ethics and Law in Health Research* (King's Fund 1990).

157 K Veatch, *The Jurisdiction of Medical Law* (Ashgate 2007); J Harrington, *Towards a Rhetoric of Medical Law* (Routledge 2017).

158 Kennedy (nn 3 and 13); M Brazier and N Glover, 'Does Medical Law Have a Future?' in D Hayton (ed), *Law's Future(s)* (Hart 2000) 371; Montgomery (n 113).

that were found more likely to be at fault).[159] It was the CQC's regulatory powers that addressed quality concerns at Marie Stopes International.[160]

We are already seeing greater use of health and safety legislation in relation to systems failures in health and significant fines have been administered for health and safety breaches in NHS organisations.[161] This should be seen as part of a pattern that emphasises the similarities between health and other industries rather than carving out a special framework. This is a further move away from Bolamisation, but also an alignment of health law with regulatory laws more generally.

Scandals, alas, are unlikely to fade away and the causes and responses must continue to be critically addressed. Responses may be administrative measures rather than, or as well as, litigation or legislation, and such extra-legal mechanisms deserve more academic attention than they have received. New law, more law is not always the answer. Thus, the consequences of the retained organs scandal in terms of the legislative response in the Human Tissue Act 2004 and the continuing debates about the role of consent (actual, deemed or presumed) have received more academic attention than the difficulties facing class actions as a mechanism of redress or the role of the Retained Organs Commission as a means towards 'truth and reconciliation'. The scholarship of the future will need to pay more attention to the range of tools available to the regulatory state and to developing frameworks for critical analysis of the uses to which they are best put.

Complex constitutional issues arise too, no doubt exacerbated through Brexit and its disturbance of the devolution settlements. The Supreme Court has already had occasion to examine the jurisdiction of the Northern Ireland Human Rights Commission in its oversight of abortion law,[162] where international human rights watchdogs are also crucial and sometimes critical of the UK's approaches.[163] This leads us to a third element of the agenda that we see for the future.

Domestic, transnational and international legal norms

'Modern medical law' tended to be largely focused on domestic law, using comparative law as a guide (and sometimes a selective one) to local reform. The governance of healthcare, bioethics and our bodies, and the oversight of scientific advances need to become more internationalised if they are to keep up with the patterns of contemporary life and testify to the claims of a right to health. Our concerns about bodies cannot be geographically limited. Body parts and their products have become a global industry.[164] Through

159 Z Kmietowicz, 'Pre-signing of Forms Found in 14 out of 249 Abortion Clinics in England' (2012) 245 British Medical Journal e4784.

160 CQC, *Marie Stopes International: Quality Report* (CQC 21 July 2017) <www.cqc.org.uk/sites/default/files/new_reports/AAAG6589.pdf>.

161 Fines have now been levied against NHS organisations for supervisory failures, 'Southern Health Fined £2m over Deaths of Two Patients' (*BBC News*, 26 March 2018) <www.bbc.co.uk/news/uk-england-43542284>. Much as the removal of crown immunity reduced special treatment for state hospitals, this signals an alignment of regulatory expectations between health and other industries.

162 *In the matter of an application by the Northern Ireland Human Rights Commission for Judicial Review (Northern Ireland)* [2018] UKSC 27.

163 Committee on the Elimination of Discrimination against Women, *Report of the Inquiry concerning the United Kingdom of Great Britain and Northern Ireland under Article 8 of the Optional Protocol to the Convention on the Elimination of All Forms of Discrimination against Women* (Committee on the Elimination of Discrimination against Women, CEDAW/C/OP.8/GBR/1 2018) <https://tbinternet.ohchr.org/Treaties/CEDAW/Shared%20Documents/GBR/INT_CEDAW_ITB_GBR_8637_E.pdf>.

164 D Dickenson, *Body Shopping: The Economy Fuelled by Flesh and Blood* (Oneworld 2008); N Pfeffer, *Insider Dealing: How Mortuaries, Medicine and Money Have Built a Global Market in Human Cadaver Parts* (Yale University Press 2017).

surveillance and research, our bodies have been transformed into data – the 'digital me' – and a whole new arena for breaching privacy has been opened up. This is no longer merely an issue about confidentiality in the patient–clinician interactions, though there is still much controversy about when disclosure is justified in the interests of others.[165] Data is produced well beyond health services, compiled using multiple sources, and accessible across countries and legal jurisdictions. Medical or health law concerns are becoming minor features of a broader agenda rather than being able to take a lead.

International health law is not a new phenomenon. Leprosy never respected political boundaries. Trade brought with it the risks of disease transmission. A long process, beginning with the first International Sanitary Conference, held in Paris in 1851, led to what are currently the International Health Regulations.[166] In some areas, such as pharmaceuticals, globalisation has been long facilitated by harmonisation of requirements for market access.[167] Since the Nuremberg war-crime trials, globally recognised principles of research ethics have been codified through the World Medical Association's Declaration of Helsinki (regularly amended). International initiatives have been launched around common standards for bioethics through UNESCO on a global level. The content and legitimacy of the Universal Declaration on Bioethics of 2005 has been criticised in the bioethics literature;[168] its relevance for domestic law has not been examined. Only one case in the LexisLibrary database cites it.[169] Scholars and practitioners seem a little more aware of the European Convention on Human Rights in Biomedicine (the Oviedo Convention) which is cited more often, even though the UK is not a signatory.

Future scholarship will need to pay more attention to global health governance.[170] The nature of the changes in service delivery, public choice on accessing care, the governance of scientific advances, all point towards international, transnational and global legal perspectives being much more important for the next phase of legal engagement with healthcare.

Our past may not be your future?

As the law in practice engages with these issues, and others that we have not identified, rigorous scholarship will be essential. Judicial and legislative interventions are generally reactive and vulnerable to pressures from the media and knee-jerk responses. Scholars have the luxury of looking at the horizon. So, although at the time of writing no womb transplant has yet taken place in the UK and ectogenesis remains in the laboratory, scholars and lawyers can analyse the issues dispassionately now, free of clamour either that such measures are 'breaking God's laws' or heavily emotional pleas that person X must be allowed whatever s/he wants to have a child. Scholars will need to critique

165 *ABC v St George's Healthcare* NHST [2017] EWCA Civ 336.

166 L Gostin, *Global Health Law* (Harvard University Press 2017) ch 6. See also the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (1995).

167 M Flear, 'Charting a Roadmap towards Membership and Formal Voice in Global Bioethics Standard-setting: Health Research and the Case of the International Council on Harmonisation' (2018) Medical Law International Online First doi: 10.1177/0968533218804598; S Dagron, *Global Harmonization through Public–Private Partnership: The Case of Pharmaceuticals* (IRPA GAL Working Paper No 2/2012, 29 January 2012) doi: 10.2139/ssrn.1995035.

168 See, for example, the contributions to the special issue: *Reflections on the UNESCO Draft Declaration on Bioethics and Human Rights* (2005) 5(3) Developing World Bioethics 179–279.

169 *Re HK (Serious Medical Treatment) (No 3)* [2017] EWHC 2991 (Fam), search conducted 15 October 2018.

170 A Krajewska, 'Bioethics and Human Rights in the Constitutional Formation of Global Health' (2015) 4(4) Laws 771; doi: 10.3390/laws4040771; C Clinton and D Sridhar, *Governing Global Health: Who Runs the World and Why?* (Oxford University Press 2017).

whether existing or proposed legal regulation can be trusted, and they will need to deploy empirical and normative methods to do so, in addition to traditional doctrinal scholarship. Scholarly analysis is needed to resist the attacks on the rule of law that are coming from populism and to rebut denials of the importance of trust. There is a crucial role here for law schools and legal scholars, and the future of health law in legal practice and in the academy lies within this challenging agenda.

We are aware that we have been somewhat casual in the use of names – medical, healthcare, health law. In our defence we plead that what we should be doing in relation to the role of law matters more than the naming of the subject. While there is a place for discussing the best label to apply to our discipline, it is of secondary importance. We have shown how the creation of a discrete named discipline, known originally as 'medical law', enabled the growth of a discrete specialism, although unfortunately serving to exclude key issues of the law's role, ignoring most health professionals who were not doctors and obscuring the important continuities with the legal scholarship and practice of the past. We should avoid falling into that trap again. Different labels such as healthcare law, health law, and public health law are useful in so far as they draw attention to neglected perspectives. However, labels too often obstruct our perception of the complexity of our work by constructing boundaries, or tempt us into unproductive rivalries in the pursuit of reputational dominance. Where lies the boundary between health law and certain issues in family law? Does it matter? The future vitality of our scholarship lies in addressing the enduring themes and future challenges.

Names do, however, have significance in the academy, marking the territory of particular groups of scholars. The power struggles of academic life cannot be ignored and are a source of considerable concern at this stage in the history of law's engagement with healthcare and whither our sub-discipline. The emergence in the UK of an area of legal scholarship focused on health resulted in part from radical changes in the nature and mission of law schools. Research as well as teaching became central to the academic's career, encouraging legal academics to engage in research in the same way as other colleagues in humanities and social sciences, and to write far more than in previous generations. Curriculum reform allowed new areas for undergraduate and postgraduate study to be consolidated and made more visible. The agendas of funders promoting more application of scholarly knowledge were one of the factors that encouraged the creation of academic centres of medical law in the 1980s.[171] The impact agenda of the Research Excellence Framework (REF) has favoured scholars working in this area, who have played a substantive role in national policy-making more often than most legal academics.[172]

While the 'impact agenda' remains strong, there are worries that the pendulum which promoted legal scholarship may be about to swing back. Law schools are once more urged to focus more and more on training and skills than attempting to instil scholarship into a law degree. Opportunities to offer undergraduate course units in health law may be reduced to make room for more practice-focused clinical legal education. Such changes are fuelled in part by the proposals of the Solicitors Regulation Authority and the death of the qualifying law degree.[173] Rather than necessarily protecting research, the REF is paradoxically leading to some universities reclassifying more staff as teaching-focused. It is possible that, save for a few leading research-based institutions, law schools may retreat

171 Wilson (n 4) 197–8.

172 *Research Excellence Framework 2014: Overview Report by Main Panel C and Sub-panels 16 to 26* (HEFCE 2015) 72 <www.ref.ac.uk/2014/panels/paneloverviewreports>.

173 <www.sra.org.uk/sra/policy/sqe/page>.

from the traditions of scholarship in which the authors have been lucky to thrive. There is cause for concern that legal scholars researching the law relating to health and biomedical science may thus become a less attractive prospect to some universities. Earning their bread on the basic curriculum and having boned up on procedure, they may have less and less time to develop research-led teaching, and students may well not want complex debates and challenging intellectual curiosity. Time for research may be at a premium.

There are perhaps two futures for the academic discipline focused on law and health: (1) scholars may enjoy the feast of developments calling for academic enquiry; or (2) scholarship may be squeezed out by radical and retrogressive changes in law schools. Fighting for the first future requires that we pay attention to the second. In this context, the establishment of new centres, such as that at Bristol, will be crucial to maintaining the integration of research scholarship and education. They enable the intellectual excitement of cutting-edge and interdisciplinary work to provide a platform for funded research that provides a buffer against the risk that legal education will become increasingly focussed on professional rather than societal needs.

In reflecting on societal needs, attention to the past is crucial. It shows us that familiar categories, and the concerns to which we have addressed our efforts over the past few decades, were understandable but contingent responses to the contemporary versions of the enduring themes that we have mapped out. We have shown how a mythology developed around Bolamisation that lost sight of history and has constrained the effectiveness of both legal practice and scholarship in keeping pace with developments in the engagements between health and law. We have suggested that we need to 'reboot' our thinking to ensure that the scholarship of the future maintains the proud tradition that we have shown goes back centuries. While 'modern medical law' was a specific twentieth-century phenomenon, the history of law and health provision is as old as the common law itself.

NILQ 70(1): 31–52

Exploring new paradigms in mental health and capacity law: persons, populations, and parity of esteem

JOHN COGGON* AND JUDY LAING**

Centre for Health, Law, and Society, University of Bristol Law School

Abstract

This paper examines key contemporary policy and legal agendas regarding mental health, with a view to highlighting contributions that may be brought from new and emerging discourses in academic health law. In particular, it does so from the perspective of the related fields of public health law and human rights law. Whilst core definitions of public health speak to questions regarding mental health and well-being, recent reports from a range of professional and advocacy organisations urge the message that mental health remains a neglected area of concern. This has led to an emphasis on the field of public mental health as a discrete area of study, policy and practice. We argue and explain how the related field of public mental health law should be conceptualised and operationalised. This entails an examination of the fundamental requirement of law to support and promote good mental health, with a renewed focus on prevention and proactive intervention rather than reactive measures. We suggest that a framing made by reference to human rights models will support the combined ethical and practical commitments that must be met by public mental health law.

Keywords: mental health; public health; law; human rights; health inequalities; parity of esteem.

1 Introduction

Mental disorders are among the most prevalent diseases worldwide.[1] Recent figures on the scale of mental ill health are staggering. The World Health Organization (WHO) has estimated that mental health problems account for more disability-adjusted life years lost than cancer or cardiovascular disease.[2] Depression is the predominant mental health

* Professor of Law; Co-Director, Centre for Health, Law, and Society, University of Bristol Law School, UK; Honorary Member, UK Faculty of Public Health; john.coggon@bristol.ac.uk

** Professor of Mental Health Law, Rights and Policy; Co-Director, Centre for Health, Law, and Society, University of Bristol Law School, UK; j.m.laing@bristol.ac.uk. We would like to express our strong gratitude to colleagues for feedback on an earlier version of this paper at the launch event of the Centre for Health, Law, and Society (CHLS) in Bristol in October 2017, and to participants at the CHLS roundtable on 'Public Mental Health Law' in April 2018. We are also extremely grateful to the two reviewers of the paper for their detailed and insightful comments on an earlier draft.

1 Theo Vos et al, 'Global, Regional, and National Incidence, Prevalence, and Years Lived with Disability for 301 Acute and Chronic Diseases and Injuries in 188 Countries, 1990–2013: A Systematic Analysis for the Global Burden of Disease study' (2013) The Lancet 386:9995, 743–800.

2 Located at WHO, *Mental Disorder and Substance Use* <www.who.int/gho/publications/mdgs-sdgs/MDGs-SDGs2015_chapter7.pdf?ua=1>.

problem, followed by anxiety, schizophrenia, and bipolar disorder.[3] Huge rises are anticipated in the number of people with dementia and Alzhemier's disease over the next 20–30 years, linked to the rapidly ageing world population. Mental ill health is now regarded as a major public and global health issue.[4]

In the UK, the figures are equally startling. The most recent Adult Psychiatric Morbidity Survey of Mental Health and Wellbeing revealed that almost one in five people in England aged 16 and over showed symptoms of anxiety or depression, and nearly half of adults (43.4%) believe that they have had a diagnosable mental health condition at some point in their life.[5] There are indications that the incidence of mental ill health has been rising steadily over the last two decades, especially in women.[6] This may be due to people being more willing to report and admit to having a mental health problem, but environmental, social and economic conditions are key contributing factors to the increase in many conditions.[7]

In spite of vast evidence on the prevalence and disabling impact of mental ill health, and although there has been progress in some countries, the WHO's *Mental Health Atlas* 2017 reveals that there is a global shortage of workers trained in mental health and a lack of investment in mental health planning, programmes and services.[8] This is bolstered by data from a range of other sources. For example, treatment provision for depression globally is low, and surveys indicate that less than half of people living with depression receive any treatment.[9] There are significant challenges which have led to a huge 'treatment gap' between physical and mental ill health, where up to 9 out of 10 people across the world do not receive even basic mental healthcare in some countries. It is clear that, on a global scale, mental health continues to be neglected, and investment in crucial services is not happening quickly enough. Failure to invest in mental health has personal, social and economic costs on a vast scale.[10]

Moreover, relevant regulatory frameworks in many countries are highly reactive and ineffective in promoting access to timely or universal mental healthcare or treatment, less still in positively promoting conditions for good mental health and well-being. The *Atlas* indicates that less than half of member states' domestic mental health laws and policies

3 Ibid.

4 Ibid. See also WHO/Alzheimer's International, *Dementia: A Public Health Priority* (World Health Organization 2012) <www.who.int/mental_health/publications/dementia_report_2012/en>.

5 The survey takes place every seven years and the latest version was published in September 2016 <https://digital.nhs.uk/data-and-information/publications/statistical/adult-psychiatric-morbidity-survey>. See also Mental Health Foundation, *Fundamental Facts about Mental Health 2016* <www.mentalhealth.org.uk/publications/fundamental-facts-about-mental-health-2016>.

6 *Adult Psychiatric Morbidity Survey of Mental Health and Wellbeing, England, 2014* (National Statistics 2016) 5. For example, the Psychiatric Morbidity Surveys in England show a 15% increase (from 24% in 2007 to 39% in 2014) of adults aged 16–74 with conditions such as anxiety or depression accessing mental health treatment. See <https://digital.nhs.uk/data-and-information/publications/statistical/adult-psychiatric-morbidity-survey>.

7 Ibid. See also John Coggon, 'Depression and Public Health Law: Ethics, Governance, and the Socio-Political Determinants of Health and Well-being' in Charles Foster and Jonathan Herring (eds), *Depression: Law and Ethics* (Oxford University Press 2017); 'What is Depression and Why is it Rising?', *The Guardian* (London, 2 June 2018) <www.theguardian.com/news/2018/jun/04/what-is-depression-and-why-is-it-rising>.

8 See <www.who.int/mental_health/evidence/atlas/mental_health_atlas_2017/en>.

9 Philip S Wang et al, 'Use of Mental Health Services for Anxiety, Mood, and Substance Disorders in 17 Countries in the WHO World Mental Health Surveys' (2007) The Lancet 370:9590, 841–50.

10 Dr Shekhar Saxena, Director of WHO's Department of Mental Health and Substance Abuse. See <www.who.int/mental_health/evidence/atlas/atlas_2017_web_note/en>.

comply fully with relevant international human rights standards.[11] Unsurprisingly, these deficiencies have been described as a 'failure of humanity' and led to some of the worst human rights abuses in the history of global health.[12] An appreciation of this global context is essential to underline that there are key rights in need of protection, many of which are shaped by social and economic conditions.[13]

Organisations including the Mental Health Foundation and Faculty of Public Health in the UK have been exploring and prioritising new approaches to tackling this 'failure'. In 2016, they published a joint report, entitled *Better Mental Health for All*, which makes it clear that mental health problems are as much a public health issue as physical disorders/illness, and that we need to shift the focus away from the current reactive and individual responses to methods of public health prevention, promotion and early intervention. This includes a focus on creating environments in which people can enjoy positive mental well-being, rather than merely avoid mental ill health: the report works with a concept of mental health that runs through a continuum that goes beyond the absence of disease.[14] It concludes that:

> There is strong evidence that investment in the protection and promotion of mental wellbeing, including early intervention and prevention, improves quality of life, life expectancy, educational achievement, productivity and economic outcomes, and reduces violence, antisocial behaviour and crime . . . Strong evidence of the poor outcomes related to having a mental health problem means that prevention and early intervention need to be a priority. Equally, there is evidence that investing in the protection and promotion of mental wellbeing should be emphasised within public mental health.[15]

The report advocates for new ways of thinking in order to 'realise the full potential of public mental health'[16] and reduce the burden of mental ill health.

In this paper, we contribute to this narrative strategy and practical agenda by explaining how legal scholarship can provide new and meaningful ways of thinking about and contributing to public mental health.[17] Just as we share the view that practice in this area should not be characterised as simply reactive to problems once they have arisen, so we envisage a concept of public mental health law that proactively seeks to provide conditions for and protections of positive mental well-being, in addition to governance structures for reactive measures in instances where mental ill health does arise. We start, in the following section, by exploring the development of public health law and mental health law, and their relationship with the broader field of health law. This allows a critical understanding of the advances that we argue are required in scholarship. We then move to consider what legal foundations and approaches may promote and constrain public mental health, and what forms of law and regulation are engaged in public mental health law. We exemplify our discussion with reference to dementia, but consider our arguments here to have broad application and importance for priorities in health law as a field of

11 At 16. See <www.who.int/mental_health/evidence/atlas/mental_health_atlas_2017/en>.

12 Arthur Kleinman, 'Global Mental Health: A Failure of Humanity' (2009) The Lancet 374:9690, 603–04.

13 Brendan D Kelly, *Mental Illness, Human Rights and the Law* (Royal College of Psychiatrists 2016) 215.

14 *Better Mental Health for All: A Public Health Approach to Mental Health Improvement* (Mental Health Foundation/Faculty of Public Health 2016) 13. See <www.mentalhealth.org.uk/publications/better-mental-health-all-public-health-approach-mental-health-improvement>.

15 Ibid 14.

16 Ibid 11.

17 See also the recent special issue of Public Health Ethics (2018) 11(2) compiled by Diego Silva, Cynthia Forlini and Carla Meurk, which explores public mental health ethics.

study and practice. Our conclusion aims to provide a clearly delineated concept of public mental health law and the rationale for its importance.

2 Health law as medical law; mental and public health law as outliers?

2.1 An early focus on medicine and law

The current wave of scholarship on the relationships between health and law began with the practice of medicine as its primary concern.[18] In a UK context, this is reflected by the focus of the earliest textbooks,[19] such as J K Mason and Alexander McCall Smith's *Law and Medical Ethics*,[20] Margaret Brazier's *Medicine, Patients, and the Law*,[21] and Ian Kennedy and Andrew Grubb's *Medical Law: Text and Materials*.[22] Critical historical reflections track the evolution of contemporary 'medical law' as a phenomenon that emerged within or alongside the broader field of bioethics, which also took the doctor–patient relationship as its main point of focus since its emergence in the 1970s.[23] This narrowing of the field is remarkable in part because, in principle, bioethics has a much wider reach than clinical medicine (and thus an interest that expands beyond situations involving the remediation of ill health within a medical or healthcare setting). The International Association of Bioethics, for example, defines its area of inquiry in the following terms:

> Bioethics is the study of the ethical, social, legal, philosophical and other related issues arising in health care and in the biological sciences.[24]

This great breadth, which incorporates, for instance, environmental ethics, the ethics of biotechnological innovation and animal ethics, was not reached through the overwhelmingly dominant debates and discourses of early bioethics. Although scholars, of course, examined those and other wider areas, health law, like bioethics more generally, primarily presented itself as distinctly medical in tone. The influence and allure of anti-medicalisation critiques, such as Ivan Illich's *Medical Nemesis*,[25] and the apparent conflation of *biomedical* ethics and bioethics writ large, meant that the central point of analysis was a universe in which one person – a patient – interacted with one other person – a doctor – with critical inquiry attending to the boundaries of the former's (moral) right to determine what treatments she should receive to serve her interests as she perceived these.

That inquiry could have lain in other areas even *within* the reach of medicine was not missed as UK medical law developed. Consider the following extract from Joseph Jacob's review of Kennedy and Grubb's *Medical Law: Text and Materials*, published in 1990:

18 For critique and rich historical context, see further Margaret Brazier and Jonathan Montgomery, 'Whence and Whither "Modern Medical Law"?', published in this special issue.

19 But note that 'medical law' is still the chosen focus of some texts whose first editions came rather later, such as: Emily Jackson, *Medical Law: Text, Cases, and Materials* (4th edn, Oxford University Press 2016; 1st edn 2006); Jonathan Herring, *Medical Law and Ethics* (3rd edn, Oxford University Press 2010; 1st edn 2006); Jo Samanta and Ash Samanta, *Medical Law* (2nd edn, Palgrave 2015; 1st edn 2011).

20 J Kenyon Mason and R Alexander McCall Smith, *Law and Medical Ethics* (Oxford University Press 1983).

21 Margaret Brazier, *Medicine, Patients, and the Law* (Penguin 1987).

22 Ian Kennedy and Andrew Grubb, *Medical Law: Text and Materials* (Butterworths 1989). Although not a textbook, see also Ian Kennedy, *The Unmasking of Medicine* (Allen & Unwin 1981).

23 See further Ruth Chadwick and Duncan Wilson, 'The Emergence and Development of Bioethics in the UK' (2018) 26(2) Medical Law Review 183–201; Duncan Wilson, *The Making of British Bioethics* (Manchester University Press 2014); Kenneth Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007).

24 See <www.bioethics-international.org/work-progress>.

25 Ivan Illich, *Limits to Medicine – Medical Nemesis: The Expropriation of Health* (Marion Boyars 1976). Note e.g. its impact on Ian Kennedy's thinking: Ian Kennedy, 'What is a Medical Decision?' in Ian Kennedy, *Treat Me Right: Essays in Medical Law and Ethics* (Clarendon 1988).

> [T]he particular commitments of the compilers are more implicit than expressed; but then it is one of the teacher's tasks to draw these out. Kennedy and Grubb have not excluded much that law teachers may be expected to ask their students to read . . . If there is a major omission, it is the scant regard for what, with some understatement, can be called the paternalism of public health law – see their brief discussion of notifiable diseases (pp. 110ff) and compulsory treatment under the Mental Health Acts (pp. 112ff) – which is part of the legacy of Chadwick and contrasts with the common law tradition. For this disregard, however, Kennedy and Grubb must be forgiven because neither public health law nor the regimes which replaced the Victorian Poor laws are their real concern.[26]

The thrust of this observation is important in itself to our current project (see sections 2.2 and 2.3 below), but also reflects a separate defining feature of health law: scholarship here has an ongoing 'self awareness'; it produces internal critiques of the boundary and coherence problems for the field.[27] Jonathan Montgomery's paradigm-shifting recharacterisation from medical law to healthcare law, notably as expounded in his textbook of that title published in its first edition in 1997, is a prominent example.[28] Montgomery explicitly provides practical rationales for the incorporation of broader theoretical commitments and practical points of concern than would be given by health law conceived simply as medical law: a need to look to healthcare systems, the role of institutions, the place of practitioners other than doctors, and the impact of health promotion measures outside of clinical medicine.[29]

Over time, not least because of the influence of scholars such as Montgomery, the field has broadened to capture wider concerns still: bioethics and health law scholarship now boasts extraordinary reach in terms of critical and (inter)disciplinary approaches, applied to myriad areas of practical concern, such as animal law, artificial intelligence, human enhancement, global and planetary health, and so on. We revisit some of these points as the paper progresses, as we argue for the value and importance of public mental health law as a part of and a contributor to the overall field of health law. But at this stage we aim to consider how the sharpening of the *early* paradigms of (modern) medical law constrained and led to (mis)characterisations of mental and public health: we will show in section 2.2 how mental health and public health came to be presented as 'outliers' in health law and bioethics. The early practical points of focus in medical law, as described above, provide the start of a rationale for this. To explain it fully, we need to consider next how the early framings of medical law create a distorting focal point with 'the autonomous patient', and then explain the impact of this in the galvanisation of received wisdoms and their implications for health law scholarship in the areas of mental and public health.

---

26 The review is also of Dieter Giesen's, *International Medical Malpractice Law*: see (1990) 53 Modern Law Review 280–2, 280. It is worth noting that Jacob is himself author of *Doctors and Rules: A Sociology of Professional Values* (Routledge 1988) (with an extended 2nd edn published in 1999).

27 Cf e.g. Veitch (n 23); Theodore Ruger, 'Health Law's Coherence Anxiety' (2008) 96 Georgetown Law Journal 625; John Coggon, *What Makes Health Public? A Critical Evaluation of Moral, Legal, and Political Claims in Public Health* (Cambridge University Press 2012) ch 5; Anne-Maree Farrell, John Devereux, Isabel Karpin and Penelope Weller, *Health Law: Frameworks and Context* (Cambridge University Press 2017).

28 Jonathan Montgomery, *Health Care Law* (Oxford University Press 1997; 2nd edn 2002).

29 Ibid ch 1.

2.2 'Empowerment' and the distorting effect of the 'paradigm patient'

The creation of medical law as characterised above was effectively the creation of a particular critical lens. This lens allowed a sharpened focus on a certain genus of questions such as: why and to what extent a patient should be informed before her consent to an intervention is considered meaningful; what reasons and considerations are relevant to a patient's decision to make fatal refusals of treatment; in what circumstances might medical care be said to incorporate rights, for example, to receive euthanasia? This sharpened focus was achieved by developing paradigms that became received analytical assumptions embodied in the idea of the 'autonomous patient'. This patient was an individual whose rights emanated from her being able and rightfully placed, once well informed (again by right), to determine her own interests. Decision-making in a medical context contained both questions of clinical judgement, for which medical expertise was relevant, and questions of wider judgement and values (personal, familial, social, ethical, religious) that were not considered the preserve of the doctor.[30] And overarching this was a broad scepticism – cynicism even – regarding 'medicalisation', wherein a dominant profession had claimed 'jurisdiction' over questions that ought, it was understood, to be determined by individuals in the vindication of their own rights.[31]

As a matter of logic, analytical points of focus such as 'the autonomous patient' clarify by simplifying: theories bring explanatory and critical potential at the cost of detail and nuance.[32] Of necessity, the further a theory's paradigms are from reality, the more *distorting* becomes the lens. Insofar as the starting points of critique allow settled and justified conclusions on questions such as (say) voluntary, active euthanasia for adults who are suffering unbearably and reaching an uncoerced decision, this is fine. But where (say) the paradigm patient is not reflective of the person under discussion (e.g. because she is not able to reach a decision on her best interests), or reflective of the practical context (e.g. because a preventive measure would need to be instituted at a population level and gaining individual consent is not even a theoretical possibility), we come into problems if our analysis is made by reference to 'the autonomous patient'.[33]

The simple response to such problems is to recognise the limits of the existing theoretical apparatus and develop appropriate machinery for critique that works with alternative, relevant and defensible paradigms.[34] However, within the early days of medical law, it might be observed that for practical scenarios that fitted uncomfortably within the dominant paradigms, the problems seemed to be for the cases rather than for the theory, at least by default.[35] In the current paper, it is pertinent to exemplify this by reference to mental health and public health, although other 'outlier' areas could equally be cited. As noted in Jacob's review, quoted above, mental and public health were acknowledged only largely to be sidelined. They became outliers as a matter, essentially,

30 Cf Kennedy (n 25).

31 See Illich (n 25).

32 Stephen R Latham, 'On Some Difficulties for any Theory of Global Health Justice,' in John Coggon and Swati Gola (eds), *Global Health and International Community: Ethical, Political and Regulatory Challenges* (Bloomsbury 2013).

33 John Coggon, 'Would Responsible Medical Lawyers Lose their Patients?' (2012) 20(1) Medical Law Review 130–49; John Coggon, 'Mental Capacity Law, Autonomy, and Best Interests: An Argument for Conceptual and Practical Clarity in the Court of Protection' (2016) 24(3) Medical Law Review 396–414.

34 See Bruce Jennings, 'Frameworks for Ethics in Public Health' (2003) 9(2) Acta Bioethica 165–76; Nuffield Council on Bioethics, *Public Health – Ethical Issues* (Nuffield 2007) 'Introduction'.

35 Consider the critique provided in Angus Dawson, 'The Future of Bioethics: Three Dogmas and a Cup of Hemlock' (2010) 24(5) Bioethics 218–25.

of convention, even whilst they could have been incorporated more fully within health law as 'medical law'. And this is of great significance because, by virtue of their exclusion, they were essentially placed in a position where defences of practice had to be made against uncritical acceptance of assumptions born of the paradigms of mainstream medical law. For mental health this is well represented by critiques framed as 'medicalism' *versus* 'legalism'.[36] For public health the same is true by references to 'healthism' or 'nanny statism' *versus* individual right.[37] And both mental and public health are united not just by reference to their relative neglect in mainstream medical law: they also share a number of a salient overlapping analytical concerns. In particular, both give rise to questions of the common good and the potential tensions between individual and public interests (e.g. in relation to measures generated in instances where an individual is considered to be a threat to the community); both draw in considerations of paternalism and intervention without consent (thus challenging the assumed wisdom of 'the autonomous patient' and her being positioned best to recognise her interests); and, as explored in section 3.2 of this paper, they invite similar forms of framing when we consider how they ought to be addressed.

The adversarial framing of competing principles or theoretical commitments that we characterise here may at first seem simplistic, but it is emblematic of the application of theory in practical questions concerning bioethics and health law.[38] Medical law had the patient's right to non-interference secured as an almost unchallengeable ethical – and, if sometimes only in principle, legal – right.[39] The duty to respect a patient's entitlement to be treated only following free and informed consent became *the* cardinal principle (albeit that on the latter, the law somewhat lagged behind the ethics).[40] In contrast, the concerns of mental health and public health were more challenging: respect for individual rights was placed at no less of a premium, but in a context where the rationales and justifications concerning the acceptability for treatments or interventions without consent were not the same. Even allowing that we might end up at the same conclusion – i.e. that intervention cannot be justified and protections of bodily integrity should be absolute – distinct theorising needed to be achieved. We move from a universe with just two people in it, and with our ethical source of concern just being one person (the autonomous patient), to a more complex social context, in which rejections of paternalism are not so straightforward (can we really accept that we are justified deferring to the individual's perspective of what serves her interests?) and in which questions of the common good and impacts on others cannot be ignored (are the person's individual interests exhaustive of our ethical concern?).

36 As first described by Kathleen Jones, see *Asylums and After: A Revised History of the Mental Health Services from the Early 18th Century to 1990* (Athlone Press 1993).

37 Petr Skrabanek, *The Death of Humane Medicine and the Rise of Coercive Healthism* (Social Affairs Unit 1994); John Coggon, *The Nanny State Debate: A Place Where Words Don't Do Justice* (Faculty of Public Health 2018).

38 Cf Michael Dunn and Charles Foster, 'Autonomy and Welfare as *Amici Curiae*' (2010) 18(1) Medical Law Review 86–95.

39 Margaret Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) 65(2) Cambridge Law Journal 397–422; John Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15(3) Health Care Analysis 235–55.

40 *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871; *Chester v Afshar* [2004] UKHL 41; *Montgomery v Lanarkshire Health Board* [2015] UKSC 11; General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (General Medical Council 2008); Anne Maree Farrell and Margaret Brazier, 'Not So New Directions in the Law of Consent? Examining *Montgomery v Lanarkshire Health Board*' (2016) 42(2) Journal of Medical Ethics 85–8; Rob Heywood and José Miola, 'The Changing Face of Pre-operative Medical Disclosure: Placing the Patient at the Heart of the Matter' [2017] 133 Law Quarterly Review 296–321.

The presumption towards gradations in the role of different principles (autonomy, welfare, the common good etc.) that are prima facie required by mental and public health presents a contrast with the zero-sum absolutism of (say) autonomy *versus* paternalism in mainstream medical law. Even in the context of the paradigm patient, medical law has started to develop towards a less absolutist framing, accounting for empirical discourses on the realities of decision-making and critical accounts such as 'relational autonomy'. But, in the early days of modern medical law, the contrast was with the robust persona of the autonomous patient. The ill-suitedness of the paradigm patient in the context of mental health was clearly recognised, and noted, for example, by Phil Fennell, who wrote in 1990:

> There is now widespread acknowledgement of the folly of rigid insistence upon the ascendancy of patient autonomy over paternalism where the result would be harm to the patient. Paternalism is recognized as legitimate up to a certain point.[41]

Similarly, in their leading textbook on *Public Health Law*, Lawrence Gostin and Lindsay Wiley reflect back on the dominant concerns of public health, indicating the contrast with mainstream medical law:

> Public health has historically constrained the rights of individuals and businesses to protect community interests. Whether through the use of reporting requirements affecting privacy, mandatory testing or screening affecting autonomy, environmental standards affecting private property, industrial regulation affecting economic freedom, or isolation and quarantine affecting liberty, public health has not shied away from controlling individuals and businesses for the aggregate good.[42]

It is clear that these wider contexts and concerns impact the basis of, and thus conclusions to, analysis. And we also see how the framing, when dominated by a medical law paradigm of self-reliant individuals with indefeasible rights, is problematic from the start.[43] Early medical law could triumph the autonomous patient and, consistently with this, reduce the medical practitioner to a party whose role was limited to the competence afforded by a technical expertise that could not speak to final value judgements or what should ultimately be done to a patient for her own good without her express agreement. And the 'universe' in which this happened was largely confined to a clinical situation with no wider societal considerations at play. However, in mental health and public health, even at the level of theory, it could not without questionable assumptions be argued that such a position would hold.[44] In both areas, inevitably, value judgements external to those of the patient (or, given the broader contexts, person or citizen) would be brought to bear on decisions that directly impacted the individual and her choices. On settled analysis, of course, we might argue that this is wrong: as libertarian scholars such as Szasz and Skrabanek did respectively in relation to mental and public health.[45] But in the alternative, where concerns for well-being and welfare at individual and population levels arose, an

41 Phil Fennell, 'Inscribing Paternalism in the Law: Consent to Treatment and Mental Disorder' (1990) 17(1) Journal of Law and Society 26–51, 26.

42 Lawrence O Gostin and Lindsay Wiley, *Public Health Law: Power, Duty, Restraint* (3rd edn, University of California Press 2016) 11.

43 Cf Jennings (n 34).

44 Lawrence O Gostin, 'Public Health: The "Population" as Patient' in Catherine D DeAngelis (ed), *Patient Care and Professionalism* (Oxford University Press 2014).

45 Thomas Szasz, *Law, Liberty, and Psychiatry: An Inquiry into the Social Uses of Mental Health Practices* (Syracuse University Press 1989 [1963]); Skrabanek (n 37).

alternative framing was needed. However, we see that the sort of gradations indicated, for example, in Fennell's words directly above, contended with the settled wisdoms of medical law.

2.3 Parallels and paradigms in the outlier areas of mental and public health law

The previous discussion has indicated that mental health and public health existed as outliers in two particular ways in health law. First, as a practical matter they suffered relative neglect in medico-legal scholarship. Of course, it is true that significant figures, such as Brenda Hale (Hogget), Phil Fennell, Lawrence Gostin and Robyn Martin, were considering these fields as a whole, and specific questions within them, for example: treatment without consent for psychiatric conditions; notifiable diseases. But measured by weight of scholarship, there was far less attention to these than was received by questions in clinical medicine, such as informed consent, euthanasia and so on. Second, and probably as a consequence, mental health and public health suffered neglect because settled conclusions on 'the autonomous patient' meant that the dice were loaded against analyses that could suitably accommodate concerns for autonomy *and* for welfare *and* the common good.[46]

In short, the upshot of early modern medical law was a framing that contraposed medical paternalism/interference on the one hand with individual rights on the other. In regard to mental health and public health this was significant and to a good extent valuable. An unbridled medicalism in mental health was demonstrably problematic, and greater legal protections for psychiatric patients overdue.[47] Equally, public health measures – notably responses to HIV/AIDS – clearly invited responses that recognised, respected and protected individual rights.[48] This was all the more important as the individuals under discussion were often members of vulnerable and/or otherwise disadvantaged or marginalised groups. Nevertheless, it allowed the enforcement of a perception that mental and public health were challenges to, and to be challenged by, human rights: the two fought against one another. And the apparent (moral) soundness of such a framing was underscored by the concern in bioethics and medical law to frame patients as autonomous rights-holders whose decision-making should not be interfered with, for their own good, by medical professionals or the state. A preponderance of citations of John Stuart Mill's 'harm principle' (generally with little regard for a wider discussion of *On Liberty*) came to serve as a knock-down argument:

> [T]he only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinion of others, to do so would be wise, or even right . . . The only part of the conduct of any one, for which he is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign.[49]

46 Cf Coggon (n 33).

47 Lawrence O Gostin, *A Human Condition Volume I: The Mental Health Act from 1959 to 1975: Observations, Analysis and Proposals for Reform* (MIND 1975).

48 Richard D Mohr, *Gays/Justice: A Study of Ethics, Society, and Law* (Columbia University Press 1988).

49 John Stuart Mill, *On Liberty*, Edward Alexander (ed) (Broadview 1999 [1859]) 52.

The impact of this type of analysis is compounded by its apparent basis in civil and political rights: rights to be left alone, with little (perhaps no) concern being given to economic, cultural and social rights. So again, the concerns that might underpin mental and public health interventions, are sidelined. In the next section, we explore and promote challenges to the paradigms that we have presented here and consider their application in practice. Our argument rests on what we consider to be a better picture, in which mental and public health are framed as *part of* human rights, rather than oppositional to them. We aim to show how a coming together of a reconceived field of public mental health law can lead to a richer and more productive health law overall, not least in affording greater potential for achieving parity of esteem between mental and physical health.

3 Beyond restraint: human rights as a framework for action in public mental health

3.1 Emerging from the shadows: mental health and parity of esteem

Various narrative, advocacy and analytical advances at the global level concerning mental health and human rights help to demonstrate how mental health is emerging from the shadows as a public health concern, and how human rights can play a key role in *promoting* preventive and population-level health improvement approaches to mental health. The WHO has helped to 'sharpen the focus' on mental health in the last decade by launching the Mental Health Gap Action Programme (mhGAP),[50] which aims to scale up services for mental disorders, especially for low- and middle-income countries. *The Grand Challenges in Global Mental Health*,[51] launched in 2010, supports new research to focus collective efforts on global mental health. These initiatives have been followed by commitments from member states to combat mental ill health in the WHO Mental Health Action Plan 2013–2020.[52]

At a domestic level, focusing here on England, there are also factors contributing to the shift away from a reactive approach, towards preventive approaches to mental health and well-being. A recent review of mental health legislation has identified mental health as emerging 'into the light'[53] with an explicit commitment to achieving 'parity of esteem' and equal treatment for mental and physical ill health. To be realised, of course, such a commitment requires adequate bolstering at political (including economic), legal, social and personal levels. And the first two of these are, we suggest, prerequisites to the sustainable achievement of the final two.

At least on its face, it can be shown that the political climate has shifted to recognise the need for a population approach to tackle the risk factors and determinants of mental ill health and to promote good mental health. Prime Minister Theresa May announced in 2017:

> [A] step-change in the way that we deal with these issues. I want to see mental health addressed not just in our hospitals, but in our classrooms and communities. I want to see the stigma stripped away so that no-one in this country feels unable to talk about what they're going through or seek help. I want

50 See <www.who.int/mental_health/mhgap/en>.

51 See further Pamela Y Collins et al, 'Grand Challenges in Global Mental Health' (2011) 475:7534 Nature 27–30.

52 See <www.who.int/mental_health/publications/action_plan/en>.

53 See *The Independent Review of the Mental Health Act: Interim Report* (1 May 2018) 5 <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/703919/The_independent_Mental_Health_Act_review__interim_report_01_05_2018.pdf>.

> to see a focus on prevention as well as treatment, especially since so many adult mental health problems – which 1 in 4 of us will suffer from at any one time – begin in childhood.[54]

This political commitment is, to an extent, supported by legislation and government policy. The Health and Social Care Act 2012 introduced the first explicit duty on the Secretary of State to promote physical and mental health and prevent, diagnose and treat physical and mental ill health.[55] This legal duty is reinforced by local authorities' health improvement duties, as well as the Care Act 2014, which imposes a further duty on local authorities to promote individual well-being, defined as including emotional, physical and mental health.[56] And it is underscored politically by the NHS Constitution, which explains that the NHS 'is designed to diagnose, treat and improve physical and mental health'.[57] Additionally, the NHS England strategy published in 2016, *Five Year Forward View for Mental Health*,[58] is committed to working towards a more equal response across mental and physical health, and achieving parity between the two.

However, we might question the real strength and impact of these political and legislative moves and commitments. An official report in 2017 has highlighted that, whilst there has been some encouraging early progress, there 'remains a long distance to travel to achieve true parity'.[59] It outlines the key foci for future development: to continue to invest in the mental health workforce and services, as well as preventive mental health approaches; and to promote a 'fresh mindset' to tackle inequalities, stigma and discrimination. Moreover, the recent report of the independent review of the Mental Health Act (MHA) 1983 has been equally critical of the lack of appropriate and preventive mental health services and support, although regrettably, the review fell considerably short of recommending a positive entitlement to support/treatment services and a complete overhaul of current mental health legislation.[60]

The need for greater work at political and legal levels is underscored if we look at evidence at the social and personal levels. This suggests that attitudinal shifts are necessary if mental health is to be understood in parity with physical health, albeit that things appear to be moving in the right direction, as the recent independent review of the MHA report[61] and Attitudes to *Mental Illness 2014 Research Report*[62] prepared for Time to

54 'Mental Health Problems Are Everyone's Problem: Article by Theresa May' (9 January 2017) <www.gov.uk/government/speeches/mental-health-problems-are-everyones-problem-article-by-theresa-may>.

55 Health and Social Care Act 2012, s 1(1).

56 Ibid s 12; Care Act 2014, ss 1(1) and 1(2).

57 See <www.gov.uk/government/publications/the-nhs-constitution-for-england>.

58 (February 2016) located at <www.england.nhs.uk/mental-health/taskforce>. See also *The NHS Long Term Plan* (14 February 2019), which has reaffirmed the government's commitment to achieving parity of esteem for mental health, located at <www.england.nhs.uk/long-term-plan>.

59 See <www.england.nhs.uk/wp-content/uploads/2017/03/fyfv-mh-one-year-on.pdf>.

60 *Modernising the Mental Health Act: Increasing Choice, Reducing Compulsion: Final Report of the Independent Review of the Mental Health Act 1983* (December 2018) 7 <www.gov.uk/government/groups/independent-review-of-the-mental-health-act>.

61 Ibid.

62 (April 2015) See <www.time-to-change.org.uk/sites/default/files/Attitudes_to_mental_illness_2014_report_final_0.pdf>; see also Public Health England/National Centre for Social Research, *Attitudes to Mental Health Problems and Mental Wellbeing: Findings from the 2015 British Social Attitudes Survey* <www.bsa.natcen.ac.uk/media/39109/phe-bsa-2015-attitudes-to-mental-health.pdf>.

Change[63] demonstrate. There are some positive indications of greater levels of public understanding in England between 2008 and 2014, evidenced by the reported 9 per cent increase in willingness to live with someone who has a mental health problem (from 57% to 66%); and a 7 per cent increase in willingness to work with someone who has a mental health problem (69% to 76%). Moreover, 78 per cent of respondents believed that for too long people with mental illness have been the subject of ridicule, and 95 per cent believed that people with mental illness are subject to stigma and discrimination. Nevertheless, it is still worrying that over a third of survey respondents thought that people with a mental health problem are prone to violence, and only 40 per cent would be comfortable speaking to their employer about a mental health problem.

The *Better Mental Health for All* report, discussed in the introduction to this paper, provides further impetus to champion a fresh, more holistic approach (including preventive and health improvement measures) and highlights the need for legal and political support for this. The report recognises that current models are highly responsive, while effective prevention of illness *and* promotion of well-being require a different strategy:

> Interventions which focus on the positive have added value over those which focus on finding or preventing the negative. Promoting mental wellbeing moves the focus away from illness and is central to an individual's resilience, social purpose, autonomy and ability to make life choices.[64]

When considering the role of law here, both for its practical force and its expressive nature in regard to social values and priorities, it is worth emphasising that regulatory (especially legal) frameworks for mental healthcare and treatment in England are coercive, reactive, and very much focused on crisis intervention. For example, the admission and treatment provisions of the MHA justify the use of compulsory care, triggered when mental health has deteriorated to a point where it is of sufficient nature and severity to justify in-patient treatment. We do not for a moment wish to deny the importance of law in contexts of acute psychiatric illness, or the need for reform in this area in ways that allow real and meaningful involvement and participation of the persons who would be affected by such laws, as required by Article 4(3) of the UN Convention on the Rights of Persons with Disabilities (CRPD). But the near-exclusive emphasis lent by this overwhelmingly *reactive* approach allows the sidelining of some of the key risk factors for mental ill health, which occur throughout the life-course and across communities and which also would benefit from the normative and practical support of legal, rather than just (potentially quite empty) political, commitments.[65] Indeed, a report in 2018 by the Care Quality Commission in England into rising detentions under the MHA suggests that the ongoing rise in compulsory detentions (the number of detentions increased by 40% – from 45,484 to 63,622 – between 2005/2006 and 2015/2016) may be symptomatic of a system under 'considerable pressure'. The report attributes this to a number of factors, including declining access to community services and an increase in the prevalence of risk factors for detention, such as rising inequality, social exclusion and drug/alcohol

63 Time to Change is a growing social movement in the UK campaigning to improve attitudes and behaviour towards people with mental health problems, with the aim of eliminating mental health discrimination and stigma – see further <www.time-to-change.org.uk>.

64 *Better Mental Health for All* (n 14) 28.

65 Cf also the distinction in conceptualisation of, and responses to, 'crisis resolution' as contrasted with 'general support' in Piers Gooding, Bernadette McSherry, Cath Roper and Flick Grey, *Alternatives to Coercion in Mental Health Settings: A Literature Review* (Melbourne Social Equity Institute, University of Melbourne 2018).

misuse.[66] The status quo only sharpens the narrow lens to much analysis, and thus scholarly priorities, in health law described in section 2 of this paper.

Let us therefore explore the wider landscape, and explain the broader space for law within it. Dahlgren and Whitehead argued several decades ago that susceptibility to mental health problems is determined by a combination of individual risk factors, influenced by settings, *and* broader socio-economic, cultural and political factors.[67] There is also an important family dimension, as relationships moulded in formative years contribute to health and well-being in later life. This point is emphasised too in *Better Mental Health for All*:

> [T]he social, physical and economic environments in which people are born, grow, live, work and age have important implications for mental health.[68]

Acceptance of these evidence-based concerns represents a shift away from the biomedical model, which has, until recently, dominated beliefs about physical and mental health and, as outlined above, the shape and scope of bioethics and health law. The biomedical model emphasises the genetic and biological causes of disease, with a consequent focus on pharmacological and clinical solutions: it is narrow and (generally) responsive. And, accordingly, it ignores the impact of the social and environmental determinants of health, with a consequent failure to account for measures that are broader and pre-emptive. Traditionally, psychiatry has focused on treatment and 'tertiary prevention': i.e. slowing the progress of disease/disability.[69] If health law is to serve mental as well as physical health, we need to move to framings that accord with growing scientific awareness of the role of mental health improvement and early detection, and acceptance of the need to develop interventions that might reduce the incidence of mental disorders.[70]

To do this, we cannot just rely on (healthcare) professionals' understanding or capacity to intervene. Health law and policy are crucial precisely because many of the general risk factors for mental ill health, such as social exclusion and inequality, cannot be addressed by psychiatrists or clinicians. The same is true for the provision and maintenance of environments that promote positive well-being. A vast range of other specialists and institutions need to cooperate within a framework that allows shared means and agendas. This includes colleagues in primary health and social care, education, employment, housing and community sectors. As *Better Mental Health for All* recognises:

> A truly multidisciplinary and inter-sectoral approach must be adopted as no one discipline has all the knowledge or power to effect the required level of change.[71]

It is also imperative to put the voices of those with lived experience of mental ill health at the heart of legislative and policy responses, in line with the ethos of the CRPD.

66 Care Quality Commission, *Mental Health Act: The Rise in the Use of the MHA to Detain People in England* (Care Quality Commission 2018) 4, 23.

67 Göran Dahlgren and Margaret Whitehead, *Policies and Strategies to Promote Social Equity in Health* (Institute for Future Studies 1991).

68 Ibid 9.

69 Celso Arango et al, 'Preventive Strategies for Mental Health' (2018) 5(7) The Lancet Psychiatry 591–604.

70 Ibid.

71 *Better Mental Health for All* (14) 28.

Service users are demanding a stronger commitment to early intervention and preventive approaches, as well as greater respect for and promotion of the right to (mental) health.[72]

Within this new agenda there is a significant part for law to play, and thus a pivotal role for health law scholarship. Law's fundamental value as a source both of empowering authority and institutional restraint makes it an essential, if understated, part of the solution. As indicated in this section, this comes both through law's regulatory/coordination capacity and its expressivist functions. We approach this analysis from a perspective of wishing to see legal methods of empowerment being developed alongside more widely discussed efforts for legal reform in relation to reactive laws on mental health, disability and incapacity. As such, in the current paper, even whilst we draw from the advocacy and learning of the UN Committee on the Rights of Persons with Disabilities, we do not engage with questions of national legal reforms aimed at achieving equality before the law on the abolition of mental health laws (as these are framed, for example, within the UK).[73] This is not because of a perceived unimportance to these topics, but because we are aiming to generate a wider research agenda too. A key point of the neglect of the sorts of interventions and measures that we are arguing for is that their less 'profound' nature leads to their being missed; and thus also the great good that may be done. We would forcefully advocate (and are doing so in other areas of our work) for the legal rights of persons who suffer discrimination in the enjoyment of their legal capacity. Here, however, we aim to explore the place of law in providing conditions for good mental health and well-being; looking beyond reactive methods of intervention and the place of law in relation to this. To do this, we will now argue that recent developments in international human rights law provide a particularly useful framework to represent and advance the need and approach that we have identified and operationalise the field of public mental health law.

3.2 Public health, mental health and human rights: conflict or conflux?

Better Mental Health for All, as we have shown, reinforces a new mindset and the need to reconceptualise the relationships between health, mental health and public health. As the report makes clear, the time has come for us to 'act in an empowering way to combat inequalities and the powerlessness that can accompany them'.[74] We have explained how and why health law, broadly enough conceived, is an essential tool to work towards achieving those goals: law shapes and underpins the necessary socio-political infrastructures and provides mechanisms for assuring that necessary and proportionate health responsibilities are realised. In this section, we consider how a human rights framing specifically can motivate both practical and normative support for law as it impacts public mental health practice, policy and obligations. It is axiomatic that an environment that respects and protects basic civil, political, socio-economic and cultural rights is fundamental to mental health. Put conversely, neglect of such rights is neglect of duties concerning mental health and well-being. This logically suggests that a powerful alliance is found between human rights advocacy and mental health promotion, with compelling implications for the obligations of governmental and other socio-political actors.

72 See, for example, National Survivor User Network, 'Our Voice our Vision our Values' (Members' Manifesto 2017), see <www.nsun.org.uk/our-manifesto>; Hearing Voices Network, *The Mental Health Act: An Alternative Review* (Hearing Voices Network December 2018) <www.hearing-voices.org/news/alternative-mental-health-act-review>.

73 See Committee on the Rights of Persons with Disabilities, *General Comment No 1* (2014) (CRPD/C/GC/1 2014), especially paras 50–2.

74 Above (n 14) 11.

Many scholars, from across fields, have identified that human rights are universal norms which are powerful tools in advancing the rights of vulnerable persons and groups. Gostin et al argue that, unlike some ethical principles or standards, human rights 'are internationally recognized and globally accepted . . . and governments have agreed to be legally bound to upholding [them]'.[75] Moreover, by defining rights-holders, duty-holders and the nature of obligations, human rights frameworks 'allow a much clearer opportunity to establish accountability (typically of government) for the realization of rights and creates a range of mechanisms to hold governments accountable', as well as 'offering a framework for pro-active development of policies and programs such that health objectives can be operationalized in ways that are consistent with human rights'.[76]

Nevertheless, historically there has been scepticism about the relationship between public health and human rights.[77] By focusing predominantly on individuals and processes, human rights approaches may be viewed as conceptually and theoretically contrary to, or in tension with, the collective or population approaches that are central to public health.[78] Such a view might seem particularly sustainable within an English context, given that domestically justiciable human rights, enforceable against public authorities under the Human Rights Act 1998, are classically conceived as civil and political ('negative') rights. However, more recent developments in rights instruments, discourse and methodologies have witnessed a more nuanced and 'positive' approach, and a shift towards tackling wider health inequalities.[79] In the early days of public health ethics,[80] there were notable examples of human rights being used successfully: in particular, in relation to HIV.[81] Such examples prompted a move to:

> [R]ethink how population approaches to health can respond to public health crises based on inequalities and exclusion, and has led us to devise new ways to integrate human rights into public health.[82]

In accordance with this outlook, Paul Hunt, former UN Special Rapporteur for Health, argues that advancements in rights-based approaches since the turn of the new millennium have moved the focus away from processes and civil/political rights, to a more contextual and less individualised approach.[83] For some, 'greater attention has been brought to negative health outcomes, and the terrain of human rights increasingly

75 Lawrence O Gostin et al, *The Domains of Health Responsiveness – A Human Rights Analysis* (WHO Health and Human Rights Working Paper Series No 2 2003) 4.

76 Leslie London, 'What is a Human Rights Based Approach to Health and Does It Matter?' (2008) 10(1) Health and Human Rights 65–80, 68.

77 A notable example, given his more recent advocacy, is found in: Lawrence O Gostin, 'Public Health, Ethics, and Human Rights: A Tribute to the Late Jonathan Mann' (2001) 29 Journal of Law, Medicine and Ethics 121–30.

78 Cf Marcel Verweij and Angus Dawson, 'The Meaning of "Public" in "Public Health"' in Angus Dawson and Marcel Verweij (eds), *Ethics, Prevention, and Public Health* (Oxford University Press 2007).

79 Kumanan Rasanathan, Johanna Norenhag and Nicole Valentine, 'Realizing Human Rights-based Approaches for Action on the Social Determinants of Health' (2010) 12(2) Health and Human Rights 49–59, 49.

80 Nancy Kass, 'Public Health Ethics: From Foundations and Frameworks to Justice and Global Public Health' (2004) 32(2) Journal of Law, Medicine and Ethics 232–42.

81 Jonathan M Mann, 'Medicine and Public Health, Ethics and Human Rights' (1997) 27(3) Hastings Center Report 6–13.

82 London (n 76) 66.

83 Paul Hunt, 'The Health and Human Rights Movement: Progress and Obstacles' (2008) 15(5) Journal of Law and Medicine 714–24. See also WHO, *A Human Rights Approach to Health* (WHO 2010). See also Office for the High Commissioner for Human Rights, *CESCR General Comment No 14: The Right to the Highest Attainable Standard of Health (Art 12)* (Office for the High Commissioner for Human Rights 2000).

intersects with the social determinants of health'.[84] This more recent and gradual change in perspective in the context of public health and human rights is to be contrasted with the longer-standing and more highly discernible relationship between mental health and human rights. Gostin and Gable have described the symbiotic relationship between human rights and mental health, characterising them as 'mutually reinforcing', and both 'powerful, modern approaches to advancing human well-being'.[85] English mental health law has been heavily influenced and shaped by human rights over the last three decades. However, this may be represented as basing itself in the antagonism between individual rights and collective good that we have just suggested historically was seen to set human rights and public health apart. Human rights' historical links to mental health may be seen as obtaining in large part in protection of civil and political rights; individuals' 'negative' freedoms against undue state (or state-sanctioned) interference.

Amongst key examples to support this claim, consider that a successful challenge in the European Court of Human Rights resulted in key changes to procedural safeguards in the then Mental Health Bill, as it passed through Parliament in the early 1980s.[86] Or note that one of the first declarations of incompatibility under s 4 of the Human Rights Act related to a provision of the MHA.[87] That things should be framed thus is unsurprising: these legal challenges are rooted in the European Convention on Human Rights (ECHR), where conceptualisations of rights are, as indicated above, focused on individual and process-driven safeguards.[88] But does this mean that a *public* mental health approach would be bound to fail? We would argue not. Bartlett et al, in their book *Mental Disability and the European Convention on Human Rights*, describe how 'mental disability has come of age as a subject of concern under the ECHR', but these rights are 'only the starting point'.[89] There are clear signs, since the introduction of the CRPD, that human rights protection is now moving towards a broader conception of rights and positive entitlements in the context of mental impairment and disability.[90] As noted in para (y) of the CRPD's preamble:

> [A] comprehensive and integral international convention to promote and protect the rights and dignity of persons with disabilities will make a significant contribution to redressing the profound social disadvantage of persons with disabilities and promote their participation in civil, political, economic, social and cultural spheres with equal opportunities, in both developing and developed countries.

84 Rasanathan et al (n 79).

85 Ibid.

86 See *X v UK* (1982) 4 EHRR 188.

87 *JT v UK* [2000] ECHR 133.

88 See, for example, Genevra Richardson, 'The European Convention and Mental Health Law in England and Wales: Moving beyond Process?' (2005) 28 International Journal of Law and Psychiatry 127–39; Phil Fennell and Urfan Khaliq, 'Conflicting or Complementary Obligations? The UN Disability Rights Convention, the European Convention on Human Rights and English Law' (2011) 6 European Human Rights Law 662–74.

89 *International Studies in Human Rights*, vol 90 (Martinus Nijhoff 2007) 28.

90 See, for example, Peter Bartlett, 'The United Nations Convention on the Rights of Persons with Disabilities and Mental Health Law' (2012) 75(5) Modern Law Review 752–78; George Szmukler et al, 'Mental Health Law and the UN Convention on the Rights of Persons with Disabilities' (2014) 37 International Journal of Law and Psychiatry 245–52; Penny Weller, 'The Convention on the Rights of Persons with Disabilities and the Social Model of Health: New Perspectives' (2011) Journal of Mental Health Law 74–83; Jill Stavert, 'Mental Health, Community Care and Human Rights in Europe: Still an Incomplete Picture?' (2007) Journal of Mental Health Law 182–93.

Overall, the CRPD aims for the eradication of barriers for persons with disabilities to 'full and effective participation in society on an equal basis with others'.[91] Of necessity, this requires the implementation of 'positive' measures. Article 4(2) of the CRPD provides, furthermore, that: 'With regard to economic, social and cultural rights, each State Party undertakes to take measures to the maximum of its available resources . . . ' And Article 9, for example, enumerates specific obligations for provision of means to ensure accessibility to 'enable persons with disabilities to live independently and participate fully in all aspects of life'. In line with the wider developments in human rights discourse, the paradigm under the CRPD has shifted away from the medical model in mental health, to a social model founded on all persons as rights-holders.

As we move to such framings, with the consequent inclusion of social, economic and cultural claims, human rights frameworks represent a source of important levers to address health inequalities, promote positive well-being, and create healthier societies.[92] Our primary jurisdictional focus within this paper is England, but we might note that, in Scotland, human rights approaches framed by reference to the human right to health are gaining strong social and political purchase (including through NHS Health Scotland) in public health advocacy and agendas.[93] There are real opportunities to learn from the Scottish experience and harness it along with the potential of the CRPD. This would expose the potential for law to bind together ethical, public and mental health approaches and shift the focus to tackling mental ill health and health inequalities in way that is consistent with the position embraced by the current UN Special Rapporteur on Health.[94] His 2017 report on the right to health reinforces the need for a 'paradigm shift', moving away from biomedical and paternalistic approaches towards a rights-based and holistic approach to the care and governance of mental health:

> Population-based approaches to mental health promotion move health systems beyond individualized responses towards action on a range of structural barriers and inequalities (social determinants) that can negatively affect mental health.[95]

The report recognises, however, that population-level approaches do not work in isolation. Another critical strand of a human rights approach is recognising the need for empowerment and effective agency to address the conditions that create vulnerability.[96] It is essential for individuals and their families to be legally empowered and be able to hold governments to account. Thus, what we refer to as a 'holistic' approach is needed; an approach that combines individualist framing of rights with collective/public ones. And to be effective, as emphasised, these require sound and effective developments in law and policy.

91 UNCRPD, Article 1.

92 Paul Hunt and Gunilla Backman, 'Health Systems and the Right to the Highest Attainable Standard of Health' (2008) 10(1) Health and Human Rights 81–92, 81.

93 This is a very broad and ambitious agenda, where the right to health is directly related to social determinants theses, and leads to a focus across the life-course, and across personal, community, occupational and political sectors. By taking a human right to health approach, the advocacy seeks to assure standards in public policy that will effect change by direct reference to concepts of health and well-being. See <www.healthscotland.scot/health-inequalities/the-right-to-health>; see also <www.scottishhumanrights.com>.

94 *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* A/HRC/35/21 (March 2017).

95 Ibid 16.

96 Rasanathan et al (n 79) 68.

3.3 The dementia 'epidemic': a case study

Dementia provides a pertinent example to demonstrate the essential place of law and the soundness of a public mental health approach that is framed by reference to human rights. It exposes the need to move beyond responsive interventions and 'negative' individual rights, and beyond the narrow medical law paradigms and conceptual antagonisms and binaries, to recognise the value of proactive and preventive approaches.

Dementia is a leading cause of death in the UK.[97] The Alzheimer's Society suggests that 850,000 people are currently living with dementia in this country, and that number is projected to increase to 2 million by 2050.[98] Globally, the number of people living with dementia will increase from 50 million in 2018 to 152 million in 2050 – an increase of 204 per cent.[99] The WHO estimates that the global number of deaths from dementia will increase by 40 per cent from 2015 to 2030.[100] These figures suggest that we are on the verge of a global dementia epidemic.

Dementia can be described as:

> [A] clinical state where a decline in cognitive function, such as loss of memory, judgment, language, complex motor skills and other intellectual functions, leads to a decline in independent daily function.[101]

It is a recognised psychiatric disorder, included in both the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders IV* (DSM-IV-TR), and the WHO *International Classification of Disease* (ICD-10) criteria.[102] Dementia results in a progressive decline of multiple areas of function, including memory, reasoning and communication skills. This decline may be accompanied by psychological and behavioural symptoms, such as depression and psychosis. Persons with dementia may, at varying stages throughout the progression of the condition, require treatment that must be authorised under mental health or capacity legislation, due to the nature of dementia and its impact on cognitive function and decision-making ability.

The causes of dementia are multifaceted. Many do stem from genetic factors, but it is increasingly recognised that 'lifestyle' and environment provide major risk factors.[103] Alzheimer's Research UK data suggest that 40 per cent of people would adopt a healthier lifestyle to reduce their risk of dementia.[104] Several studies have suggested a link between mentally-stimulating leisure activities and a reduced risk of dementia.[105] Indeed, National Institute for Health and Care Excellence (NICE) guidance to healthcare providers in England explicitly recognises that individuals can adopt approaches in mid-life, such as reducing alcohol consumption, stopping smoking, being more active, and adopting a healthier diet, in order to delay or prevent the onset of dementia and disability in later

97 See <www.dementiastatistics.org/statistics-about-dementia/prevalence>.

98 Ibid.

99 Ibid.

100 See <www.who.int/news-room/fact-sheets/detail/dementia>.

101 Elissa L Ash, 'What is Dementia?' in Charles Foster, Jonathan Herring and Israel Doron (eds), *The Law and Ethics of Dementia* (Hart 2018).

102 (APA 2000) and (WHO 1992).

103 Amos D Korczyn and Veronika Vakhapova, 'Can Dementia be Prevented?' in Foster at al (n 101).

104 See <www.dementiastatistics.org/statistics/attitudes-to-dementia>.

105 See, for example, Hui-Xin Wang, Weili Xu and Jin-Jing Pei, 'Leisure Activities, Cognition and Dementia' (2012) 1822(3) Biochimica et Biophyscia Acta (BBA) – Molecular Basis of Disease, 482–91; Joe Verghese et al, 'Leisure Activities and the Risk of Dementia in the Elderly' (2003) 348 New England Journal of Medicine 2508–16; Colette Fabrigoule et al, 'Social and Leisure Activities and Risk of Dementia: A Prospective Longitudinal Study' (1995) 43(5) Journal of the American Geriatrics Society 485–90.

life.[106] And Public Health England's five-year strategy in 2014 identified reducing the risk, incidence and prevalence of dementia in people aged 65–75 as one of its key priorities.[107]

In accordance with the discussion above in section 3.1, public perceptions of dementia are a significant contributing factor for effective management and treatment.[108] This is referred to as 'mental health literacy',[109] and various studies from across the globe have demonstrated the correlation between public/lay beliefs concerning dementia, stereotyping and help-seeking.[110] There is evidence to suggest that, despite increased awareness, many people still have relatively poor levels of knowledge about the causes, symptoms and treatments.[111] Furthermore, people with the Alzheimer's disease 'label' report that they experience increased stigma.[112]

A report by the WHO and Alzheimer's International, entitled *Dementia: A Public Health Priority*,[113] recognises that 'although dementia mainly affects older people, it is not a normal part of ageing', as it is a condition which develops, and is caused by several different factors and illnesses of the brain. Carers, relatives and persons with dementia have unique insights into their condition and life, and should be central to formulating policies, laws, and decision-making and services that relate to them.[114] However, evidence suggests that many people with dementia either do not receive basic care to which they are entitled or are subjected to restraint and highly coercive care practices.[115] As the WHO states:

> It is widely recognized that people with dementia are frequently denied the basic rights and freedoms available to others. In many countries physical and chemical restraints are used extensively in aged-care facilities and acute-care settings, even when regulations are in place to uphold the rights of people to freedom and choice. The majority of people who are restrained have cognitive impairment.[116]

This clearly suggests a need for an appropriate and supportive legislative environment, based on human rights standards, as an important tool to promote the highest levels of

106 NICE Guideline [NG16], *Dementia, Disability and Frailty in Later Life – Mid-life Approaches to Delay or Prevent Onset* (NICE October 2015).

107 Public Health England, *From Evidence into Action: Opportunities to Protect and Improve the Nation's Health* (Public Health England, 23 October 2014).

108 Perla Werner, 'Common Perceptions of Dementia' in Foster et al (n 101).

109 Anthony F Jorm et al, '"Mental Health Literacy": A Survey of the Public's Ability to Recognise Mental Disorders and their Beliefs about the Effectiveness of Treatment' (1997) 166 Medical Journal of Australia 182–6.

110 See, for example, W J Tan et al, 'The Lay Public's Understanding and Perception of Dementia in a Developing Asian Nation' (2012) 2 Dementia and Other Geriatric Cognitive Disorders 433–44; V G Wadley and W E Haley, 'Diagnostic Attributions Versus Labelling: Impact of Alzheimer's Disease and Major Depression Diagnoses on Emotions, Beliefs, and Helping Intentions of Family Members' (2001) 56(4) Journals of Gerontology 244–52; Monica Cations et al, 'What Does the General Public Understand about Prevention and Treatment of Dementia? A Systematic Review of Population Based Surveys' (2018) 13(4) PLoS ONE: see <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0196085>.

111 John M Hudson et al, 'Beliefs about Alzheimer's Disease in Britain'(2012) 16(7) Aging and Mental Health 828–35.

112 Wadley and Haley (n 110); Naheed Mukadam and Gill Livingston, 'Reducing the Stigma Associated with Dementia: Approaches and Goals,' (2012) 8 Aging Health 377–86.

113 (2012) see <http://apps.who.int/iris/bitstream/handle/10665/75263/9789241564458_eng.pdf;jsessionid=6ACB2D62C2CDCE3A8567F0B0F68DAA49?sequence=1>.

114 Ibid 4.

115 See (n 100).

116 WHO/Alzheimer's International (n 4).

care and service provision for people with dementia. In addition, we need to look at how appropriately law serves the needs of persons with dementia outside of institutional and acute-care situations.

Focusing on England, the government has attempted to address some of the deficits identified. At a policy level, the 2010–2015 Coalition government developed a dementia strategy with the aim of providing a framework for addressing health inequalities relating to dementia and dementia services.[117] This was followed in 2015 by then Prime Minister David Cameron's *Challenge on Dementia*, with a vision for targeted action and implementation by 2020.[118] The plan included training for NHS staff on dementia, meaningful care for everyone diagnosed with dementia, and equal access to diagnosis. The current Conservative government announced in May 2018 that it is reviewing the *Challenge on Dementia* plan to reflect on progress and what further action is needed to meet the objectives,[119] as we are still a long way from realising many of the goals set out in the 2020 challenge. Successive governments' dementia policies have faced some criticism for not going far enough,[120] and there are further concerns that dementia has not been included in the recent NHS spending priorities.[121]

Law is not being used to its full potential here. Existing legal responses to provide treatment and care in England are centred primarily on the MHA and Mental Capacity Act 2005 (MCA), which are highly responsive, protective and coercive; albeit, as noted above, the Care Act regulates social care in a community, as opposed to a healthcare, setting. The MHA, as explained above, is reactive. It is deeply paternalistic and takes little account of the views of the individual patient or family/carers.[122] Notwithstanding its empowering aims and ethos, there are significant challenges to applying the MCA's determination of capacity and welfare approach to people with dementia. For instance, there are tensions in disentangling persons' past *and* present wishes (as required in application of the 'best interests' standard under s 4), and the capacity test is individualised – 'decision-specific' – and thereby focused heavily on immediate processes of cognition.[123] It provides binary distinctions that are rooted in functional mental competences, and which are not suited to decision-making of persons with conditions such as dementia. As such, Mary Donnelly has argued that 'the law must address issues raised by dementia on their own terms and not simply as a subset of a broader capacity/incapacity agenda'.[124] In several respects, current regulatory frameworks in England are crude and inappropriate for individuals with dementia.[125] They focus on

117 *Living Well with Dementia: A National Dementia Strategy* (Department of Health 2009) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/168220/dh_094051.pdf>.

118 *Prime Minister's Challenge on Dementia – Delivering Major Improvements in Dementia Care and Research by 2015* (Department of Health March 2012).

119 See further House of Commons Library, *Dementia: Policy, Services and Statistics* (Briefing Paper 07007 10 July 2018) 3.

120 See, for example, Ian Greaves and David Jolley, 'National Dementia Strategy: Well Intentioned – But How Well Founded and How Well Directed?' (2010) 60(572) British Journal of General Practice 193–8; 'Dementia Strategy Criticised by Alzheimer's Trust' *The Guardian* (London, 3 February 2009).

121 'Dementia is Conspicuously Absent from New NHS Priorities' (*Alzheimer's Research UK Blog*, 31 July 2018) <www.dementiablog.org/dementia-is-conspicuously-absent-from-new-nhs-priorities>.

122 See, for example, *Independent Review* (n 53) 26–9.

123 See, for example, Jonathan Herring, 'Losing It? Losing What? The Law and Dementia' (2009) 21(1) Child and Family Law Quarterly 3–29.

124 Mary Donnelly, 'A Legal Overview' in Foster et al (n 101) 279.

125 Ibid.

reactive biomedical models and ignore social/external factors and determinants, as well as the need to promote individual agency within a broader, more relational 'community' framework.[126] A broader-reaching network of supports and interventions that respect and honour persons' rights, as explained above, is what is required.

Investing in evidence-based public health measures and associated regulatory responses could have a measurable impact, as a recent *Lancet* Commission report on dementia in England has highlighted.[127] It is imperative to act now in order to transform society and 'vastly improve living and dying'[128] for individuals with dementia. As the WHO and Alzheimer's International recommend, we must develop responses across sectors and disciplines which maximise agency, as well as prevention and protection for individuals, families and communities:

> It is essential that rights are recognized, respected and protected in order to empower people with dementia, those who support them and the community as a whole. An appropriate and supportive legislative environment is also required to ensure the highest quality of service provision to people with dementia and their caregivers.[129]

Such recognition of the need for a supportive legislative environment accords with our analysis in this paper. In Part 2, we demonstrated the inadequacies of the over-atomised individual of medical law, and indeed general conceptualisation around the figure of 'the (autonomous) patient'. In explaining these inadequacies, we noted the challenges rooted in relationality of persons, and the need to move within rights framings to more robust and realisable 'positive' rights. The consequent discussions in section 3, in particular on the need for real and practicable effect being given to the protection of socio-economic rights (as re-enforced through the CRPD), have shown why law is essential to providing the conditions for people's enjoyment of good mental health: political commitment is necessary, but alone demonstrably inadequate.

Legal frameworks that are truly empowering require to be able, in practice, actually to accommodate the nature of the persons that they govern: this is not just about conceptualising a 'patient' and will not adequately be provided without tests and standards that are fitting given the impact and effect of dementias. They equally must be able to accommodate the relevant social concerns, allowing for informal as well as formal provision of care, economic realities, and the roles and responsibilities of myriad public, private and community actors. The task is vast, and ambitious. If health law is to make the contributions that are required of it, it needs to match that ambition.

4 Conclusions: public mental health law and the future of health law scholarship

Health law as a field of study and of practice has grown enormously over the past decades. Looking towards the coming decades, we see necessary value in securing this expansion. Health lawyers are crucial partners in work across sectors, and in securing legal support and constraint on questions of policy, practice and personal health and well-being. It is essential, as explained in this paper, that we move beyond paradigms that emerged in *medical* law, or even *healthcare* law. We are interested in actors across society, and

126 Ibid. Cf also Camillia Kong, *Mental Capacity in Relationship: Decision-making, Dialogue, and Autonomy* (Cambridge University Press 2017).

127 Gill Livingston et al, 'Dementia Prevention, Intervention and Care' (2017) 390 The Lancet Commissions 2673–4. See also Vikram Patel et al, 'The Lancet Commission on Global Mental Health and Sustainable Development' (2018) 392; 10157 The Lancet 1553–98.

128 Ibid 2673.

129 WHO/Alzheimer's International (n 4).

empowering concepts of law that do not just protect narrow, 'negative' rights. We need to grasp legal levers that support positive claims to socio-economic goods. And in so doing, we need frameworks that provide normative as well as practical authority (and security) to such claims. Health law must be considered as more than holding strengths as a *reactive* or *defensive* force.

As an important component of this agenda, we have in this paper presented an account of *public mental health law*; an area whose time is now and which requires active, positive engagement between law and other fields. The vision that we have advocated for underscores the crucial role for human rights for academic and activist activities. We are witnessing a global crisis in mental health. Traditional responsive measures are not effective in combating it. We need to reinvigorate the debate, move to a new way of thinking, and put prevention of ill health and promotion of well-being at the heart of our response. Public mental health law will assist us to move towards that goal. And human rights can provide us with a universal and workable analytical framework to do so. As Gostin and Gable argue:

> The various systems for the protection of human rights present the opportunity to provide tangible human rights protection for persons with mental disabilities at both the individual and population level . . . Human rights are not a panacea for persons with mental disabilities. Nevertheless, more focused attention on the civil and political, as well as social and economic rights of this group is vitally important.[130]

Discourse around the right to health and ECHR rights will be crucial motivating factors. And the CRPD undoubtedly has a valuable role to play in shifting the paradigm and combating the underlying determinants of mental disability and ill health. The time is ripe for relevant stakeholders to explore the evidence base and prioritise mental health promotion and illness prevention. As the WHO has recognised in a report on *Prevention of Mental Disorders: Effective Interventions and Policy Options*:

> Limitations on the basic human rights of vulnerable individuals and communities may act as powerful determinants of mental disorders. Hence it is not surprising that many of the effective preventive measures are harmonious with principles of social equity, equal opportunity and care of the most vulnerable groups in society. [131]

The science of public mental health is well understood; the art, less so.[132] We have explained here the foundations of law's contribution to debate and practice. This is an ambitious research agenda, and one whose practical importance cannot be overstated.

130 Lawrence O Gostin and Lance Gable, 'The Human Rights of Persons with Mental Disabilities: A Global Perspective on the Application of Human Rights Principles to Mental Health' (2004) 63 Maryland Law Review 20.

131 (WHO 2004).

132 Cf John Coggon, 'Law' in Sridhar Venkatapuram and Jo Bibby (eds), *A Recipe for Action: Using Wider Evidence for a Healthier UK: A Collection of Essays Exploring Why We Need Trans-disciplinary Approaches to Improve the Public's Health* (Health Foundation 2018).

NILQ 70(1): 53–75

Centralisation of procurement and supply chain management in the English NHS: some governance and compliance challenges

Dr Albert Sanchez-Graells*

Centre for Health, Law, and Society, University of Bristol Law School

Abstract

This paper provides a critical analysis of the new operating model for NHS procurement that is being implemented in 2018/2019 (the NOM). The government expects NOM to generate significant savings through centralised procurement and strategic supply chain management, which would then be dedicated to frontline NHS healthcare services through newly devised 'sustainability and transformation plans' (STPs). The paper stresses that the NOM rests on a complex network of contracts resulting in a layer of contractualised governance that obscures its architecture and decision-making processes. It maps the changes that the NOM introduces in the operation and governance of the NHS supply chain and identifies key challenges in ensuring that the NOM is subjected to adequate oversight and accountability mechanisms, in particular from the perspective of public procurement and competition law. The paper advocates for the location of all NOM relationships on the NHS Business Services Authority, especially to facilitate judicial review.

Keywords: NHS; procurement; centralisation; supply chain; efficiency; savings; service delivery; governance.

JEL codes: H57; H75; I18; K23; K49.

Introduction

Attaining public health goals and satisfying a population's need for healthcare services requires a complex mix of governance and delivery structures. States have a wide range of choices in the design of healthcare governance and delivery systems along a continuum that goes from pure in-house public service management, delivery and governance, to purely privatised delivery, outsourced management and light-touch public oversight of healthcare services. In almost any of these models – with the only exception being completely self-sufficient systems (which remain a theoretical possibility) – the delivery of public services requires the acquisition of goods and equipment from the market through public procurement. In other words, states do not tend to manufacture the large and diverse

* Reader in Economic Law and Member of the Centre for Health, Law, and Society at the University of Bristol Law School; Former Member of the European Commission Stakeholder Expert Group on Public Procurement (2015–2018). All opinions are my own and do not reflect those of the institutions to which I am affiliated. I am grateful to Catherine Wolfenden (Osborne Clarke), Dr Jule Mulder, Professor Keith Syrett, Professor John Coggon and two anonymous reviewers for comments to previous drafts. The standard disclaimer applies. Further comments welcome: a.sanchez-graells@bristol.ac.uk.

Note: all websites last accessed on 4 December 2018.

volumes of healthcare equipment and consumables (such as diagnostic equipment, test chemicals or surgical materials, but also simpler products, such as hospital food) that they require, but rather buy them from the market, and generally from private companies.[1] In that regard, states also have policy choices between, for example, central procurement by a public authority, decentralised procurement by hospitals, either of those types of procurement by private bodies, or an entirely private contracting system subject to public (i.e. statutory) obligations.

From a governance perspective, each of these models creates a different balance of risks and benefits, and mixed systems (which are by and large the majority in developed economies) are exposed to governance needs and risks that not only involve the public authorities, bodies and institutions tasked with the delivery of healthcare services, but also private providers. As evidenced in recent UK scandals – such as Carillion, Capita, Southern Cross or G4S[2] – governance vulnerabilities derived from private involvement are increasingly seen as a major flaw of mixed systems. Contractualised and privatised systems are also exposed to increased litigation risks, in particular concerning the tendering of new contracts – as also evidenced in recent UK experiences, such as the DHL challenge to the implementation of the new healthcare procurement system discussed in this paper.[3] All of this is prompting a reconsideration of the system architecture for the delivery of public services – both in healthcare and in other areas. More generally, the choice between different system design options is clearly influenced by the underlying economic model of a given state's constitutional settlement, social preferences, capability and funding constraints, and a number of other factors – amongst which free trade agreements and liberalisation efforts are gaining prominence. Economic efficiency in the expenditure of public funds for the provision of healthcare services is an increasingly important consideration or driver in the (re)design of healthcare systems. This has become particularly acute in the post-2008 financial crisis austerity-driven world.

1 This may be particularly obvious (and sometimes problematic) concerning medicines and other pharmaceutical products. However, these are not covered by the discussion in this paper, as their acquisition is subjected to a separate set of statutory and contractual mechanisms. For background, see NHS Specialist Pharmacy Service, *An Overview of NHS Procurement of Medicines and Pharmaceutical Products and Services for Acute Care in the United Kingdom* (22 October 2018) <www.sps.nhs.uk/articles/an-overview-of-nhs-procurement-of-medicines-and-pharmaceutical-products-and-services-for-acute-care-in-the-united-kingdom>.

2 Carillion may have been the most prominent of recent scandals, as widely evidenced in the report by the Business, Energy and Industrial Strategy and Work and Pensions Committees, *Carillion* (HC 2017–19 769). However, similar vulnerabilities of overly reliant privatised and contractualised systems are also evident in the difficulties resulting from Capita's mismanagement of primary care support services; see NAO, *NHS England's Management of the Primary Care Support Services Contract with Capita* (HC 2017–19 632). The evidence piles up in other examples concerning Southern Cross's mismanagement of nursing and care homes – see e.g. Care Quality Commission, *Report on the Stability of the Care Market and Market Oversight in England* (February 2014) <www.cqc.org.uk/sites/default/files/201402-market-stability-report.pdf> – or the repeated failings of G4S in the area of security services and prison management, which most recently required a governmental step-in: see Jessica Elgot, 'MoJ Seizes Control of Birmingham Prison from G4S' *The Guardian* (London, 20 August 2018) <www.theguardian.com/business/2018/aug/20/moj-seizes-control-of-birmingham-prison-from-g4s>.

3 This is discussed in more detail below. Suffice it to indicate here that, as the incumbent provider, DHL challenged the award of a logistics contract to new entrant Unipart, and this resulted in significant delays in the implementation of the new operating model for NHS procurement. See *DHL Supply Chain Ltd v Secretary of State for Health and Social Care* [2018] EWHC 2213 (TCC) (17 August 2018) and Nick Carding, 'DHSC awards £730m NHS Logistics Contract Following High Court Victory' (*Health Service Journal*, 5 September 2018) <www.hsj.co.uk/finance-and-efficiency/dhsc-awards-730m-nhs-logistics-contract-following-high-court-victory/7023285.article>.

Indeed, the celebrations of the 70th anniversary of the English NHS arrived in 2018 after a decade of funding cuts and austerity policies, coupled with constant experimentation in the re-regulation of the market-based governance mechanisms that had been employed since the creation of the 'NHS internal market' in the 1990s. The most recent effort to re-regulate the governance of the NHS concentrates on the implementation of rather ambitious sustainability and transformation plans (STPs), which could be seen as the first step towards putting an end to the NHS internal market and reconstructing mechanisms of public governance and oversight, albeit through the conduit of newly created 'integrated care systems'.[4] The purpose of this paper is not to assess the STPs, but rather to concentrate on flanking policies aimed at liberating public funds already dedicated to healthcare services that can then fund the ambitions of the STPs (or whichever NHS re-regulation strategy replaces them in the future). In particular, this paper concentrates on recent efforts to achieve savings in the expenditure of NHS funds in the acquisition of the medical equipment, consumables and services required for the provision of healthcare services. As one of the biggest publicly funded healthcare systems in the world, the NHS has a non-pay expenditure of approximately £27 billion a year, of which nearly £6 billion is spent on goods (everyday hospital consumables, high-cost devices, capital equipment and common goods). Achieving savings, even relatively small ones, on such a large volume of expenditure could liberate significant funds that could be reallocated to frontline delivery.

The most recent wave of efficiency-seeking re-regulation of NHS procurement through the so-called Procurement Transformation Plan (PTP), and the resulting New Operating Model (NOM), pivots around the exercise of public buying power through aggregation of demand and, in particular, through the centralisation of procurement and the streamlining of supply chain management. Interestingly, these strategies are channelled through entirely privatised (or contractualised) structures that take the procurement function away from NHS trusts and grants significant decision-making powers to non-statutory bodies and private entities – which creates a high level of opacity of both the architecture and the governance of NHS procurement under the NOM. While theoretically capable of delivering significant cost efficiencies, these reforms also create significant implementation and governance challenges. This could shield important decision-making processes from adequate mechanisms of control, in particular through judicial review, and result in a circumvention or watering-down of significant constraints, such as those derived from public procurement and competition law.

After providing an overview of the recent reforms of the NHS market-based governance through the STPs to contextualise the discussion, this paper critically analyses how the NHS is trying to take advantage of centralised procurement and supply chain management strategies through the NOM; and how this strategy triggers governance and legal compliance challenges, in particular from the perspective of public procurement and competition law.

Abandoning the 'NHS internal market'? Recent NHS governance reforms

In England, economic efficiency, value for money or savings in healthcare expenditure (however one wants to label it) has been the main driving factor behind the constant transformation of the governance and public/private boundaries of the NHS over the last three decades. These reforms have sought to rely on market-based governance

4 Note that these were initially labelled as 'accountable care systems', and they may appear as such in NHS documents cited in this paper. For more details, see NHS, 'Integrated Care Systems' (undated) <www.england.nhs.uk/integratedcare/integrated-care-systems>.

structures to unlock economic efficiency and high-powered incentives for the generation of ever-increasing savings in healthcare expenditure. This has taken place in different waves, starting with the creation of the 'NHS internal market' on 1 April 1991.[5] Indeed, since the 1990s, in England, the activities of the NHS have been characterised by a rather distinctive purchaser–provider split whereby some branches of the NHS act as purchasers or commissioners of healthcare services (currently, clinical commissioning groups, or CCGs), while other branches of the NHS (trusts and foundation trusts) act as providers of healthcare services and compete with private providers in some markets. The commissioning of services within the NHS internal market is subject to special rules that seek to further the patients' interest.[6] The activities of these entities in such quasi-markets for healthcare services are overseen by NHS Improvement as sector regulator.

The purchaser–provider split policy was introduced with the aim of creating an 'NHS internal market' to generate competition-based incentives for the improvement of service delivery and cost management.[7] However, the system has been permanently evolving (or in a 'continuous revolution'),[8] and this has both created increased scope for public–private competition[9] and notable difficulties in keeping pace with the successive waves of NHS re-regulation. Most recently, government policy has shifted towards a roll-back or undoing of the NHS internal market.[10] Since the adoption in 2014 of the *Five Years Forward View* for the NHS in England,[11] the system has been progressively reoriented. Current reforms are geared towards experimentation with the so-called STPs, which aim to suppress the purchaser–provider split and bring about integrated funding and delivery for a given geographical population through integrated care systems.[12]

However, important elements of the STP strategy are still unclear and there are open questions concerning its feasibility and/or desirability.[13] The National Audit Office (NAO) has already warned that the 'partnerships' effectiveness varies and their tight financial positions make it difficult for them to shift focus from short-term day-to-day pressures to delivering transformation of services', which led it to estimate that the

5 Ray Robinson, 'The Impact of the NHS Reforms 1991–1995: A Review of Research Evidence' (1996) 18(3) Journal of Public Health Medicine 337.

6 For discussion, see Albert Sanchez-Graells, 'New Rules for Health Care Procurement in the UK. A Critical Assessment from the Perspective of EU Economic Law' (2015) 24(1) Public Procurement Law Review 16.

7 For discussion, see Barbara Ann Allen, Elizabeth Wade and Helen Dickinson, 'Bridging the Divide – Commercial Procurement and Supply Chain Management: Are There Lessons for Health Care Commissioning in England?' (2009) 9 Journal of Public Procurement 505.

8 Alan Maynard, in 'Should the NHS Abolish the Purchaser–Provider Split?' (*British Medical Journal*, 12 July 2016) <https://doi.org/10.1136/bmj.i3825>.

9 Okeoghene Odudu, 'Competition Law and the National Health Service' (*Competition Bulletin*, 8 October 2012) <https://competitionbulletin.com/2012/10/08/competition-law-and-the-national-health-service>; David J Hunter, 'Does the NHS still Reside in a Grey Area for EU Competition Law?' (*UKiCE* blog, 6 April 2016) <http://ukandeu.ac.uk/does-the-nhs-still-reside-in-a-grey-area-for-eu-competition-law>.

10 'Is this the End of the NHS's Internal Market?' (*Economist*, 2 November 2017) <www.economist.com/britain/2017/11/02/is-this-the-end-of-the-nhss-internal-market>.

11 NHS England, 'NHS Five Year Forward View' (22 October 2014) <www.england.nhs.uk/publication/nhs-five-year-forward-view>.

12 This has not changed after the adoption of the NHS, see <www.longtermplan.nhs.uk>. For discussion on current STP implementation, see Public Accounts Committee, *Oral Evidence: Integrated Health and Social Care* (HC 2016–17 959) Q93. For discussion, see Allyson Pollock and Peter Roderick, 'Why We should be Concerned about Accountable Care Organisations in England's NHS' (*British Medical Journal*, 30 January 2018) <https://doi.org/10.1136/bmj.k343>.

13 David Hare, 'The End of the Purchaser/Provider Split?' (*NHS Confederation*, 14 March 2017) <www.nhsconfed.org/blog/2017/03/the-end-of-the-purchaser-provider-split>.

implementation of STPs' plans would require £10 billion of extra capital.[14] This issue had significant salience in the 2017 general election, with both the Conservative[15] and the Labour[16] manifestos pledging more funding for the NHS and alluding to a change of system. Despite renewed pledges for additional NHS funding made by the current Conservative government on the occasion of the NHS's 70th anniversary[17] – and even if there was a change of government and Labour implemented its own view for the future of the NHS[18] – the transformation or abandonment of the NHS internal market will require further additional funding.

Seeking savings to support the transformation: NHS procurement in the spotlight

At this juncture, it is worth stressing that, regardless of the way in which the NHS is internally managed – i.e. with or without the NHS internal market – the provision of public healthcare services requires and will continue to require the acquisition of supplies and services from the market. That is, even in the absence of the NHS internal market, the provision of healthcare services by the NHS will continue to require an interaction with the (broader/external) market through the acquisition of goods and services. Indeed, NHS providers do not produce all equipment, consumables and services needed for the provision of healthcare to the general population and they will continue buying them from the market in the future. Therefore, 'doing more with less', or seeking savings in *NHS procurement* seems one way (or the only way, if further savings in workforce are no longer sought)[19] of freeing up additional funds for the transformation of the NHS without (significantly) increasing overall healthcare expenditure. Put simply, seeking 'more bang for your pound' becomes one (or the) main goal in NHS procurement governance.

This realisation materialised in a particularly acute manner in 2012, when the Department of Health and Social Care identified scope for the NHS to save at least £1.2 billion through improved NHS procurement[20] – which doubled the previous estimate of £500 million by the NAO,[21] and would have required NHS trusts to find over £1.5 billion of procurement efficiencies over the three years following the 2013 NHS England

14 NAO, *Sustainability and Transformation in the NHS* (HC 2017–19 719).

15 Conservative Unionist Party Manifesto 2017 <https://s3.eu-west-2.amazonaws.com/conservative-party-manifestos/Forward+Together+-+Our+Plan+for+a+Stronger+Britain+and+a+More+Prosperous....pdf>. The relevant pledge was to 'consult and make the necessary legislative changes. This includes the NHS's own internal market, which can fail to act in the interests of patients and creates costly bureaucracy. So we will review [its] operation . . . and, in time for . . . the 2018 financial year, we will make non-legislative changes to remove barriers to the integration of care' (at 67).

16 Labour Party Manifesto 2017 <https://labour.org.uk/wp-content/uploads/2017/10/labour-manifesto-2017.pdf>. The relevant pledge was to 'reverse privatisation of our NHS and return our health service into expert public control [including the] repeal [of] the Health and Social Care Act . . . and [making] the NHS the preferred provider' (69).

17 Denis Campbell, 'Theresa May Pledges to Accelerate NHS Long-term Funding Plan' *The Guardian* (London, 27 March 2018) <www.theguardian.com/society/2018/mar/27/theresa-may-pledges-to-accelerate-nhs-long-term-funding-plan>.

18 Jessica Elgot, 'Labour Consults on Plan for Major NHS Restructuring' *The Guardian* (London, 2 June 2018) <www.theguardian.com/society/2018/jun/02/labour-consults-on-plan-for-major-nhs-restructuring>.

19 Haroon Siddique, 'NHS to Receive £487m Technology Boost. Matt Hancock Lists Top Three Priorities as Tech, Workforce and Illness Prevention' *The Guardian* (London, 20 July 2018) <www.theguardian.com/society/2018/jul/20/nhs-to-receive-487m-technology-boost-matt-hancock>.

20 Department of Health and Social Care, 'NHS Procurement: Raising our Game' (28 May 2012) <www.gov.uk/government/publications/nhs-procurement-raising-our-game>.

21 NAO, *The Procurement of Consumables by NHS Acute and Foundation Trusts* (HC 2010–11 705).

Procurement Development Programme.[22] Even if of a smaller magnitude, the potential for significant savings in NHS procurement was later confirmed in 2016 by the Carter Review,[23] which estimated potential NHS procurement savings resulting from reduced variation across NHS trusts of at least £700 million.

All of these studies and estimates pointed at the potential economic savings derived from a more homogeneous, streamlined selection of supplies and suppliers to the NHS (i.e. reduced variation) and a more strategic exercise of NHS buying and negotiating power vis-à-vis its main suppliers (which was expected to lead to cost reductions and/or increased quality, depending on the relevant goods and services). On the whole, the realisation that there were (and still are) efficiencies to be had in NHS procurement resulted in the launch of the PTP and its current goal for the NHS to deliver £700 million in savings from improving procurement by the end of the financial year 2020/2021,[24] reaching £2.4 billion savings delivered by the end of 2022/2023,[25] and for the NOM to result in end-state annual savings of £615 million in real terms from 2022/2023 onwards.[26] These estimates and expectations of savings need to be taken with appropriate caution, as other complex NHS transformation programmes have resulted in significant problems that limited or wiped out any expected efficiencies.[27] Government assessments in this area have often focused on the demand-side and assumed that NHS bargaining power is infinite, so that it is just a matter of applying it better. However, it is clear that (at least) in some areas there will also be supplier bargaining power, and efforts by the NHS to achieve lower prices (on average) will be resisted by suppliers. Thus, these estimates and projections need to be taken with a pinch of salt. However, the purpose of this paper is not to challenge these savings estimates, but rather to critically assess the legality and governability of the structures that are being put in place to unlock them.

It is thus worth zooming in on the fact that the Department of Health and Social Care expects the NHS to achieve these savings through *procurement centralisation and a more strategic supply chain management*.[28] This is not a new goal, but rather a revamp of a strategy that already underpinned the creation in 2005 of the NHS Business Services Authority – an

22 Department of Health/NHS England, 'Better Procurement, Better Value, Better Care: A Procurement Development Programme for the NHS' (5 August 2013) <www.gov.uk/government/publications/improving-procurement-in-the-nhs>.

23 Lord Carter of Coles, *Independent Report for the Department of Health on Operational Productivity and Performance in English NHS Acute Hospitals: Unwarranted Variations* (February 2016) <www.gov.uk/government/publications/productivity-in-nhs-hospitals>. See also Will Green, 'Procurement Can Deliver £1 billion of NHS Savings a Year, says Lord Carter' (*Supply Management*, 11 June 2015) <www.cips.org/supply-management/news/2015/june/procurement-can-deliver-1-billion-of-nhs-savings-a-year-says-lord-carter>.

24 This is a rather ambitious goal, the feasibility of which has been doubted. See e.g. Richard McIntosh, 'The Carter Report – Can NHS Procurement Transformation be Accelerated?' (*Health Service Journal*, 7 March 2016) <www.hsj.co.uk/comment/the-carter-report--can-nhs-procurement-transformation-be-accelerated/7003033.article>.

25 NHS Supply Chain, 'SCCL News: Supply Chain Coordination Limited of NHS Supply Chain' (2018) <www.supplychain.nhs.uk/sccl>.

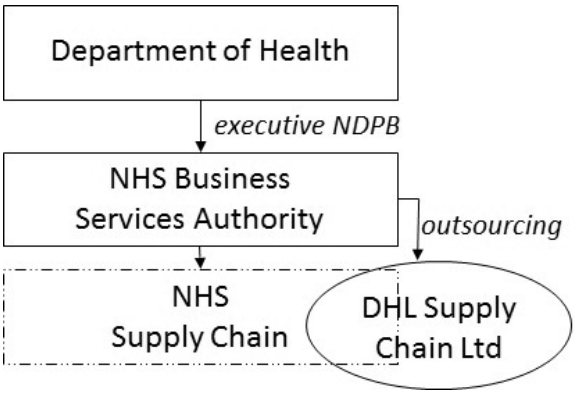
26 NHS Procurement Transformation Programme, 'Future Operating Model (FOM) Handbook' (Issue 1: October 2017) (hereinafter, the 'FOM Handbook') <www.supplychain.nhs.uk/icc/~/media/Files/News/FOM_HANDBOOK%20Oct%202017.ashx> .

27 See NAO (n 2).

28 For an overview of the evolution of NHS procurement structures up to 2015, see Joe Sanderson et al, 'Towards a Framework for Enhancing Procurement and Supply Chain Management Practice in the NHS: Lessons for Managers and Clinicians from a Synthesis of the Theoretical and Empirical Literature' (2015) 18 Health Services and Delivery Research 3 <www.ncbi.nlm.nih.gov/books/NBK286079>.

executive non-departmental public body (NDPB) of the Department of Health and Social Care that provides some support services to the NHS in England and Wales.[29] At the same time, there was a reorganisation of the NHS Logistics Authority and parts of the NHS Purchasing and Supply Agency (PASA), which became part of what is known as the NHS Supply Chain.[30] NHS Supply Chain is not a separate entity or body, but rather a logistics management unit under the umbrella of the NHS Business Services Authority, currently operated by the private company DHL (DHL Supply Chain Ltd) under a long-term outsourcing contract. NHS Supply Chain does not have separate legal personality, but is rather a front or holding place for the underlying contract for logistical and other services. However, this is not necessarily observable in all or most interactions with third parties, as NHS Supply Chain externally presents itself as an 'organisation'.[31] Figure 1 provides a schematic representation of the relationships between these entities.

Figure 1: NHS supply chain governance



Source: own elaboration

NHS Supply Chain provides centralised procurement services to the NHS. It manages framework contracts and other contractual mechanisms that allow direct access to suppliers by NHS procurers. NHS Supply Chain is thus a procurement intermediary for NHS trusts (and the 'NHS family' more generally) that has generated savings through aggregation of purchasing needs and professionalisation of the management of the NHS supply chain. After the Carter Review, NHS Supply Chain became the focal point of the Department of Health and Social Care's *Future Operating Model for NHS Procurement* (the FOM, which has now become the NOM),[32] which it expects to 'flex the tremendous buying power of the NHS to unlock annual savings of £615 million', and with which it seeks to 'make a major contribution to healthcare efficiency'. The transition towards the NOM was foreseen as a staged process. A first stage involved streamlining the existing work of NHS Supply Chain, as well as launching pilot programmes for the centralised acquisition of standard supplies. A second stage would involve the roll-out of a significantly changed supply chain structure managed by NHS Supply Chain (as described in the next section). In April 2016, the NHS PTP resulted in the introduction of the

29 NHS Business Services Authority <www.nhsbsa.nhs.uk>.

30 NHS Supply Chain, 'What We Do' <www.supplychain.nhs.uk/about-us/what-we-do>.

31 See e.g. its website <www.supplychain.nhs.uk>.

32 FOM Handbook (n 26).

High-Cost Tariff-Excluded Devices (HCTED) programme, a new nationwide system for purchasing high-cost medical devices and implants used in specialised services.[33] The HCTED system concerns centralised collaborative procurement between NHS Supply Chain and designated NHS trust champions for different device categories. Similarly, in early 2017, a further centralisation programme was launched: the NHS Nationally Contracted Products (NCP) programme,[34] which is an NHS Supply Chain initiative that aggregates national demand for selected standardised products to purchase them on behalf *of the whole of the NHS* in order to optimise value and deliver savings. Both programmes served as stepping stones towards the NOM. The HCTED programme will be fully incorporated into the NOM, as part of the new NHS Supply Chain, while the NCP was effectively adopted as an interim measure to establish principles and working practices in advance of the NOM.

The streamlining of NHS Supply Chain activities and the implementation of the NCP were expected to unlock significant savings (c. £300mn) by October 2018,[35] when the current contract with DHL would have expired and the NOM would be fully operational. It was also expected that the HCTED would see savings of over £60 million reinvested into specialist care in its first two years. However, migration into the NOM's second (or fully operational) stage has seen some delays, in particular concerning the award of the NOM logistics contract – which has been the object of a legal challenge by DHL, which opposed the award of the contract to a different operator (Unipart).[36] In order to bridge the transition in to NOM, the pre-PTP contract with DHL was extended until 28 February 2019. After the High Court dismissed DHL's challenge,[37] the NOM is now expected to become (fully) operational in March 2019. These delays suggest a more limited (or at least a slower) unlocking of savings than initially anticipated,[38] and an extended period of implementation of the NOM, or at least some of its aspects. The Department of Health and Social Care, however, remains committed to the NOM.

Centralisation of NHS procurement and supply chain management: the NOM

Collaborative and centralised procurement strategies have progressively been implemented in the NHS over the last decade or so.[39] This has resulted in savings through reduced unit costs for standard equipment and supplies,[40] and reoriented non-pay expenditure by NHS trusts to new channels. NHS procurement expenditure is currently roughly split across three procurement routes: 20 per cent direct expenditure by NHS trusts, 40 per cent expenditure through ad hoc collaborative procurement in NHS hubs, and 40 per cent expenditure through centralised mechanisms managed as 'consolidated

33 NHS England, 'New System for Buying and Supplying High-cost Medical Devices in Specialised Services' <www.england.nhs.uk/commissioning/spec-services/key-docs/medical-devices>.

34 NHS Supply Chain, 'Nationally Contracted Products' <www.supplychain.nhs.uk/savings/nationally-contracted-products>.

35 NHS Business Services Authority, 'Strategy 2017–22' (May 2017) <www.nhsbsa.nhs.uk/sites/default/files/2017-05/nhsbsa-strategy-2017-2022.pdf>.

36 See above (n 3).

37 Ibid.

38 Peter Smith, 'Delays to NHS Future Operating Model Supply Chain Contracts' (*Spend Matters UK/Europe*, 12 April 2018) <https://spendmatters.com/uk/delays-to-nhs-future-operating-model-supply-chain-contracts>.

39 This is reflective of a broader trend of procurement centralisation across government, which, however, still requires significant improvement. For an early assessment, see NAO, *Improving Government Procurement* (HC 2012–13 996).

40 See e.g. NHS Supply Chain, '£250 Million Cash Releasing Savings Achieved for the NHS' (26 October 2017) <www.supplychain.nhs.uk/news/press-releases/2017/250-million-cash-releasing-savings-achieved>.

procurement' by NHS Supply Chain.[41] The PTP strategy is to further centralise procurement in order to leverage the NHS's buying power in the expenditure of the c. £6 billion a year in goods and services. This requires a redesign of a new NHS Supply Chain.[42] The current plan is to progressively migrate towards the NOM, so that by 2023/2024 the proportion of consolidated procurement doubles, from 40 per cent to 80 per cent.[43] Such a significant increase in consolidated expenditure will in principle reduce the scope for both direct procurement by NHS trusts and for collaborative procurement through NHS hubs, although some hubs have indicated that they will continue to seek collaboration in areas of NHS non-pay expenditure not covered by the NOM.[44]

In a somehow simplified manner, the NOM can be conceptualised as a network of contracts enabling a different work system for the NHS Supply Chain. The NOM comprises 14 separate contracts let to organisations that will manage the service for an initial period of three years (although delays have already been incurred, in particular concerning the logistics contract, as mentioned above), with potential contract extensions based on meeting performance targets. The NOM has been launched on the basis of a commercial arrangement that allows contractors to obtain profit margins in their supplies or provision of services, which is the way in which NHS Supply Chain has been funded until now. Differently, however, the NOM will be centrally funded from 1 April 2019, in what has been described as a 'top slicing', which should facilitate the application of pricing and tariff structures designed through the normal tariff consultation processes run by NHS England and NHS Improvement. However, it is worth stressing that centrally funding the cost of the new system will require further reallocation of NHS funds within the 'NHS family'. In fact, the central funding of the NOM will be drawn from funds currently allocated to NHS trusts,[45] which will force the latter to use the system (and thus benefit from its expected savings) or else have to find other sources of efficiencies to compensate for their reduced funding. Crucially, if the NOM fails to deliver procurement-related savings commensurate to (at least) the cost of its central funding, the implementation of the system will result in yet one more source of erosion of funding for frontline NHS services – which is the opposite of what it sets out to achieve. Given current delays and foreseeable implementation difficulties, it is not out of the question that the implementation of the NOM will result in a negative financial impact for English NHS trusts, at least in the short run. This comes to put additional pressure on the NOM to deliver financial savings quickly, which may also affect the way some important decisions are made. This can only reaffirm the importance of gaining a better understanding of the checks and balances in the system, and the reviewability of the decisions adopted by NOM-agents, which is the focus of the remainder of this paper.

41 FOM Handbook (n 26) 8.

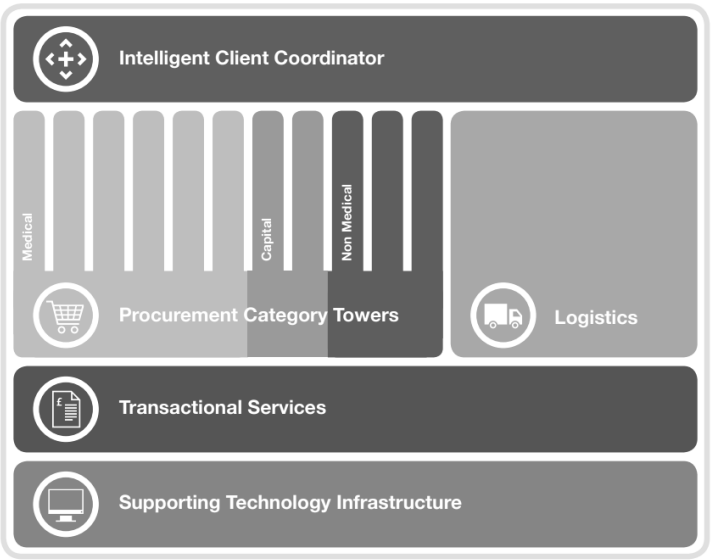
42 Note that NHS Supply Chain has relabelled the initially described as FOM (*future* operating model) as the NOM (*new* operating model). In order to provide updated discussion, the paper refers to the NOM. However, please note that most materials referred to in the footnotes still use the FOM.

43 Department of Health and Social Care, 'Procurement Transformation Programme: Future Operating Model' (December 2016) <www.abhi.org.uk/media/1288/procurement_transformation_programme_brief_fom_brief__131216-1.pdf>.

44 Presentation given by Keith Rowley, Managing Director, North of England Commercial Procurement Collaborative, at the 'Procurement4Health' 2018 Conference on 12 July 2018.

45 Nick Carding, 'Half a Billion Pounds to be Withheld from Trusts over Two Years' (*Health Service Journal*, 22 August 2018) <www.hsj.co.uk/finance-and-efficiency/half-a-billion-pounds-to-be-withheld-from-trusts-over-two-years/7023189.article>.

Figure 2: NOM structure



Source: NHS Supply Chain[46]

Figure 2 represents the general architecture of the NOM, which adopts a 'tower' structure around cross-cutting horizontal services and vertical procurement 'category towers' for different types of medical, capital and non-medical goods and services.

The NOM thus initially comprised contracts for:

(a) 11 'category tower' service providers (consisting of buying teams focused on specific product categories);

(b) logistics;

(c) transactional services (although these have been finally internalised by the NHS Business Services Authority);[47] and

(d) IT services.[48]

Figure 3 identifies the category towers and the providers of those and other services as of the time of writing.

The oversight and operational management of the new NOM contracts and services along with customer engagement activities will be delivered by a new organisation known as the Intelligent Client Coordinator (ICC). The ICC contract has been entrusted to Supply Chain Coordination Ltd (SCCL), a subsidiary company set up by the Department

46 NHS Supply Chain, 'New Operating Model – Frequently Asked Questions' (28 June 2018) <www.supplychain.nhs.uk/icc/~/media/Files/News/NHS%20SC%20Customer%20FAQs%20280618.ashx>.

47 Presentation given by Chris Holmes, Supply Chain Director, Supply Chain Coordination Ltd, at the 'Procurement4Health' 2018 Conference on 12 July 2018.

48 The extent to which transactional and IT services beyond the NOM's internal needs form part of the tower system is unclear. See e.g. the recent tender of a large value contract by NHS Shared Business Services: 'Salford: Hospital and Related Services' (2018/S 143–327281) <https://ted.europa.eu/udl?uri=TED:NOTICE:327281-2018:TEXT:EN:HTML&WT.mc_id=RSS-Feed&WT.rss_f=Other+Services&WT.rss_a=327281-2018&WT.rss_ev=a >.

Figure 3. NOM providers

Source: NHS Supply Chain; information as of 28 November 2018.[49]

49 NHS Supply Chain (n 25).

of Health and Social Care and registered in Companies House. However, SCCL is described as a public sector organisation that forms part of the 'NHS family' tasked with rationalising and simplifying the procurement landscape and improving responsiveness to NHS organisations. SCCL is seen as providing a vital role in the clinical and product assurance (CaPA) of the NOM. In that regard, SCCL will help the category tower service providers (the CTSPs) to ensure that, where necessary, products are clinically evaluated. The aim is that all products will go through a product assurance over a 4–5 year rolling period.

The key role given to CTSPs

Functionally, then, the key difference between the current NHS Supply Chain system and the NOM is the significant active role given to the CTSPs in developing category management strategies (that is, the 'go to market approach' at product level). Every CTSP sourcing strategy has to go through the newly created SCCL Category Council for approval.[50] Once approved by the SCCL Category Council, the CTSPs' category management strategies determine the approach to the procurement of the equipment, consumable and/or services included in the relevant category by practically the entirety of the NHS. Their role is described as comprising 'the clinical evaluation of products and [running] procurement processes on behalf of the NHS. These providers will use category management techniques to create strategies that sustainably provide the NHS with clinically assured products at the best value'.[51]

Under the NOM structure, CTSPs are incentivised to reduce total cost in the system, not just reduce unit prices of the goods and services covered by the relevant category. They hold Guaranteed Maximum Price Target Cost (GMPTC) contracts, under which CTSPs will be paid the operational costs incurred in performing the services against an annual target set out in the contract, but will only make a profit when savings are delivered, on a gainshare basis that is capped.[52] This is seen as creating adequate incentives for overall cost reduction through system-wide savings – and is probably the justification for the centralised funding of the NOM, which seems based on the premise that those who are bound to benefit from its generated savings (i.e. NHS trusts) should bear the financial cost of the new procurement infrastructure. It is also worth noting that CTSPs will be taking on the operational responsibility of the relevant category tower from the current NHS Supply Chain, and that they are also bound to absorb, where possible, existing procurement team staff from NHS Supply Chain under TUPE. On the whole, then, it seems that NOM is largely a restructuring of the current NHS Supply Chain by means of a spin-off of general tasks to the newly created SCCL and a transfer of branches of activity to NOM contractors through the CTSP contracts, as well as a reallocation of financial risks to NHS trusts (despite the contrary appearance resulting from centralised funding).

50 Apparently, more than 50 category strategies went through the Category Council approval process before the end of July 2018. Presentation given by Jo Gander, CaPA Director, Supply Chain Coordination Ltd, at the 'Procurement4Health' 2018 Conference on 12 July 2018.

51 Department of Health and Social Care, 'Procurement Transformation Programme. Future Operating Model. Frequently Asked Questions for Suppliers' (5 January 2018) <www.supplychain.nhs.uk/Home/News/~/media/Files/News/DH%20FOM%20%20Supplier%20QA%20%20FINAL.ashx>.

52 The contracts are described as establishing efficiency-generating incentives via key performance indicators (KPIs) and intangible system cost changes, which not only determine the possibility for CTSPs to share in the gains of significant savings, but also the application of performance management measures. Indeed, CTSPs will be withheld payment if they do not achieve 50% of the relevant KPIs, and will be put on notice of critical service failure if they do not achieve at least 80% of the relevant KPIs.

From a governance perspective, crucially, as a result of the NOM structure, CTSPs are not the direct providers of the equipment, consumables or services required under each of the category towers, but rather intermediaries, consultants or advisors (or a hybrid of these functions) that will design and set up additional contractual mechanisms (implicitly, in the form of framework agreements or dynamic purchasing systems, probably underpinned by electronic catalogues) with third parties *on behalf of* the NHS. CTSPs then take the place of the current NHS Supply Chain in the provision of centralised purchasing services. However, given that not all CTSPs are part of the 'NHS family' and that their relationship with the new NHS Supply Chain (and in particular SCCL as the ICC) is purely contractual, understanding the exact fit of the CTSP–(user) NHS trust relationship within existing English public law structures will be challenging (as discussed below). Indeed, one of the implicit changes in the move towards the NOM is a potential de facto loss of accountability and reviewability of key decisions in the operation of the NHS supply chain, which is now heavily dependent on the CTSPs. From a functional perspective, it seems that the NOM has created an additional layer of contractualised governance, the effectiveness of which will depend on its interaction with other layers of additional regulation, both upstream (i.e. NHS trust and 'NHS-family' structures) and downstream (procurement and commercial contracts). It has also created an additional layer of potential conflicts of interest that will raise equally peculiar challenges (which are discussed below).

Lights and shadows of the NOM

It is of course still too early to assess the practical impacts of the NOM and the extent to which it will deliver the expected savings and efficiencies that have been used to justify setting it up – although harbouring doubts about their (timely) materialisation does not seem unjustified. Be that as it may, the NOM's structural and functional design raises important questions.[53] Some of these questions concern the extent to which the NOM truly generates a different way of working and a more strategic approach than the previous mechanisms for collaborative and centralised NHS procurement. Other questions arise in the context of the subjection of NHS expenditure through the NOM to public procurement and competition law requirements. Before assessing the latter (in the next section), it is worth reflecting on some of the strategic issues. Looking at the list of NOM-contract holders (above, Figure 3), it becomes evident that there are two contractors that accumulate a significant number of contracts: DHL (through DHL Life Sciences and Healthcare UK) and the Collaborative Procurement Partnership LLP (which is made up the four NHS procurement hubs: NHS Commercial Solutions; NHS London Procurement Partnership NHS; East of England NHS Collaborative Procurement Hub; and the North of England Commercial Procurement Collaborative – the latter also holding an additional NOM contract in its own name). It is also worth noting that the largest public sector central purchasing body, the Crown Commercial Service, also holds a NOM contract. This raises two important issues.

First, that the NOM may represent a smaller transition from decentralised towards centralised procurement than it may at first appear. Given that the four pre-existing NHS procurement hubs have partnered together and received major NOM contracts, there may be a displacement rather than a substitution effect between hub-based and NOM-based NHS procurement. In that regard, given that the current level of hub-channelled

53 See e.g. Rob Knott, 'The Future of NHS Procurement? Look into your Procurement Strategy, not a Crystal Ball' (*Health Care Supply Association*, nd) <https://nhsprocurement.org.uk/the-future-of-nhs-procurement-look-into-your-procurement-strategy>.

procurement is 40 per cent and consolidated procurement managed by NHS Supply Chain is also 40 per cent, the extent to which the 80 per cent of NOM-related procurement that should be achieved by 2023/2024 is significantly different from the current structure raises important questions. To some extent, it would seem that the NOM could result in rather small incremental changes, which may then be insufficient to unlock the very significant reductions in costs that are currently anticipated – and thus result in an undesirable net reduction of funding for frontline NHS services through the NHS trusts' contribution to the central funding of the NOM. Moreover, there is a risk of parallel or competing procurement structures if there is insufficient coordination between NOM and hub-based procurement. For example, recent tenders for enteral feed products and services by individual NHS trusts and regional hubs show that there will be difficulties in migrating over to the NOM system, as these contracts should have been procured under NOM category tower 1 since May 2018.[54]

Second, regarding the accumulation of contracts in DHL's hands, a note of caution may be needed in view of very negative recent experiences with other 'strategic suppliers' of outsourced services, such as Carillion[55] and Capita.[56] Given the clear strategic risks that result from the accumulation of large volumes of complex and delivery-sensitive services by one (conglomerate) provider, and the ineffectiveness of the government's approach to managing relationships with 'strategic suppliers',[57] the desirability of the NOM strategy may require some additional analysis – in particular from the perspective of systemic risks and resilience and continuity of supply. In a sector where supply disruption can have negative impacts on population health and human lives, this is not a minor concern. Recent examples of failed concentration of risks in NHS suppliers provide evidence of the need for careful analysis of such vulnerabilities of highly concentrated procurement,[58] which the NOM can only increase exponentially.

Moreover, even if it is not its main driver, it is also clear that the NOM aims to aggregate buying power beyond the 'NHS family' by allowing non-NHS organisations to use the NOM – that is, the NOM would provide procurement and logistics services in the private market, competing with other providers to the public and private sectors, and non-NHS NOM users would be subject to a different pricing model depending on whether they are another public sector organisation or a private company.[59] This characterises the NOM as a commercially orientated strategy rather than a 'mere' conduit for the self-organisation of the healthcare (public) sector in England. This can have an impact on the way it is run and on the way in which public interest considerations are embedded in NOM-related decision-making and governance. The commercial exploitation of the NOM can also generate additional risks – e.g. concerning the liability of the NOM vis-à-vis commercial clients – complex tax issues, and other considerations – e.g. state aid. Moreover, the fact that the NOM is open to non-NHS and private organisations raises important additional issues from both a competition and public procurement law perspective. All of this results in a certainly complex set of legal and governance issues that require some close analysis.

54 See e.g. 'United Kingdom-Sheffield: Enteral Feeds' (2018/S 123–279618) <https://ted.europa.eu/TED/notice/udl?uri=TED:NOTICE:279618-2018:TEXT:EN:HTML>.

55 Business, Energy and Industrial Strategy and Work and Pensions Committees (n 2).

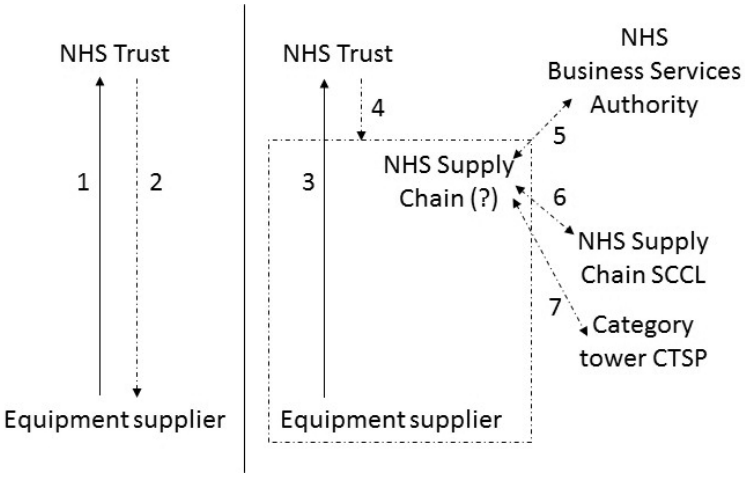
56 NAO (n 2).

57 NAO, *Managing Government Suppliers* (HC 2013–14 811).

58 Kat Lay, 'Aprons Crisis "Threatens NHS Patients and Staff"' *The Times* (London, 20 January 2018) <www.thetimes.co.uk/article/chinese-plastic-aprons-crisis-threatens-nhs-patients-and-staff-m6s6pxnss>.

59 FOM Frequently Asked Questions (n 51).

Figure 4: Changes introduced by NOM supply chain compared to direct procurement



Source: own elaboration

Governance and legal compliance challenges of the NOM

As mentioned in the previous section, the migration towards the NOM creates an additional layer of contractualised or privatised management of the NHS supply chain that triggers significant governance and legal compliance issues. Figure 4 depicts a comparison of alternative procurement routes for medical equipment that provides a useful framework for the discussion of these issues. It compares the direct procurement and supply of the equipment between the NHS trust and the equipment supplier with a 'NOM' supply.

The direct procurement of medical equipment for its own use by an NHS trust (depicted to the left of Figure 4) creates two relatively straightforward legal relationships. The evident one is a direct contractual relationship with the equipment supplier (1). Underpinning that, the NHS trust would have been obliged to comply with the applicable public procurement rules in the tendering of that contract (2). The first contractual relationship would be subject to its own terms and any disputes would be directly resolved or litigated between the parties (or possibly subjected to alternative dispute resolution mechanisms). Regarding the second legal relationship (procurement), the NHS trust would have been constrained by the Public Contracts Regulations 2015 (PCR2015)[60] and its decisions would have been open to both the system of procurement-specific remedies and, potentially, to judicial review.

Conversely, the NOM model of procurement (depicted to the right of Figure 4) creates some analytical challenges. In this case, the procurement architecture is much more complex, despite the simplified official account that CTSPs will 'run procurement processes on behalf of the NHS'. This cannot be understood as a simple substitution or intermediation of CTSPs for the benefit of the ultimate 'client' contracting authorities (in the example, the NHS trust). It rather entails a very different approach to the design and execution of procurement operations. Indeed, by tendering a framework agreement *on behalf of* the NHS under the NOM structure, the CTSP would not hold a straightforward

60 SI 2015/102.

direct procurement relationship (or any explicit procurement relationship at all) with the equipment supplier (7). The tendering of the contract would have followed a certain level of scrutiny and authorisation by the NOM ICC, namely the SCCL (6), and the framework agreement would (most likely) have been tendered on the specific behalf of NHS Supply Chain as the relevant contracting authority. However, given that NHS Supply Chain has no separate legal personality, the standard approach under the current (pre-NOM) operation of NHS Supply Chain has been for the latter to act as the agent of NHS Business Services Authority (5), which would be the entity ultimately (indirectly) holding the contract.[61] Moreover, it is worth noting that the Secretary of State for Health has represented the NHS Business Services Authority in the award of the main NOM contracts to CTSPs,[62] which can add an additional layer of complication to the procurement of the NOM framework agreements.

The setting-up of a framework agreement under the NHS Supply Chain umbrella would then allow an individual NHS trust to place a call-off for the required medical equipment without the need for any additional public tender (4).[63] The delivery of the equipment would then be subject to a direct relationship between the equipment supplier and the NHS trust (3), which would, however, be strongly influenced by (and dependent on) the generally applicable clauses of the framework agreement. It would also be possible for the NOM-logistics operator to be involved in part of the implementation of the call-off, although this is more likely for supplies of consumables than for supplies of equipment, in particular if they require installation. In addition to that, the management of this contractual relationship could involve the active participation of the CTSP (or potentially SCCL), as part of the NOM approach to post-sales customer management. While the contract law implications of this solution may be easier to resolve through carefully drafted framework agreements and call-off contracts, the procurement dimension of the NOM creates complications of a different nature. The extent to which compliance with the PCR2015 and the effectiveness of procurement-specific and general judicial review mechanisms can be ensured requires some careful analysis.

Indeed, the rather complicated NOM structure raises important questions and challenges from a governance and legal compliance standpoint. It is submitted that there are four salient issues that require particular attention. First, the classification of the activities of the CTSP *on behalf of* the 'NHS family' under public law for the purposes of judicial review. Second, the subjection of NOM procurement to the PCR2015 and its implications in terms of procurement compliance not only by CTSPs, but also by NHS trusts. Third, the management of conflicts of interest in this setting. Last, but not least, the applicability of competition law to the NOM structure.

Public law fit of CTSP activities on behalf of the 'NHS family'

One of the difficulties implicit in the NOM – and, previously, in the management of important aspects of NHS governance and delivery through arms-length organisations and publicly owned commercial entities, such as the NHS Business Services Authority

61 However, it is worth noting that (some of) the NOM contracts with CTSP have been tendered and entered into by the NHS Business Services Authority, represented for procurement purposes by the Secretary of State for Health. This complicates the picture even further, as discussed in the main text.

62 See 'United Kingdom-Newcastle upon Tyne: Procurement Consultancy Services' (2018/S 021–044459) <https://ted.europa.eu/udl?uri=TED:NOTICE:44459-2018:TEXT:EN:HTML>.

63 Please note that, depending on the design of the framework agreement, this could require an additional mini-competition between the potential providers included in the framework agreement. This would raise additional procurement issues. However, in order to keep some simplicity in the discussion, it is assumed that this is a single supplier framework where all call-off conditions are set at the time of award.

and NHS Supply Chain – is the accountability and reviewability of the decisions of the ever-changing 'NHS family'. If one wants to challenge a given decision, e.g. subjecting it to judicial review, one must first be able to answer complex questions about the attribution to specific authorities or entities of authority and decision-making powers, as well as of the consequences for those decisions. There is a chain of contractual arrangements and directions that are relevant in that regard, which interact with pre-existing legislative and statutory instruments.

The NHS Business Services Authority has been given statutory functions[64] and issued directions by the Department of Health and Social Care under the National Health Service Act 2006 (most recently in 2016)[65] in relation to the management of the NHS supply chain.[66] The Department of Health and Social Care has also concluded a 2014 framework agreement with the NHS Business Services Authority that concerns, amongst other things, the way in which the latter discharges its statutory function by 'managing a 10-year outsourced Master Services Agreement (MSA) for the delivery of supply chain services to the NHS'.[67] The framework agreement makes it clear that the NHS Business Services Authority acts in accordance with the delegated authority issued to it by the Department of Health and Social Care. Therefore, it seems straightforward to conclude that, in the exercise of its functions concerning the NHS supply chain and, in particular, in the context of the MSA, the NHS Business Services Authority is exercising delegated authority from the Department of Health and Social Care – to which, in turn, the acts of the NHS Business Services Authority are attributable as those of its *delegate*. The MSA to which the abovementioned delegation refers is the pre-NOM outsourced relationship between NHS Business Services Authority and DHL (i.e. the current NHS Supply Chain), which was revised and extended in 2015.[68] Under this agreement, DHL (as the outward-facing front of the NHS Supply Chain) acts as the *agent* of the NHS Business Services Authority[69] – that is, as the agent of the delegate of the Department of Health and Social Care.

The structure of the NOM suggests that a similar approach may be followed in the future. Contract opportunities that should be covered by category towers have been advertised, e.g. by 'DHL Supply Chain acting on behalf of Supply Chain Coordination Ltd acting on behalf of the NHS Business Services Authority'.[70] This means that, as a result of NOM – or along the process of transitioning into NOM – there has been a 'simple' displacement of the NHS Business Services Authority, which is now further removed from the tender of new contracts and framework agreements through the

64 The NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005, SI 2005/2414.

65 NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) Directions 2016 <www.nhsbsa.nhs.uk/sites/default/files/2017-02/Section_2_-_B1_NHSBSA_Directions_2016.pdf>.

66 Ibid Direction 15 and Schedule 4.

67 The latest version was concluded in August 2014. See Framework Agreement between the Department of Health and NHS Business Services Authority <www.nhsbsa.nhs.uk/sites/default/files/2017-02/2014-08-08_-_NHSBSA_Framework_Agreement_2014.pdf>.

68 On file with the author.

69 This is made explicit in relevant notices, such as the standard registration notice of the NHS Supply Chain website, which reads 'NHS Supply Chain is operated by DHL Supply Chain Limited (Company Registration No: 528867), as agent for the NHS Business Services Authority' <www.supplychain.nhs.uk>.

70 See 'United Kingdom-London: Disposable Non-chemical Medical Consumables and Haematological Consumables' (2018/S 126–287428) <https://ted.europa.eu/udl?uri=TED:NOTICE:287428-2018:TEXT:EN:HTML>. See also 'United Kingdom-London: Continuous Paper for Computer Printers' (2018/S 135–307468) <https://ted.europa.eu/udl?uri=TED:NOTICE:307468-2018:TEXT:EN:HTML>.

interposition of SCCL (the NOM ICC) as a second-tier agent. This suggests the emergence of a structure where the Department of Health and Social Care, despite holding responsibility for the management of the supply chain of the NHS, is now rather detached from operational decisions, as its own *delegate* (NHS Business Services Authority) is two steps away from the operational decisions of DHL (as the operating part of NHS Supply Chain, which will progressively be replaced by the CTSPs and/or the new logistics operator, Unipart) acting as the *agent of its own agent*, the SCCL.

This seems problematic in terms of establishing responsibility along the chain, in particular if one starts from the bottom. It is conceivable that the transparency of the chain of delegation and representation is not always completely clear or visible (in particular concerning decisions not subjected to procurement transparency notices), and third parties may not always have a very detailed understanding of how the different entities within the 'NHS family' relate to each other. Additionally, this structure does not clarify the position of the CTSPs. Publicly available information issued by the Department of Health and Social Care and the strategic design of the NOM make it clear that CTSPs carry out their activities, in particular their procurement activities, *on behalf of the NHS*. However, the legal structure given to those activities (at least the procurement activities, where CTSPs may not even be mentioned) makes CTSPs practically invisible, inasmuch as they do not tender and enter into the contracts directly in their own name, but acting as second-tier agents of the NHS Business Services Authorities. It thus seems that CTSPs' activities are purely advisory and that the entity formally adopting the decisions is, most likely, NHS Supply Chain or *rectius* SCCL – which, in both cases, amounts to imputing the decision to the NHS Business Services Authority. This does not seem to represent a situation where CTSPs carry out activities *on behalf of* the NHS, but rather where the NHS (Business Services Authority) carries out activities designed or shaped by CTSPs.[71] This can, indeed, liberate CTSPs from a certain degree of responsibility (and liability) for their decisions, as they will rarely be subject to direct challenges by third parties and, most likely, will be solely subjected to and accountable under the specific terms of relevant NOM contracts (which could include alternative dispute resolution mechanisms).

This can make it difficult for interested parties to challenge CTSPs' decisions in judicial review if they assume that, (most of) the CTSPs being private or commercial entities, they are not subjected to the jurisdiction of the administrative courts – as the defendant in judicial review cases is presented as 'the public body/public office which made the decision under challenge'.[72] Moreover, even if the avenue for judicial review is identified, this structure can still create a disincentive if, in order to challenge CTSPs' decisions, affected parties have to bring an action against the NHS Business Services Authority – which they may not see as directly involved with the decision they wish to challenge. It may also be difficult to access CTSPs' internal documents, as the rules on access to documents and freedom of information may not be easy to apply in this setting.

De facto, the NOM structure, and, in particular, the additional layer of contractualised relationships between CTSPs and the SCCL (acting as NHS Supply Chain's ICC and, ultimately, the agent for the NHS Business Services Authority), results in legal uncertainty. In order to avoid seeing their challenges set aside for procedural reasons, it seems that the NOM structure most likely requires third parties to address their complaints *simultaneously*

71 This could, for example, make rather challenging the application of precedent concerning the judicial review of decisions adopted by private companies exercising statutory powers. See e.g. *R v Northumbrian Water Ltd, ex p Newcastle and North Tyneside HA* [1999] Env LR 715.

72 The Administrative Court Judicial Review Guide 2018 (July 2018) para 2.2.2.1.

or *globally* against all entities in the chain (including CTSPs, and possibly all the way up to the Secretary of State for Health) due to the uncertainty that the attribution of decision-making powers, authority and legal liability creates. This can hardly be seen as a desirable state of affairs from the perspective of public accountability and judicial review.

Subjection to and compliance with the PCR2015

The uncertainty derived from the NOM structure not only affects third parties, but also internal NHS users. Indeed, NHS trusts (and any other contracting authorities within the 'NHS family') have an interest in understanding exactly who holds relevant contractual arrangements under NOM and where do the public/private boundaries lie. NHS trusts qualify as contracting authorities under EU and UK public procurement law and are thus subject to a *direct* obligation to tender the contracts for acquisitions and supplies above certain value thresholds. One of the advantages of the NOM is that it allows NHS trusts to dispense with those tendering obligations on the basis that acquisitions within the 'NOM system' ensure *indirect* compliance with the relevant obligations. However, this possibility of indirect compliance is not unqualified.

Under the current rules, a 'user' contracting authority (such as an NHS trust) fulfils its obligations under the PCR2015 when it acquires supplies or services from a 'central purchasing body' (CPB) or using contractual mechanisms concluded by a CPB (reg 37(4) and (5) PCR2015). For these purposes, a 'central purchasing body' means a contracting authority which provides centralised purchasing activities (reg 2(1) PCR2015). This is relevant in two respects. First, where an NHS trust acquires from or through a CPB it does not face independent liability for breach of the procurement rules – unless it directly carries out additional selection activities ('mini-competitions') on top of the more basic (or open-ended) CPB procurement activities (cf reg 37(6) PCR2015). This applies even if the CPB has not adequately complied with the relevant rules in the tendering of the underlying contracts. The assumption here is that CPBs will comply with the relevant rules and that, where they do not comply, they will be directly exposed to challenges. Second, for this mechanism of *indirect* compliance to apply, the acquisition needs to be from or through contractual mechanisms established by *a CPB that is a contracting authority*. 'Contracting authorities' are in turn defined (reg 2(1) PCR2015). In addition to the state, regional and local authorities, this includes 'bodies governed by public law'. The latter are defined as:

> bodies that have all of the following characteristics: –
>
> (a) they are established for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character;
>
> (b) they have legal personality; and
>
> (c) they have any of the following characteristics: –
>
> (i) they are financed, for the most part, by the State, regional or local authorities, or by other bodies governed by public law;
>
> (ii) they are subject to management supervision by those authorities or bodies; or
>
> (iii) they have an administrative, managerial or supervisory board, more than half of whose members are appointed by the State, regional or local authorities, or by other bodies governed by public law;

The assessment of whether the NOM architecture complies with these conditions and can, thus, be considered as enabling indirect compliance with the relevant procurement rules under the CPB regime requires, first and foremost, locating the analysis in a given entity along the NOM chain. If the entities holding NOM contracts and framework

agreements tendered *on behalf of the NHS* were the CTSPs *themselves* or even the SCCL, it would seem clear that this exemption would not be applicable – as they are operating as commercial entities. However, we have seen above that the contracts are tendered by DHL (or, in the immediate future, perhaps the relevant CTSP) 'acting on behalf of Supply Chain Coordination Ltd acting on behalf of the NHS Business Services Authority'. This seems to (legally) allocate the contract to the NHS Business Services Authority. If this is the correct interpretation, then the legality of this mechanism from a procurement perspective mainly derives from the fact that the NHS Business Services Authority was 'established for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character' – as the other two conditions are also clearly met. However, locating the contract under the CTSPs, or even under SCCL (as the formal legal entity seemingly backing the NHS Supply Chain, in particular after the expiry of the service management agreement with DHL) would raise questions as to the fit of the NOM architecture under the CPB-based exemption from direct compliance with the procurement rules. More importantly, given that the NOM architecture is open to commercial exploitation for the benefit of non-NHS and even private organisations, the 'non-commercial' nature of the NOM system may be open to future challenges (as well as triggering competition law concerns, see below).

It seems that there is a converging interest in (legally) locating all NOM contracts under the legal personality of the NHS Business Services Authority – despite the fact that the latter seems to have made great efforts to distance itself from the direct management of the NOM, most recently through the creation of SCCL. However, for this not to limit third-party rights and interests and to avoid generating risks of non-compliance with the applicable procurement rules, it seems necessary that: (i) any and all acts and decisions involved in the operation of the NOM – including those of private entities and, in particular, CTSPs – are attributable to the NHS Business Services Authority for the purposes of legal challenge and judicial review (as discussed above); and (ii) that the commercial exploitation of the NOM for the benefit of non-NHS and even private organisations is either significantly constrained or, preferably, completely excluded. This would, in practice, resolve some of the issues discussed so far through the simple (legal fiction and) solution of assigning all 'NOM activity' to the NHS Business Services Authority for the purposes of accountability, reviewability and legal compliance. However, even if these two issues are galvanised in the operation, governance and accountability of the NOM, there would still be additional challenges in ensuring adequate legal compliance with other aspects of procurement and competition law.

Particular challenges in the management of conflicts of interest

A challenge that may seem difficult to resolve concerns the identification, prevention and management of conflicts of interest within NOM. One of the innovations of the PCR2015 was the transposition into the UK system[73] of new EU requirements for the prevention of conflicts of interest. Regulation 24 PCR2015 is clear in demanding that contracting authorities 'take appropriate measures to effectively prevent, identify and remedy conflicts of interest arising in the conduct of procurement procedures so as to avoid any distortion of competition and to ensure equal treatment of all economic operators'. In the context of NOM, given that contracts are being advertised as tendered by the DHL (or the CTSP in the future) 'acting on behalf of Supply Chain Coordination

73 For general discussion, see Albert Sanchez-Graells, 'The Implementation of Directive 2014/24/EU in the UK', in Steen Treumer and Mario Comba (eds), *Modernising Public Procurement: The Approach of Member States, vol 8 European Procurement Law Series* (Edward Elgar 2018) 278–307.

Ltd acting on behalf of the NHS Business Services Authority', this requires measures to ensure that the CTSPs are within the scope of this rule. Given that CTSPs will be the ones establishing procurement strategy and, most likely, drafting procurement documents, a narrow interpretation of the scope of application of the rules on conflict of interest as only applicable to the formal contracting authority (the NHS Business Services Authority) would be undesirable – and possibly subject to challenge.[74] CTSPs must thus be under a strict obligation to take measures to prevent, identify and remedy conflicts of interest.

In a mirror image, reg 57(8)(e) PCR2015 allows the contracting authority to exclude economic operators 'where a conflict of interest within the meaning of regulation 24 cannot be effectively remedied by other, less intrusive, measures'. This provision is intended as a residual clause whereby situations where the contracting authority cannot take internal measures to resolve a conflict of interest (e.g. the substitution of individual members of the evaluation team affected by a conflict of interest) can be resolved through the exclusion of the economic operator concerned. This seems more difficult to interpret where the conflict of interest is not between the contracting authority (the NHS Business Services Authority) and the potential provider, but rather between the CTSP and the potential provider (e.g. if they have common business interests), as the contracting authority cannot take effective internal measures.

The peculiarities of the potential conflicts of interest in the context of NOM suggest that there is a need for careful analysis and, potentially, for explicit guidance to be adopted. Given the existence of rather detailed NHS England statutory guidance on managing conflicts of interest for clinical commissioning groups,[75] that would seem like a good starting point.

Applicability of competition law to NHS Supply Chain and the NOM

Another difficulty arising from the structure of the NOM concerns the assessment of the extent to which the activities of the different operators are subjected to competition law scrutiny – which is a rather fundamental check and balance for market-based governance mechanisms. An exhaustive analysis of this issue would exceed the possibilities of this paper. However, there are two salient issues that require particular attention. First, the extent to which competition law is applicable to the NOM as a *sui generis* CPB. Second, whether the NOM structure creates risks of violation of competition law standards, in particular concerning the exchange of competition-sensitive information.

The first issue is important because the NOM, by aggregating and exercising public buying power, seems particularly prone to potential claims of anticompetitive behaviour – and, in particular, of exclusionary and/or abusive behaviour against the interests of (potential) NHS suppliers. In that regard, the received wisdom is that entities that are engaged in procurement activities are shielded from the application of competition law, unless they *also* engage in downstream competitive markets. Or, in other words, that competition law does not apply to the procurement activity *in itself*. This is the result of case law of the Court of Justice of the European Union (CJEU)[76] that reversed the previous domestic position of the UK Competition Appeal Tribunal (CAT) that

74 Indeed, the concept of conflict of interest needs to be given an expansive interpretation. See *Counted4 Community Interest Company v Sunderland City Council* [2015] EWHC 3898 (TCC).

75 NHS England, 'Managing Conflicts of Interest: Revised Statutory Guidance for CCGs 2017' (16 June 2017) <www.england.nhs.uk/publication/managing-conflicts-of-interest-revised-statutory-guidance-for-ccgs-2017>.

76 Judgment of 11 July 2006, *FENIN v Commission*, C-205/03 P, EU:C:2006:453. Albert Sanchez-Graells, *Public Procurement and the EU Competition Rules* (2nd edn, Hart 2015) 156–71.

competition law and its prohibitions applied to any entities which behaviour generated the effects that competition law sought to prevent, including in the context of their procurement activities.[77]

This could be seen as an exemption from the competition law prohibitions for the procurement activities covered by the NOM. However, it is worth noting that the CJEU case law did not exclude the possibility of applying competition law to entities that *engage in procurement as an economic activity*.[78] In that regard, the applicability of the prohibitions in the Competition Act 1998 (CA1998)[79] and Articles 101 and 102 of the Treaty on the Functioning of the EU (TFEU) to the NOM is not out of the question. To the contrary, it is submitted that the NOM and, in particular, NHS Supply Chain (as a front entity jointly run by the relevant CTSP, SCCL and the NHS Business Services Authority) is subject to competition law. Indeed, to the extent that the NOM is premised on the existence of commercial activity (both in the generation of savings and their split between the CTSPs and the NHS Business Services Authority) and is not a 'closed-system', but rather susceptible to commercial exploitation through the participation of non-NHS and private organisations, *by design*, it represents the carrying out of an economic activity that triggers the applicability of competition law.

Independently from the above, and even if the NOM was not seen as *itself* subject to competition law, the second issue it raises from a competition law perspective concerns a risk of potential illegal exchanges of information in violation of the prohibition in Chapter I CA1998 and Article 101 TFEU – or, at the very least, a heightened risk of collusion in NHS procurement markets. The need to ensure confidentiality of purchasing prices has been a primary concern of the NHS Business Services Authority's Scorpio Price Benchmarking project,[80] which pledged to its participants to keep information confidential and to not share it with NHS Supply Chain. Indeed, the need to keep price information confidential and to prevent its dissemination in the market is aligned with competition law requirements, which oppose competitors' access to commercially sensitive information. However, the extent to which sensitive price information will be used in a competition law-compliant manner under NOM raises some questions. Indeed, one of the mechanisms underpinning the NOM is the development and further use of the purchase price index and benchmarking tool, as well as other price-monitoring tools required to set baseline prices and assess the generation of savings (especially by CTSPs). In that regard, the creation of databases of prices should be accompanied by adequate competition safeguards.

Amongst others, these issues seem relevant enough for the Competition and Markets Authority (CMA) to take an interest in any complaint concerning the functioning of the NOM and for it to keep a close eye on the potential emergence of competition problems.

77 *BetterCare Group Ltd v Director General of Fair Trading* [2002] CAT 7. For discussion, see Sanchez-Graells (n 76) 159.

78 Albert Sanchez-Graells and Ignacio Herrera Anchustegui, 'Impact of Public Procurement Aggregation on Competition: Risks, Rationale and Justification for the Rules in Directive 2014/24', in Rafael Fernández Acevedo and Patricia Valcárcel Fernández (eds), *Centralización de compras públicas* (Civitas 2016) 129; and Albert Sanchez-Graells and Ignacio Herrera Anchustegui, 'Revisiting the Concept of Undertaking from a Public Procurement Law Perspective – A Discussion on EasyPay and Finance Engineering' (2016) 37(3) European Competition Law Review 93.

79 SI 1998/41.

80 On file with the author.

Even if NHS Improvement is co-competent for the enforcement of competition law,[81] given the proximity of entities within the 'NHS family' and the strategic interests of the Department of Health and Social Care in the NOM, this seems a clear case where independent CMA involvement could generate better outcomes than a softer (self)regulatory approach by NHS Improvement.

Conclusion

This paper has explored the fit of the NOM within the broader context of efficiency-driven NHS re-regulation, and its potential to unlock funds to support the delivery of current aspirations for the transformation of the NHS through STPs. It has explored the legal and business structure of the NOM and assessed the strategic, governance and legal compliance challenges it presents. The paper has suggested that, in order to address such challenges, it is necessary to functionally disregard the multiple layers of contractualised management of the NHS supply chain and proceed to effectively locate all relevant NOM relationships, including those resulting from CTSP activity, under the NHS Business Services Authority for the purposes of their judicial review and their subjection to procurement law. The paper has also identified the need for explicit guidance on the management of conflicts of interest with the NOM and for independent oversight by the CMA of the potential anticompetitive effects of the exercise of buying power on which the NOM rests, as well as of the potentially excessive exchange of commercially sensitive information. Only if these checks and balances are made effective will the operation of the NOM be subjected to effective oversight.

81 See the memorandum of understanding between the Competition and Markets Authority and NHS Improvement (1 April 2016) <https://improvement.nhs.uk/documents/29/NHS_Improvement_and_CMA_MoU_-_010416.pdf>. For discussion, see A Sanchez-Graells, 'Monitor and the Competition and Markets Authority' (University of Leicester School of Law Research Papers No 14 2014) <https://lra.le.ac.uk/handle/2381/29333>.

NILQ 70(1): 77–92

The legal duty of candour in healthcare: the lessons of history?

DR CATHERINE KELLY* AND DR OLIVER QUICK**

Centre for Health, Law, and Society, University of Bristol Law School

Abstract

Providers of health and social care in England are under a statutory duty to be open and honest with patients who suffer harm when receiving care or treatment. This 'duty of candour' was introduced by regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and is one of 13 fundamental standards of care regulated by the Care Quality Commission (CQC). This was hailed as a landmark for openness in patient–professional relationships and as having the potential for enhancing a safety culture in healthcare. However, the decision to supplement existing ethical duties and policy initiatives encouraging openness with a statutory duty was contentious and encountered considerable medical resistance. This paper will trace the background to the legal duty, analyse its contents and consider its enforcement and potential obstacles to its effectiveness. Our analysis will foreground resistance based in practitioners' and healthcare institutions' fear of litigation and prosecution in the UK. However, opposition to candour emerged within the medical profession prior to the emergence of modern liability systems. This paper will argue that in order to create a culture of candour it is important to look beyond the more commonly identified professional concerns about litigation and understand these historical trends. In particular, we argue that a longer-term understanding of medical resistance to openness has important lessons for the likely effectiveness of the legal duty of candour.

Keywords: law; history; candour; patient safety; professionalism; regulation.

Introduction

In November 2014, England introduced a statutory duty of candour on healthcare providers to be open and honest with patients in the aftermath of medical harm.[1] The immediate impetus for this was a recommendation in the public inquiry report into the failings at Mid Staffordshire NHS Foundation Trust, following revelations about poor standards of care and the neglect of patients there between 2005–2009.[2] Unlike the majority of the 290 recommendations contained in this vast three-volume report which remain unimplemented, the Department of Health swiftly signalled its intent to legislate for

* ck16846@bristol.ac.uk.

** oliver.quick@bristol.ac.uk.

1 Reg 20 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

2 Recommendation 181 of the *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (The Stationery Office 2018).

candour.[3] The end product is the lengthy and complex reg 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Scotland introduced its own version on 1 April 2018,[4] and similar reforms are likely to follow in Ireland and Northern Ireland based on the recommendations in recent inquiry reports.[5] In Wales, regulations for dealing with complaints and concerns require patients or their representatives to be advised of medical harm, but only in the event of a complaint being made.[6] Calls for a more wide-ranging legal duty have since been made there[7] and form part of the Welsh government's legislative programme for 2018–2019.[8]

Being honest with patients who have been harmed by healthcare treatment is a relatively basic requirement, but one which has been problematic in practice. This article examines the new legal duty of candour in its historical context and offers some insight into cultural aspects of medicine that need to be addressed for the new duty to be effective. We first trace the background to the duty, which included an interesting medico-political debate about the necessity of turning to law, and also a somewhat unedifying discussion about the level of patient harm which should trigger the duty.[9] We then provide a detailed analysis of the duty and consider some of the early evidence about its enforcement. In terms of potential obstacles to its effectiveness, our analysis will foreground theories explaining resistance based in practitioners' and healthcare institutions' fear of litigation and prosecution in the UK. However, as we will discuss in our third section, opposition to some forms of candour emerged within the medical profession prior to the emergence of modern liability systems. This paper will argue that to create a culture of candour it is important to look beyond the more commonly identified concerns about litigation and understand these historical trends.

1 The problem of patient safety and open disclosure

Ensuring and improving the safety of patient care is a global public health problem. International studies have demonstrated that between 8–12 per cent of hospitalised patients in advanced healthcare systems experience an adverse event whilst receiving care.[10] Medical error is reported to be a leading cause of mortality in first-world health systems.[11] The broader category of unsafe care has been estimated to account for 43 million injuries across the world each year.[12] Whilst the accuracy of such striking claims

3 Department of Health, *Patients First and Foremost: The Initial Government Response to the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (CM 8576 2013) 46.

4 The Duty of Candour Procedure (Scotland) Regulations 2018 <http://www.legislation.gov.uk/ssi/2018/57/made>.

5 Recommendations 34 and 35 of the *Scoping Inquiry into the Cervical Check Screening Programme* (Final Report 2018) <http://scallyreview.ie/wp-content/uploads/2018/09/Scoping-Inquiry-into-CervicalCheck-Final-Report.pdf>; and Recommendation 1 of the *Report of the Inquiry into Hyponatraemia related Deaths* (IHRDNI 2018) <www.ihrdni.org>

6 The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011, reg 12(7).

7 K Evans, *A Review of Concerns (Complaints) Handling in NHS Wales: 'Using the Gift of Complaints'* (Health in Wales 2014) Recommendation 49.

8 <https://beta.gov.wales/legislative-programme>.

9 D Dalton and N Williams, *Building a Culture of Candour: A Review of the Threshold for the Duty of Candour and of the Incentives for Care Organisations to be Candid* (Royal College of Surgeons 2014).

10 C Vincent, *Patient Safety* (2nd edn, Elsevier 2010) 54.

11 M A Makary and M Daniel, 'Medical Error – The Third Leading Cause of Death in the US' (2016) 353 British Medical Journal i2139.

12 A K Jha, I Larizgoitia, C Audera-Lopez et al, 'The Global Burden of Unsafe Medical Care: Analytic Modelling of Observational Studies' (2013) 22 BMJ Quality and Safety 809.

is likely to be contestable, the harms associated with patient safety failures are undeniable. Most obviously, there are physical and emotional harms to patients and professionals, but also financial costs to health systems; in 2017–2018, the English NHS Litigation Authority paid out £2.23 billion in compensation and fees for clinical negligence claims.[13] From the perspective of patients, such harms may be exacerbated by the secondary harm of being denied a truthful explanation of events. A recent survey of 728 claimants in England confirms that obtaining an explanation and apology continues to motivate the vast majority of clinical negligence claims.[14] The psychological harm of discovering dishonesty can have a particularly profound impact on patients in terms of trust in professionals and providers of care.[15]

Ensuring and improving patient safety is not easy, involving complex issues of care, competency, culture and communication.[16] Confronting medical failure and being candid with patients is emotionally difficult for clinicians,[17] although writing about this has become a popular publishing genre in recent years.[18] Candour is commonly defined as the 'quality of being open and honest' and is perceived positively.[19] Arguably, candour is a particularly detailed form of honesty which includes revealing insider information to those who are less well informed. In the context of patient safety, being candid has implications for therapeutic relationships between patients and professionals, but also for organisations in terms of creating the conditions whereby staff feel able and supported to be candid about medical harm. For clinicians, a broad approach to candour extends beyond admitting individual mistakes to informing patients about problems associated with the resourcing and management of hospitals and health systems. This clearly raises issues for clinicians who may feel conflicted in terms of loyalty to their patients, colleagues and the health service which employs them, although professional guidance is clear that patient protection must be prioritised.[20]

Interestingly, codes of medical ethics, such as the Hippocratic Oath and the Declaration of Geneva do not oblige truthfulness.[21] However, the ethical case for doctors to disclose errors to patients is clear and based on the importance of truth-telling and respect for persons.[22] Despite support for the principle of disclosure, this has not always translated into practical implementation. In 2005, a National Audit Office report revealed that only 24 per cent of English hospital trusts routinely informed patients who had been victims of adverse incidents.[23] Research from the USA has suggested a disclosure rate of

13 NHS Resolution, *Annual Report and Accounts 2017–18* (2018) 17.

14 *Behavioural Insights into Patient Motivation to Make a Claim for Clinical Negligence: Final Report by the Behavioural Insights Team* (NHS Resolution 2018) 45.

15 J Robinson, 'The Price of Deceit: The Reflections of an Advocate' in M M Rosenthal, L Mulcahy and S Lloyd Bostock (eds), *Medical Mishaps: Pieces of the Puzzle* (Open University Press, 1999) 246–56 ; W Powell, 'Robbie's Law: Lack of Candour – The Impact on Patients and their Families' Clinical Risk (3 February 2014).

16 O Quick, *Regulating Patient Safety: The End of Professional Dominance* (Cambridge University Press 2017).

17 D Hilfiker, 'Facing our Mistakes' (1984) 310 New England Journal of Medicine 118.

18 For example, A Gawande, *Complications: A Surgeon's Notes on an Imperfect Science* (Profile Books 2003); H Marsh, *Do No Harm: Stories of Life, Death and Brain Surgery* (Weidenfeld & Nicolson 2014); S Westaby, *Fragile Lives: A Heart Surgeon's Stories of Life and Death on the Operating Table* (Harper Collins 2018).

19 Oxford English Dictionary.

20 GMC, *Raising and Acting on Concerns about Patient Safety* (GMC 2012) para 10.

21 T L Beauchamp and J F Childress, *Principles of Medical Ethics* (5th edn, Oxford University Press 2001) 283.

22 N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (John Hopkins University Press 2005); M L Smith and H P Forster, 'Morally Managing Medical Mistakes' (2000) 9 Cambridge Quarterly of Healthcare Ethics 38.

23 National Audit Office, *A Safer Place for Patients: Learning to Improve Patient Safety* (The Stationery Office 2005) 4.

between 30 per cent and 40 per cent.[24] This evidence also suggests that doctors are less likely to disclose when errors are not obvious to patients, or when they have more serious consequences. Regrettably, disclosure has often been half-hearted and based on half-truths.[25] Ultimately, the principled commitment to candour has not prevented what Leape and Berwick have called an 'ethically embarrassing debate' within healthcare about whether or not to disclose such harmful events.[26]

A complex range of factors conspire to explain this 'disclosure gap'. Fundamentally, this is explained by a system of medical education which has not prioritised the communication skills necessary for effective disclosure.[27] Fear about a range of repercussions, including the threat of legal and disciplinary actions, is also commonly cited as a factor inhibiting disclosure. In the healthcare context, professionals worry about the legal significance of saying too much, despite the legislative promise in England and Wales that 'an apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty'.[28] Survey research from the USA and Australia confirms that healthcare professionals state that the fear of law is the main barrier to the practice of open disclosure.[29] This is consistent with a vast body of literature which considers the barriers to reporting of adverse incidents in medicine. In a comprehensive analysis of research published between 1980–2014 into barriers to incident reporting, Archer et al produced a useful synthesis of the available evidence. The authors found that the three most frequently cited barriers to incident reporting were: 'fear of adverse consequences including litigation (161/748), process and systems of reporting (110/748) and incident characteristics (92/748)'.[30] We return to a discussion of this research in section 3 below, but turn now to a review of recent policy responses to the problem of encouraging open disclosure to patients.

Concerns about a lack of openness and the chilling effect of law prompted health systems around the world to introduce policies aimed at encouraging clinicians to be open with harmed patients and their carers. Australia introduced the first national Open Disclosure standard in 2003, which has been updated into a national framework and is overseen by the Australian Commission on Safety and Quality in Health Care.[31] There

24 R J Blendon et al, 'Views of Practicing Physicians and the Public on Medical Errors' (2002) 347 (24) New England Journal of Medicine 1933; L Lopez et al, 'Disclosure of Hospital Adverse Events and its Association with Patients' Ratings of the Quality of Care' (2009) 169 (20) Quality of Care Archives Internal Medicine 1888.

25 E O'Connor et al, 'Disclosure of Patient Safety Incidents: A Comprehensive Review' (2010) 22(5) International Journal for Quality in Health Care 371.

26 L Leape, and D Berwick, 'Five Years after To Err Is Human: What Have We learned? (18 May 2005) 293(19) Journal of the American Medical Association 2384, 2388.

27 L Leape et al, *Unmet Needs: Teaching Physicians to Provide Safe Patient Care* (Report of the Lucian Leape Institute Roundtable on Reforming Medical Education, National Patient Safety Foundation 2010).

28 S 2 of the Compensation Act 2006.

29 T H Gallagher et al, 'Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors' (2003) 289 Journal of the American Medical Association 1001; D Studdert et al, 'Legal Aspects of Open Disclosure II: Attitudes of Health Professionals – Findings from a National Survey' (2010) 193(6) Medical Journal of Australia 351.

30 S Archer, L Hull, T Soukup et al, 'Development of a Theoretical Framework of Factors Affecting Patient Safety Incident Reporting: A Theoretical Review of the Literature' (2017) 7 BMJ Open doi:10.1136/bmjopen-2017–017155.

31 Australian Commission on Safety and Quality in Health Care, *Australian Open Disclosure Framework* (ACSQHC 2013).

have been similar initiatives in New Zealand,[32] Canada[33] and Ireland.[34] In England, the now defunct National Patient Safety Agency issued a best practice framework about 'Being Open' in 2009.[35] This was supported by statements encouraging openness by the NHS Litigation Authority[36] (now rebranded as NHS Resolution) and also enshrined in the NHS Constitution,[37] which pledges to:

> . . . ensure that when mistakes happen or if you are harmed while receiving health care you receive an appropriate explanation and apology, delivered with sensitivity and recognition of the trauma you have experienced, and know that lessons will be learned to help avoid a similar incident occurring again.

Whilst all laudable attempts at encouraging openness and honesty, these policy initiatives and pledges are legally unenforceable. They also lack evidence about their effectiveness in actually altering behaviour.[38] The creation of the statutory duty of candour is arguably a reflection of the failure of such policies for affecting meaningful change. However, before analysing this duty, it is worth remembering that the possibility of placing candour on a legal footing has long been considered. For example, in *Lee v South West Thames Regional Health Authority*[39] Sir John Donaldson MR stated that 'some thought should be given to what is the duty of disclosure owed by a doctor and a hospital to a patient after treatment', albeit that this issue wasn't central to the appeal in that case. Two years later, in the case of *Naylor v Preston*[40] the same judge went further in stating that 'in professional negligence cases, and in particular in medical negligence cases, there is a duty of candour resting on the professional man'. Whilst the common law hasn't evolved to create such a duty, the idea of so doing should not really be considered radical. The duty of care in negligence endorses the prudent patient test for determining the standard of care in relation to information disclosure *before* medical intervention,[41] so why should the same not apply to post-treatment communication?

Although previous calls for creating a legal duty of candour had been unsuccessful,[42] a combination of campaigning and the catalyst of a high-profile public inquiry report prompted governmental action. The immediate trigger was provided by recommendation 181 in the Francis report into the Mid Staffordshire NHS Foundation Trust Public Inquiry. This called for a statutory duty of candour on healthcare providers and registered healthcare professionals who believe or suspect that treatment or care has caused death or serious injury.[43] As we see below, the enacted duty is different in two important respects: it is limited in its application to organisations, but broader in applying to

32 Health and Disability Commissioner, *Guidance on Open Disclosure Policies* (HDC 2009).

33 Canadian Patient Safety Institute, *Canadian Disclosure Guidelines. Being Open with Patients and Families* (Canadian Patient Safety Institute 2011).

34 Health Service Executive, *Open Disclosure Policy* (HSE 2013).

35 National Patient Safety Agency, *Being Open: Communicating Patient Safety Incidents with Patients, their Families and Carers* (NPSA 2009).

36 NHS Litigation Authority, *Saying Sorry* (NHS Litigation Authority 2017).

37 The NHS Constitution for England (2015) (Complaint and Redress: Your Rights).

38 O Quick, 'A Scoping Study on the Effects of Health Professional Regulation on those Regulated' (Council for Healthcare Regulatory Excellence 2011).

39 [1985] 1 WLR 845, 851.

40 [1987] 1 WLR 958, 967.

41 Confirmed by the UK Supreme Court in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

42 Ian Kennedy (Chair), *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995: Learning from Bristol* (Cmnd 5207 (I) 2001); Department of Health, *Making Amends: A Consultation Paper Setting out Proposals for Reforming the Approach to Clinical Negligence in the NHS* (Department of Health 2003).

43 Recommendation 181 of the *Report of the Mid Staffordshire Inquiry* (n 2).

moderate harm, as well as to death or serious injury. The longer-term explanation must be credited to the campaigning of Mr William Powell aided by the medical charity Action against Medical Accidents (AvMA). Mr Powell's son Robbie died in 1990 aged nine from undiagnosed Addison's disease, a rare auto-immune disorder of the adrenal glands. Whilst the health authority admitted liability in relation to the failure to diagnose and made a payment of £80,000, in *Powell v Boladz*,[44] an action for psychiatric harm suffered by his parents, the Court of Appeal held that no duty of care existed between the doctor and Robbie's parents. Regrettably, the court held that the doctors were not legally obliged to explain the circumstances surrounding the death of Robbie to his parents, thus further illustrating tort law's ambivalent relationship with patient safety.[45]

Whilst the General Medical Council (GMC) responded by revising its guidelines to oblige candour in such circumstances,[46] the option of creating a separate legal duty met with considerable medical resistance. For example, a statement by the Medical Defence Union,[47] in response to the House of Commons Health Committee recommendation for introducing a statutory duty of candour in 2009, is revealing and worth quoting in full:

> We do not support the Committee's recommendation that the Chief Medical Officer's proposal for a statutory duty of candour be considered. The inference of the recommendation is that no effective duty of candour currently exists, but this is not the case for doctors who already have an ethical duty and our experience is that doctors do raise concerns. We do not know what the sanction would be if such a legal duty were introduced, but doctors can already be erased from the medical register if their fitness to practise is impaired because they have not complied with GMC guidance. Surely that is sanction enough?

This statement was problematic in several respects. The claim that an ethical duty of candour is effective is inconsistent with the research evidence noted above, which suggests a relatively low rate of disclosure to patients. In terms of the medical profession, relying on the GMC to enforce the ethical duty also appears to be somewhat misplaced. A parliamentary debate in 2010 revealed that the GMC had not dealt with a single case for breach of the duty contained it its guidance.[48] Nevertheless, despite the lack of enforcement activity around candour, professional regulators have demonstrated their commitment to candour in the form of revised guidance.[49] It is worth noting that the duty enshrined in professional regulation is broader than the legal duty in applying to situations where something has gone wrong with 'treatment or care causes, or has the potential to cause, harm or distress'.[50] Whilst this guidance was a welcome regulatory reaffirmation of the importance of being open, it was not enough to prevent the creation of a statutory duty of candour to which we now turn to analyse.

44 (1998) 39 BMLR 35.

45 J Miola, 'The Tort of Negligence and Patient Safety' in J Tingle and P Bark (eds), *Patient Safety, Law Policy and Practice* (Routledge 2011).

46 GMC, *Good Medical Practice* (GMC 1998).

47 Medical Defence Union, press release 3 July 2009.

48 HC Deb 1 December 2010, cols 276WH.

49 Professional Standards Authority, *Can Professional Regulation Do More to Encourage Professionals to be Candid when Healthcare or Social Work Goes Wrong? Advice to the Secretary of State for Health* (Professional Standards Authority 2013); General Medical Council and Nursing and Midwifery Council (NMC), *Openness and Honesty when Things Go Wrong: the Professional Duty of Candour* (GMC/NMC 2015).

50 GMC/NMC (n 49).

2 The statutory duty of candour

The statutory duty of candour is contained in reg 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Reflecting the style of much modern-day statutory drafting, this is a lengthy provision which requires careful reading.[51] It is striking that, whilst telling harmed patients the truth may seem a basic requirement, this has been translated into legal complexity via nine detailed clauses within reg 20. It came into force in November 2014 and initially applied only to 'health service bodies' which means health and social care organisations registered with the CQC. Primary care organisations, dentists, private healthcare and adult social services were initially excluded, but brought within reg 20 from April 2015, albeit with a different harm threshold for triggering the duty. The duty applies in England and to organisations rather than individual healthcare professionals, who are instead bound by the ethical duties of candour within professional codes of conduct noted above. However, in practice it is expected that those responsible for the patient's care would be expected to have candid conversations with harmed patients, although the regulation refers to 'representatives' of the organisation, who may therefore not be clinicians.

There are two parts to the statutory duty. First, reg 20(1) imposes a general requirement for 'registered persons' to be open and transparent with patients or their representatives about care and treatment. This reflects the aim of creating a culture of candour which is seen as crucial to improving patient safety. In the words of the influential Williams and Dalton report which argued strongly in favour of the duty: 'A culture of candour is a culture of safety, and vice-versa.'[52] Second, there are specific reporting requirements placed on providers in relation to 'notifiable safety incidents'. This is set out in reg 20(2) and involves notifying, apologising and supporting patients who have suffered harm as a result of such an incident. This includes providing them with an honest account of the facts about the incident, advice on appropriate further enquiries and must be followed up by written notification (reg 20(3) and (4)).

A key issue which dominated pre-legislative debate was in relation to setting the appropriate harm threshold for triggering the duty. Many who opposed the duty then argued in favour of confining it to cases involving death or severe harm. The argument that honesty should depend on the degree of harm suffered by patients was unprincipled and ultimately rejected by a Department of Health-commissioned review of the evidence and competing arguments. In a strongly worded report,[53] Professor Sir Norman Williams (then President of the Royal College of Surgeons) and Sir David Dalton, Chief Executive of an NHS trust, recommended that candour be extended to cases of moderate harm, where the bar has now been set. In fact, the term moderate is itself slightly misleading given that it includes significant harm such as 'unplanned return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area' (reg 20(7)). The duty does not apply to harm deemed to fall below moderate, or to near misses, with legitimate fears about the bureaucratic burden and defensive documentation around candour defeating this.[54]

51 J R Spencer, 'The Drafting of Criminal Justice Legislation – Need it be so Impenetrable?' [2008] Criminal Law Journal 585; D Greenberg, 'Dangerous Trends in Modern Legislation' (2015) (Jan) Public Law 96.

52 Dalton and Williams (n 9) 12.

53 Ibid.

54 D Berwick, *A Promise to Learn – A Commitment to Act* (National Advisory Group on the Safety of Patients in England August 2013) 34.

Regrettably, 'notifiable safety incident' is defined differently depending on whether care was provided by 'health service bodies' (organisations registered with the CQC such as hospital trusts) or 'other registered persons' (primary care organisations, dentists, private healthcare organisations and adult social services). In relation to 'health service bodies', notifiable safety incidents are defined as 'any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a healthcare professional, could result in, or appears to have resulted in' death, severe, moderate or prolonged psychological harm to the service user (para 8). In terms of primary care organisations, dentists, private healthcare organisations and adult social services, there is no requirement for them to inform patients about incidents which 'could' result in significant harm but haven't yet done so (reg 20(9)). According to the CQC, the 'definitions have been differentiated in this way to account for the different notification systems for health service bodies and all other providers. In doing so, they are intended to reduce the administrative burden caused by the introduction of this new statutory duty of candour.'[55] Whilst concerns about the additional workload associated with delivering candour are valid, it is nevertheless regrettable that the commitment to openness is potentially diluted in this context. For the duty to be effective in creating a culture of candour, it is imperative that all signs point in the same direction. Having such a distinction effectively permits a weaker form of candour outside of NHS secondary healthcare.

The statutory duty is enforced by the CQC, the health and social care regulator in England, as one of 13 'fundamental standards of care' it monitors. The CQC has no specific approach to monitoring compliance with the duty, but approaches it as part of its inspection of whether good care is being provided.[56] It claims to focus on whether systems are in place to deliver greater candour, as opposed to looking for specific breaches of the duty, although surely the latter would be good evidence of whether the system itself is effective. It has stated that such systems would include training and supporting staff to communicate with patients about safety incidents, and reporting systems which might include the recording of the duty of candour notification.[57] Regulatory action includes refusal or removal of registration, issuing warnings, special measures, fines and prosecution. Whilst prosecutions are likely to be rare, it is worth noting that breaches of the duty may be prosecuted without a warning notice being issued by the CQC. It is disappointing that the CQC has no statistics in relation to the implementation of a fundamental standard of care and no central training programme for enforcement. The lack of centralised records is a concern, although the CQC has been able to confirm that 15 actions have been taken against NHS trusts and 90 actions taken against primary care and private care providers in relation to failure to comply with the duty.[58] These are mainly in the form of 'requirement notices', for example, to provide adequate training to staff about the duty. Overall, the early evidence suggests a light-touch approach to regulating the duty, with concerns raised about a lack of detailed reference to candour in CQC inspection reports.

The bureaucratic process of delivering and monitoring candour risks losing sight of its grounding in ethical values. With this in mind, the Williams and Dalton review warned that:

55 CQC, *Regulation 20: Duty of Candour. Information for all Providers: NHS Bodies, Adult Social Care, Primary Medical and Dental Care, and Independent Healthcare* (CQC 2015) 9.

56 Ibid 7.

57 Ibid 10.

58 H Blythe, *Regulating the Duty of Candour: A Report by Action against Medical Accidents on CQC Inspection Reports and Regulation of the Duty of Candour* (AvMA 2015).

> A compliance-focused approach will fail. If organisations do not start from the simple recognition that candour is the right thing to do, systems and processes can only serve to structure a regulatory conversation about compliance. The commitment to candour has to be about values and it has to be rooted in genuine engagement of staff, building on their own professional duties and their personal commitment to their patients.[59]

Whether a compliance approach to candour will fail in practice remains to be seen. These are still early days for the legal duty and there is a need for research evidence to understand its positive and negative impacts. There is some limited anecdotal evidence that the duty has led to increased disclosure to patients and empowered staff to remind colleagues about the legal obligation.[60] For those who opposed the duty, such as medical defence organisations, the reliance on law and regulation was misconceived and might even exacerbate existing disinclinations to disclose. Without denying the possible negative impact of legal and regulatory interventions, it is important to understand that the tension between candour and concealment in medicine has been a persistent theme in medical practice for hundreds of years. Our next section will explain the existence of tensions around this issue long before litigation and insurance cultures could have contributed to the creation of a professional norm.

3 Lessons from history: cultures of truth-telling in medicine 1800–1950

As described above, Archer et al's recent comprehensive review of scholarship on the issue of disclosure of medical errors drew on work produced across relevant disciplines and methodologies, incorporating quantitative, qualitative and mixed-methods studies. It is our hypothesis that the findings of these modern empirical studies of medicine can be enhanced by also considering the works of historians of medicine and the medical profession on this issue. This will enable us to more fully understand the professional and cultural context in which any aversion or inclination to candour developed, prior to the emergence of insurance and litigation cultures in medicine.

This section considers debates over candour in medicine across the period 1800 to 1950. In the early nineteenth century, the medical profession in the UK took on a form recognisable today with the emergence of, what is often termed in historical accounts, 'hospital medicine'.[61] It is generally seen as a period of increasing professionalisation in medicine which was accompanied by important regulatory developments such as the first moves toward accreditation for practice and the concept of 'legally qualified practitioners' in the Apothecaries Act 1815.[62] It was also the period in which the forerunner to the British Medical Association was founded in 1832 as a professional interest group for medical doctors, by the middle decades of the century playing an active role in the regulation of the practice of medicine, via the Medical Act of 1858, which established the GMC.[63] Equally of importance for this inquiry, during the nineteenth century the

59 Dalton and Williams (n 9) 17.

60 P Walsh, 'Challenges and Opportunities for Patient Safety and Justice in the UK' (2018) 23(1) Journal of Patient Safety and Risk Management 7; J McHale, 'Patient Safety, The "Safe Space" and the Duty of Candour: Reconciling the Irreconcilable?' in J Tingle, C O Neill and M Shimwell (eds), *Global Patient Safety: Law, Policy and Practice* (Routledge 2018).

61 On 'hospital medicine', see E H Ackerknecht, *Medicine at the Paris Hospital, 1794–1848* (Johns Hopkins University Press 1967).

62 I Loudon, *Medical Care and the General Practitioner, 1750–1850* (Oxford University Press 1986).

63 Harry Eckstein, *Pressure Group Politics: The Case of the British Medical Association* (Allen & Unwin 1960); M J D Roberts, 'The Politics of Professionalization: MPs, Medical Men, and the 1858 Medical Act' (2009) Medical History 53.

practice of medicine became more akin to the medicine that is practised today. Hospital medicine, or 'modern medicine' emerged in Britain in the early 1800s and represented a revolutionary change, moving as it did away from the intimate relationship between practitioner and patient at the bedside, drawing on Galenic or constitutional theories that were specific to each patient and their own narrative of illness.[64] Histories of medicine that consider the issue of candour focus on either traditions of truthful reporting of failure to other doctors, or (less commonly) traditions of truth-telling to patients.

Early pioneers of modern approaches to medicine were hugely excited by the potential 'hospital medicine' presented for collating, refining and disseminating the results of medical experiments and treatments. Often this collectivising project in the service of improving medicine necessitated the reporting of failure. War was an important driver of this idea and the Napoleonic Wars (1803–1815) cultivated medical administrators such as Dr James McGrigor, Surgeon-General for the Duke of Wellington's army in Spain and Portugal during the Peninsular Wars (1808–14) and later Head of the British Army Medical Department, who used his powerful position heading a vast department treating thousands of sick and injured men to institute cultures of reporting among medical officers.[65] Statistics were collected and mined for useful data, but McGrigor also encouraged (and sometimes demanded) what we would now call case notes of treatments, both successful and failed, with the specific purpose of finding out what was effective or not and disseminating that knowledge throughout his department. For this to work, in a time when medicine was arguably 'less certain', it was important that failure was well documented. Thus, in the vast military medical enterprises of the early to mid-nineteenth century, strong cultures of reporting failure were developed. McGrigor's confidence in the importance of candid reporting to other practitioners is borne out in his published account of the Army Medical Department's work on the Egyptian Campaign in 1801:

> Humble as the labours may seem, and confined as the abilities of an individual may be, were he only faithfully to relate observations made with care, to compare them with those of his contemporaries, and by these to correct the opinions of his predecessors, he would perform no mean service to his art.[66]

Regularised returns and reports encouraged the candid discussion of failed experiments or attempts to combat disease, and encouraged a culture of openness regarding medical practice. Alongside this open culture, military norms allowed senior officers to push for regularisation of practice and the close surveillance of practitioners who were considered to be using treatments differing widely from consensus approaches:

> It is very desirable that an eye be kept on the cases of Hospital Gangrene which have been treated . . . by SS Burmeister, and that the final result of each be known. This mode of treatment is at variance with that which has ultimately been found successful in most of the Hospitals in the Peninsula.[67]

64 On 'neo-classical' medicine, see, N Jewson, 'Medical Knowledge and the Patronage System in Eighteenth Century England' (1974) 8 Sociology 369; for studies discussing the evolution of medicine in Britain at this time, see: R French and A Wear, *British Medicine in an Age of Reform* (Routledge 1991); C Hamlin, *Public Health and Social Justice in the Age of Chadwick, Britain 1800–1854* (Cambridge University Press 1998); C Lawrence, *Medicine and the Making of Modern Britain 1700–1920* (Routledge 1994); I Loudon, 'Medical Practitioners 1750–1850 and the Period of Medical Reform in Britain' in A Wear (ed), *Medicine in Society* (Cambridge University Press 1992).

65 C Kelly, *War and the Militarization of British Army Medicine 1793–1830* (Pickering & Chatto 2011) esp chs 3 and 5.

66 J McGrigor, *Medical Sketches of the Expedition from Egypt to India* (London 1804) 56–7.

67 Wellcome Library, Royal Army Medical Corps Collection, 799/6 (book II) 229: McGrigor to D I Higgins, 28 January 1814.

While failure was something about which there was a culture of 'candour' in an intra-professional sense within the military, those failures were also communicated to civilian medical audiences – for example, McGrigor published in medical journals about the successes and failures of military medicine. This replicated an existing culture in civilian medicine of case reports – often detailing failed interventions – in journals such as *Medico-Chirurgical Transactions*. A simple example of one of the hundreds of such reports to be found is as follows from the *Edinburgh Medical and Surgical Journal*:

> I. Case of Brachial Aneurism – Mr W.G. of East Aytoun, near Scarborough, was bled in the median basilic about the 20th October 1835, and unfortunately the point of the lancet penetrated the brachial artery. From the blood flowing per saltum it was apprehended that such was the case, and, in order to effect a cure, compression was employed, but without any effect, as in three weeks, a pulsating tumour, of the size of a hen's egg had formed at the elbow, bearing the usual cases of aneurism.[68]

In civilian medicine at this time, most surgery was performed in the presence of an audience, literally in a theatre. Thus, questions of candour or concealment of mistakes may have been moot, contributing to a broader culture of intra-professional candour. The public display of failure, however, was not without consequence. Botched operations, or perceptions of medical incompetence, could elicit much comment and debate in the pages of medical journals such as *The Lancet* and could even permeate the popular press.[69]

In a detailed study of mistakes in civilian medicine, 'Learning from Mistakes: Early Twentieth Century Surgical Practice 1900–1920',[70] Wilde and Hurst consider the work of Archibald Watson, an Australian doctor who had been educated in Gottingen and Paris, was a Fellow of the Royal College of Surgeons of England, and professor of anatomy at the University of Adelaide. He made an extraordinary contribution through his observation and note-taking on thousands of surgical operations in Australia, as well as in South Africa, the USA and in Britain. He used his notes in teaching, and one student recalled that he would 'illustrate his subject with unqualified descriptions of the surgical triumphs and disasters' he had witnessed.[71] Watson's focus was on difficult or 'elite' surgery, but nonetheless by the sheer volume of cases he witnessed, his records enable the modern reader to glean a strong sense of surgical practices and cultures at the time. Watson criticised others but was also very critical of himself. Wilde and Hirst argue that his diaries are good evidence that many 'adverse events' we experience now – such as postoperative bleeding after tonsillectomy – were also experienced by early twentieth-century surgeons and patients. Watson also recorded many professional arguments about the best way to perform operations, which, as Wilde and Hirst explain, demonstrates the difficult tension present when investigating 'failure' – it can be hard to draw the line between a clear error and a practice which was a matter for legitimate debate. Watson's journals reveal that debates over best practice were often carried on loudly among the medical audience of operations at the Mayo Clinic. As Wilde and Hirst point out 'Doing things the "right way", and finding better ways to do things, were overlapping categories;

68 'Report of Various Surgical Cases' (1839) 140 EMSJ 139.

69 For an example, see discussion of the case of Bransby Cooper in M Brown, '"Bats, Rats and Barristers": The Lancet, Libel and the Radical Stylistics of Early Nineteenth-century English Medicine' (2014) 39 Social History 182.

70 (2009) 64 Journal of the History of Medicine and Allied Sciences 38.

71 Ibid 46.

but it is often difficult or impossible to draw any distinction at all between doing things the wrong way and failed attempts to find a better way to perform an operation.'[72]

Watson was well known by his peers for his critical observation of surgical operations and his pull-no-punches style. However, it is clear from Wilde and Hirst's study that his candour was not resented by his colleagues, or the surgeons he observed. On the contrary, Wilde and Hirst show that the profession embraced Watson's searing honesty – in 1899 he gave a paper to the gynaecology and obstetrics division of the Australian Medical Congress, entitled 'The Saving of Blood in Gyneaecological Operations'. His lecture drew heavily on his records of mistakes, and what not to do, from his notebooks. The lecture was received with a strong positive reaction, indeed doctors in the room 'fell over themselves to pay tribute' to him and his contribution to their art. From this we can surmise that at least in an 'intra-professional' context the majority of surgeons were open to the importance of discerning and learning from mistakes. Importantly, however, Watson did not publish what he saw; his observations and critiques were passed on by word of mouth. In the small number of cases where Watson did identify a fatal technical error being made, 'none of those responsible was called to account to anyone except their immediate peers and their consciences'.[73]

The notion that observation of failure was important, but to be kept strictly within the profession, is reinforced by other historical studies such as Sally Wilde's work on the diaries of Sydney urologists, John Laidley and Malcolm Earlam, and their study trips to Britain and North America in the 1930s and 1940s. Based on these diaries, Wilde concludes that different forms of candour were considered important and that some forms of concealment were considered highly unethical and punished within professional networks and structures: 'evidence of dishonesty was treated with a shrug and a metaphorical "cold shoulder", while evidence of honesty about bad results was greeted with warm approbation'.[74] Importantly, however, these sanctions were still very much held within the professional sanctum. Similarly, histories detailing the work of Harvey Cushing, the pioneering neurosurgeon, emphasise his practice of writing up case notes and publicising his errors in the hope of educating others.[75] The American Surgeon Ernest Codman took the concept further and developed what he called the 'end-result-system', based on the notion 'that every hospital should follow *every* patient it treats long enough to determine whether or not the treatment has been successful and if not, ask "why not?" with a view to preventing similar failures.'[76]

These historical studies build a picture of a medical profession which embraced the importance of intra-professional candour for the improvement of medicine; based on peer observation, recording of failure and following up on patients. An important distinction is drawn out by the professional reaction to Codman, who advocated *public reporting* of deficiencies in medical work – including an assessment of reasons for the failure of the treatment. Unlike Watson, he faced some considerable opposition. By replacing individual conscience with documented competence as a basis for clinical evaluation, Codman was thought to be challenging the moral and professional autonomy

72 Ibid 52.

73 Ibid 58.

74 S Wilde, *The History of Surgery: Trust, Patient Autonomy, Medical Dominance and Australian Surgery 1890–1940* (Finesse Press 2011) 132.

75 R L Pinkus 'Mistakes as a Social Construct: An Historical Approach' (2001) 11(2) Kennedy Institute of Ethics Journal 117; M Bliss, *Harvey Cushing: A Life in Surgery* (Oxford University Press 2005).

76 E A Codman (1984) xii, quoted in V A Sharpe and A I Faden, *Medical Harm: Historical, Conceptual and Ethical Dimensions of Iatrogenic Illness* (Cambridge University Press 1998) 29.

of the physician. However, despite its unpopularity with many doctors, his work gained credibility in 1916 when the American College of Surgeons incorporated his Committee on Hospital Standardization, an attempt to study and improve hospital outcomes, and it was his work which led to early moves towards accreditation and hospital quality measures in the USA in the 1950s.

In contrast to the reasonably well-settled professional view on intra-professional candour described above, the question of whether doctors should be candid with their patients has always been more fraught. In a more recent study Gallagher et al reported that:

> Physicians agreed that harmful errors should be disclosed but 'choose their words carefully' when telling patients about errors. Although physicians disclosed the adverse event, they often avoided stating that an error occurred, why the error happened, or how recurrences would be prevented. Patients also desired emotional support from physicians following errors, including an apology. However, physicians worried that an apology might create legal liability.[77]

However, it is questionable whether legal liability on its own provides the central plank of professional resistance to candour to patients at the turn of the nineteenth century. As Wilde describes:

> . . . when things went wrong there was an inclination from the courts and from the press to trust that those concerned did their best, and there was an almost fatalistic acceptance of poor outcomes. Surgeons were seldom called to account for themselves before either the court of public opinion, or via civil litigation.[78]

Despite the low risk of litigation, professional anxiety about candour to patients was exemplified at this time through commentary in Frederick Treves' *Manual of Operating Surgery* 1892, 'the leaving of a sponge or instrument within the peritoneal cavity is a catastrophe which no surgeon would feel greatly disposed to make public'.[79] Claire Brock suggests this is indicative of the 'level of secrecy surrounding such incidents' within the professional culture of the time,[80] but it may be that she draws too long a bow, and instead this quote is more solid evidence of an acknowledgment of the devastating impact of such a revelation on the professional reputation (and thus livelihood) of the doctor.

The issue of how doctors approached telling patients about errors historically can be difficult to glean – it is not common for historical actors to leave extensive evidence of secrets and concealment. The sources above give us insight into the anxieties of the profession, but much of what we know of historical traditions of candour to patients in medicine or debates about its importance comes from studies of consent to treatment and, so, often relate to candour prior to treatment and focus on the experience of the patient. Much of the literature on consent builds on or responds to Jay Katz's seminal work *The Silent World of Doctor and Patient* in which he claimed that 'disclosure and consent, except in the most rudimentary fashion, are obligations alien to medical thinking and practice'.[81]

A more sympathetic perspective on the development of candour-led dialogue between doctor and patient is advanced by Andreas-Holger Maehle, who coins a useful term in his research on doctor–patient dialogues and questions of consent and

77 T H Gallagher, A D Waterman et al, 'Patients' and Physicians' Attitudes regarding the Disclosure of Medical Errors' (2003) 289(8) Journal of the American Medical Association 1001.

78 Wilde (n 74) 33.

79 F Treves, *Manual of Operating Surgery* vol II (Cassell & Company 1892) 234.

80 Claire Brock, 'Risk, Responsibility and Surgery in the 1890s and Early 1900s' (2013) 57(3) Medical History 317, 322.

81 Jay Katz, *The Silent World of Doctor and Patient* (The Free Press 1984) 1.

truthfulness when he refers to 'medical traditions of truth-telling'. He points to long-held ideas about the constitution and emotional state of the patient, and the notion that doctors should not 'alarm and harm' those in fragile conditions. While families of patients might be given a more candid assessment of the patient's condition and prognosis, 'restricted truth telling' was often seen to be in the best interest of the patient throughout the eighteenth and nineteenth centuries.[82] This attitude was reflected in Percival's Statement of Medical Ethics published in 1803 in which it was stated that there were cases where telling the truth might even kill the patient and in that circumstance 'the practitioner shall sacrifice that delicate sense of veracity . . . to this claim of professional justice and social duty'.[83]

In another study of this issue which pushes back against the trope that candour is alien to the medical profession, 'Truth, Trust, and Confidence in Surgery', Sally Wilde considered questions of candour and consent in the context of the 'dramatic rise in the range of surgical procedures that doctors . . . were prepared to attempt'[84] during a period of intense surgical innovation and development at the beginning of the twentieth century. Along with this rise in the number of procedures was a dramatic rise in the number of people who were prepared to undergo them. In this piece Wilde challenges the received view that patients lacked autonomy in this period and, importantly, that doctors didn't care about it. She argues that consent and trust, especially from private paying patients, was won through communication between doctors, patients, their families and friends. Her study considers published case reports in the 1890s from two hospitals (one in London, one in Brisbane, Australia). She notes in this period (mirroring medical print culture described in the 1800s above) that doctors publicised their successful operations, as well as those ending in death, and suggests that this was a way of publicly explaining or making excuses for failures. She argues there were many cases where consent was given, even from some public patients who admittedly had less autonomy than their fee-paying counterparts. While consent was often recorded, records of provision of information to patients about the dangers of the operation are rare but quite often present where the operation was particularly dangerous, exploratory or experimental.[85] In addition she highlights the scrutiny surgeons were under from coroners' courts, the press, their peers and also from patients who sued or refused to pay when they didn't like the outcome. Instead of building a culture centred on secrecy and litigation avoidance, in Australia this prompted a consensus view that full disclosure of risks prior to treatment was the best way for doctors to protect themselves and, Wilde argues, also bred a culture of trust between doctor and patient more generally.

Moving forward in time we continue to see historical studies that emphasise the nuanced cultures of truth-telling in medicine, and which problematise the professional, cultural and reputational aspects of professional hesitation. In his seminal 1970 study, *Forgive and Remember: Managing Medical Failure*, Charles L Bosk reported on his investigation of a major teaching hospital in America.[86] This is one of the only studies of this time that directly looked at errors and the practicalities of self-regulation in surgery. Mirroring the

82 A H Maehle, 'Silence or Negotiation? Doctor Patient Dialogue and the Questions of Consent and Truth in Late Nineteenth Century England' Social History of Medicine Conference, Liverpool 2018.

83 T Percival, *Medical Ethics: Or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons* (S Russell 1803) 166.

84 S Wilde, 'Truth, Trust, and Confidence in Surgery, 1890–1910' (2009) 83 Bulletin of the History of Medicine 302–330, 302–3.

85 Ibid 315.

86 (University of Chicago Press 1970).

observations of Wilde in the nineteenth century, Bosk noted that doctors perceived strong distinctions between technical errors and breaches of the 'moral code of surgery' – or what he termed normative errors. Echoing the attitude of his historical forbears, technical errors were perceived as inevitable and provided learning opportunities attracting only minor penalties, if punished at all. Normative errors, including dishonesty and the hiding of mistakes, were perceived as more serious – reflecting on the character and trustworthiness of the doctor concerned and, in Bosk's observation, not often forgiven.

Cumulatively, the historical studies considered above show that the medical profession has long embraced the clinical importance of learning from mistakes and thus favoured intra-professional candour. However, it is also apparent that the profession has not been united on the need for an equivalent approach to patients.

Conclusion

It is an easy reflex to turn to the effects of insurance requirements and the zero-sum game of adversarial litigation as explanations for the emergence of non-candid cultures in medicine today. However, it is unlikely that, historically, those are the only reasons for the emergence of a professional culture which doesn't seem to fit with candour. It may well be that notions of what 'failure' is and what it means (or does not mean) about expertise, about the dynamic of trust and power within the therapeutic relationship, and about the relationship of the medical profession with the public have as much to do with it. All the historical studies that touch on the question of candour from doctors to patients highlight complexities in the medical profession's attitude. While it appears that informal professional sanction and disapprobation could be, and often was, seen as an appropriate response to any dishonest behaviour, such as actively hiding mistakes, there has traditionally been very little support for a norm requiring candour about mistakes to patients. While cultures of truth-telling have been important and perceived as important to the mission of medicine for several hundred years, historically, it appears that the central debate for doctors, even in the absence of insurance and litigation, was not whether it was important to observe, reflect and honestly discuss failure, but whether it was necessary (or helpful) to do so with patients. One of our concerns about the duty of candour is that its legal complexity could erode the historically strong commitment of practitioners to openness amongst themselves about failure as a cooperative learning project in medicine.

The duty of candour as enacted seems a blunt and confusing instrument with which to unpick the various barriers for medical professionals identified in this article. Although there are early signs that the duty has provided some support to professionals who already have a strong commitment to the principle, the confusing, convoluted and highly legalistic and fragmented construction of the duty creates another obstacle for any health practitioner already intimidated by the potential consequences of a candid disclosure. Even the far-reaching and onerous connotations of the word 'candour' itself have the potential to put off the uncertain practitioner considering disclosing an adverse event. The enduring problem of defining medical failure is likely to be played out again in terms of agreeing the boundaries of notifiable safety incidents, especially in terms of what is appropriately deemed 'unexpected'. The recent decision in *Montgomery v Lanarkshire Health Board* places significant emphasis on ongoing and engaged dialogue between patient and clinician.[87] It may be that a similar approach to discussion of adverse events within the complex system of a healthcare episode, rather than a laser focus on the single incidence

87 [2015] UKSC 11, [2015] 2 WLR 768.

of an individual's failure, could provide healthcare workers with a more accessible way to contextualise an incident and engage in a conversation about it with affected patients and their families. For the duty to work, its operation and requirements need to be clearer, less legally impenetrable, and give more reassurance to healthcare workers about the relationship between a candid disclosure and legal liability. Regulators need to consider the profession's historical commitment to reducing failure through intra-professional candour in contrast to its aversion for candour with patients. Such attitudes reflect an unsurprisingly surgical need for empirical evidence of therapeutic benefit to motivate disclosure and could signal strategies more likely to attract professional approbation.

NILQ 70(1): 93–109

'My child, my choice': parents, doctors and the ethical standards for resolving their disagreement

DAVE ARCHARD*

Queen's University Belfast

Abstract

Disagreements between doctors and parents as to the appropriate treatment of a child have been exacerbated by a number of recent developments, especially the use of the internet. In normative terms there has been a popular assertion of a parent's right to choose the treatment of his or her child and this has been defended in the bioethics literature, often in the context of a preference for a harm over a best interests principle for adjudicating these differences. This article affirms the centrality of a best interest standard and criticises arguments for giving parental views a certain moral weight based upon the view that parents know best, or on the interests of the parents, or as consistent with the use of child protection principles, or in value uncertainty.

Keywords: best interests; harm; threshold; trigger; proprietarian; parental discretion; interests; value uncertainty.

Introduction

Recent high-profile cases arising from unresolved disagreements between doctors and parents as to how the latter's children should medically be treated might suggest that conflict is now the norm in paediatric practice. These four cases – Ashya King, Charlie Gard, Isaiah Haastrup and Alfie Evans – are well-known and much discussed.[1] The use of the courts to make a final determination of what should be done compounded the existing divisions between the parties. Any legal resolution of the issues is public and pits the disagreeing parties against one another in antagonistic fashion. Such judicial resolutions of the disagreement may well be final. Yet at the same, they may only serve to confirm an abiding sense of tragic loss, deep frustration at the outcome and an irretrievable, rancorous breakdown of relations between the litigating parties.

* School of History, Anthropology, Philosophy and Politics; d.archard@qub.ac.uk.

1 *Portsmouth City Council v (1) Nagmeh King (2) Brett King (3) Southampton Hospital Trust (4) Ashya King (by his Children's Guardian)* [2014] EWHC 2964 (Fam); *Great Ormond Street Hospital v (1) Constance Yates (2) Chris Gard (3) Charles Gard (a Child by his Guardian Ad Litem)* [2017] EWHC 972 (Fam); *King's College Hospital NHS Foundation Trust v (1) Takesha Thomas (2) Laure Haastrup; (3) Isaiah Haastrup* [2018] EWHC 127 (Fam); *Alder Hey Children's NHS Foundation Trust v (1) Thomas Evans (2) Kate James (3) Alfie Evans (a Child by his Guardian)* [2018] EWHC 308 (Fam).

Nevertheless, it is important to add the following. First, partnership in decision-making is not an impossible ideal. Such evidence as there is suggests that discussions between parents and doctors as to the best treatment of a child, even in end-of-life cases, need not result in conflict. A study of the Rapid Response work of the Clinical Ethics Service at Great Ormond Street Hospital showed that of 203 cases in which doctors recommended the withdrawal of treatment from children in intensive care, 186 cases yielded agreement after discussion with the parents, and further discussions produced resolution in six of the remaining 17.[2]

Second, at the same time, a combination of factors has encouraged parents to challenge the views of doctors and to pursue alternative forms of treatment. Most obviously, access to the internet and to social media have given parents the means to research and share with other parents treatment options, to crowd-fund such treatments as might be thereby disclosed, and to publicise both their disagreement with doctors and their own preferred options of care.[3]

These factors merit further extended discussion. However, what will be considered here is the emergence of a view – one that these factors undoubtedly gave particular emphasis to – that parents should be permitted to make the final decision as to what care is appropriate for their child. The supposed corollary of that view – that doctors should make such decisions – is then regarded as an illicit detention of the child by health professionals against the will of the child's parents. These two views found popular expression in slogans on posters or in public statements by support groups at the time of the *Charlie Gard* case. 'My child, my choice'[4] was one such slogan, and a spokesperson for Charlie Gard's parents said of the court's decision, in that case to cease treatment, that it was tantamount to Charlie being 'taken prisoner by the NHS and by the state'.[5]

These views can be contrasted with the view which holds that, where there is disagreement between doctors and parents, what ought medically to be done for any child is what is in the child's best interests. Indeed, that should be the sole decisive consideration. What is determined to be in a child's best interests may be what the parents want, but it need not be. Crucially, what is important is what is best for the child, not what either doctors or parents want.

In what follows I want to defend this view against the emergent view of parental rights of choice. I will do so by casting doubt on such reasons as have been given for thinking parents should be free to choose their child's medical care and by making clear why it is important to see best interests as the appropriate standard for medical decision-making in the context of disagreement. I shall regard the most plausible alternative

2 Joe Brierley, Jim Linthicum and Andy Petros, 'Should Religious Beliefs be Allowed to Stonewall a Secular Approach to Withdrawing and Withholding Treatment in Children?' (2013) 39(9) Journal of Medical Ethics 573–7.

3 Tessa Richards, 'When Doctors and Patients Disagree' (2014) British Medical Journal 349–50; Brynn K Wainstein et al, 'Use of the Internet by Parents of Paediatric Patients' (2006) 42 Journal of Paediatric Child Health 528–32; Neera Bhatia, 'Three Ways the Charlie Gard Case Could Affect Future End-of-life Cases Globally' (*The Conversation*, 25 July 2018) <https://theconversation.com/three-ways-the-charlie-gard-case-could-affect-future-end-of-life-cases-globally-81168>. See also, Bernadette Richards, 'Social Media: The Unnamed Plaintiff' (2018) Journal of Bioethical Inquiry (2018) <www.semanticscholar.org/paper/Social-Media%3A-The-Unnamed-Plaintiff.-Richards/572b1b5649d65c22738242c47250515880da4ca6>.

4 'Reality Check: Why Don't Charlie Gard's Parents Have the Final Say? ' (*BBC News*, 14 July 2017) <www.bbc.co.uk/news/uk-40600932>.

5 'Gard Spokesperson: Baby Charlie is Effectively "a Prisoner of the State"' (*Sky News*, 16 July 2017) <https://news.sky.com/story/gard-spokesperson-baby-charlie-is-effectively-a-prisoner-of-the-state-10949732>.

standard to best interests as that which permits parents to make decisions for their children so long as they do not, in making such choices, cause or seriously risk causing significant harm to the child. In the interests of simple expression, I shall thus contrast a 'best interests' and a 'harm' standard or principle.

Crucially, what follows is *not* an essay in the legal interpretation of the relevant cases. It is not about whether the judgments in these are correctly argued. Rather it is an exercise of normative jurisprudence. It asks the question: what moral – rather than juristic – reason might there be for thinking that parents do have the right to make medical decisions for their children, or that something other than the interests of the child is the appropriate way to resolve disagreements between doctors and parents? Reference will be made to legal cases, but in order to illustrate what is here argued to be of normative relevance and importance. If judges are cited it is not to the end of showing their legal judgment to be the right one, but rather as providing good expressions of the underlying principle that is defended here. The conclusion of this essay is that best interests should continue to be what it is stated, in the words of Baroness Hale cited below, to be, namely the law's 'gold standard' for adjudicating disagreements between parents and doctors.

In this spirit let me cite at the outset some clear legal statements of the centrality of the best interests standard. In the *Charlie Gard* case at appeal McFarlane LJ stated:

> As the authorities to which I have already made reference underline again and again, the sole principle is that the best interests of the child must prevail and that must apply even to cases where parents, for the best of motives, hold on to some alternative view.[6]

In the case of Alfie Evans the appeal judges stated that the decision as to what treatment Alfie should receive 'must be governed by an objective assessment by the court of what is in the child's best interests'.[7] They cited Baroness Hale's view in the Supreme Court that in such cases the best interest principle is the 'gold standard' by which decisions as to what shall be done for a child medically must be adjudicated.[8] What follows now is an ethical vindication of the claim that the best interests standard is indeed gilded.

The liberal family and parental rights

I start with a simple-minded, and simplified, model of the role of parents in the care of children, one that operates within what can be broadly characterised as liberal democratic societies.[9] This is that children fare best if their upbringing is entrusted in the first instance to some adults who discharge a duty of care. It is further thought that this duty is discharged by the provision of certain goods (such as a safe and secure environment in which the child might develop) and by the exercise of parental choices – as to such matters as food, play, television viewing, bedtime reading and culture – to the exclusion of others and in private. It is for the parents to make these choices and for them to do so in the absence of supervision and monitoring of their parental activities.

6 *Great Ormond Street Hospital for Children NHS Foundation Trust v Yates* [2017] EWCA Civ 410, per McFarlane LJ, para 112.

7 *Alder Hey Children's NHS Foundation Trust v Evans* [2018] EWCA Civ 805, per Davis, King, and Moylan LJJ, para 67.

8 Ibid para 34.

9 David Archard, *The Family: A Liberal Defence* (Palgrave Macmillan 2010).

Within contemporary English-speaking moral and political philosophy this liberal model is generally endorsed.[10] It is essentially a model of the family minimally understood as an institution in which some adults[11] undertake responsibility for the care and upbringing of a particular child or children. Nevertheless, the family thus understood can take a number of different familial forms.[12]

The liberal model is thus neutral on questions of how many adults may be parents, on the question of the gender and marital status of the parent, and on their genetic relation to the children. It is consistent with different accounts of how adults get to be parents of any particular child. It can be defended in terms of the value to individuals of acting as parents,[13] or by the thought that alternatives to the family – such as collective-rearing institutions – are appallingly bad.[14]

The important point to make is that no one who endorses the liberal model believes that parents are free to make any choice for the child in their care. Some indeed believe that parents should be constrained so as not to impose on their child any particular life view, such as a set of religious beliefs. They should not 'enrol' children into any such view,[15] or must ensure that children have an 'open future'.[16] But at a minimum parents are not entitled to act contrary to the interests of those in their care.

For instance, it is perfectly possible to view adults as deriving value from being parents whilst insisting that the terms of permissible parenting are given in the first instance by what serves the interests of children. Thus, Brighouse and Swift, who defend this view of why parents should be allowed to make decisions for their children, are clear that parents are to be viewed as trustee or fiduciary rights-holders, possessing and exercising such parental rights as they do because these rights are instrumental to the well-being of those for whom they act as trustees, in this instance children: 'Parents' rights over their children – what others have a duty to let them do to, with, or for those children – are justified, at root, by the children's interests, not those of their parents'.[17]

This is important. Allowing that people should be parents where this means making choices – in private and free of interference from others – of how children within their care are brought up does not amount to the grant to parents of a general permission to make any choice in respect of those children's care. It is an entrusting to adults of a right or permission to make choices for children that is justified in the last analysis by the welfare or interests of those children.

10 Harry Brighouse and Adam Swift, *Family Values: The Ethics of Parent–Child Relationships* (Princeton University Press 2014); John Bigelow, John Campbell, Susan M Dodds, Robert Pargetter, Elizabeth W Prior and Robert Young, 'Parental Autonomy' (1988) 5(2) Journal of Applied Philosophy 183–96; Ferdinand Schoeman, 'Rights of Children, Rights of Parents, and the Moral Basis of the Family' (1980) 91 Ethics 6–19; David Archard, *Children, Rights and Childhood* (3rd edn, Routledge 2015) Part III 'Children, Parents, Family and State'.

11 'Adults' is understood as including the possibility of a single adult.

12 David Archard, 'Family and Family Law: Concepts and Norms' in Elizabeth Brake and Lucinda Ferguson (eds), *Philosophical Foundations of Children's and Family Law* (Oxford University Press 2018) 59–72.

13 Brighouse and Swift (n 10).

14 Veronique Munoz-Dardé , 'Is the Family then to be Abolished?' (1999) XCIX Proceedings of the Aristotelian Society 37–56.

15 Matthew Clayton, *Justice and Legitimacy in Upbringing* (Oxford University Press 2006).

16 Joel Feinberg, 'On the Child's Right to an Open Future' in William Aiken and Hugh LaFollette (eds), *Whose Child?* (Rowman & Littlefield 1980) 124–53.

17 Brighouse and Swift (n 10) 54.

Thus, on the liberal model of the family, the standard view of the limits of parenting is that a parent who occasions or risks causing serious harm to a child in his or her care should be subject to officially sanctioned measures. These can run from regular or ongoing monitoring, through the temporary removal of children from their care, to the re-allocation of parental responsibilities to other adults. This is both the justification of and the specification of the form taken by child protection within a liberal society. The state acts as *parens patriae*, entrusted with the safeguarding in the final analysis of the interests of the weakest members of its citizenry.[18]

Significantly, child protection on this model is normally action taken *after* the children have been initially allocated to their parents. It thus falls short of *ex ante* parental licensing defended by some philosophers[19] that would deny anyone deemed to risk seriously harming a child in their care the opportunity to be a parent.

Even the USA, which is seen as constitutionally enshrining a principle of parental libertarianism, does not endorse unconstrained parental choice. It is true that US Supreme Court judgments have expressed the ideal of parental rights and the sanctity of the family. A classic example is *Meyer v Nebraska* (1923), which concerned a prohibition on the teaching of a foreign language by a parent to his child. The court held that such a prohibition violated the Fourteenth Amendment to the Constitution that affirms: 'No State shall . . . deprive any person of life, liberty, or property, without due process of law.' The court took that liberty to denote:

> . . . not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, *establish a home and bring up children*, to worship God according to the dictates of his own conscience and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.[20]

It thus set the liberty of parenting on all fours with freedom of conscience and religion.

Yet, US Supreme Court judgments have also emphasised what parents cannot do. They have done so inasmuch as they recognise that the liberty of adults to make life choices that are self-harming does not encompass a freedom to make choices that are harming of those in their care.

There is thus a classic judgment to be found in *Prince v Massachusetts* [1944]. The case arose from the actions of a Jehovah's Witness, Sarah Prince, who took a nine-year-old girl under her care onto the streets to distribute religious literature in exchange for voluntary contributions. She thereby violated child labour laws, and the Supreme Court in upholding her conviction clearly affirmed that parental authority over a child is not absolute and can be restricted if the parent, or guardian, is acting against the child's

18 Classic statements of the liberal standard of child protection include: Richard Bourne and Eli H Newberger, '"Family Autonomy" or "Coercive Intervention"? Ambiguity and Conflict in the Proposed Standards for Child Abuse and Neglect' (1977) 57 Boston University Law Review 670–706; M D A Freeman, 'Freedom and the Welfare State: Child-Rearing, Parental Autonomy and State Intervention' (1983) Journal of Social Welfare Law 70 –91; Michael Wald, 'State Intervention on Behalf of "Neglected" Children: A Search for Realistic Standards' (1975) 27(4) Stanford Law Review 985–1040. A classic account of how the liberal standard works in practice is Robert Dingwall, Joen Eekelaar and Topsy Murray, *The Protection of Children: State Intervention and Family Life* (2nd edn, Quid Pro 2014).

19 Hugh LaFollette, 'Licensing Parents' (1980) 9 Philosophy and Public Affairs 182–97 and 'Licensing Parents Re-visited' (2010) 27(4) Journal of Applied Philosophy 327–43; Andrew J Cohen, 'The Harm Principle and Parental Licensing' (2017) 43(4) Social Theory and Practice 825–49.

20 262 US [1923] 390, 399; emphasis added.

interests. The judges memorably stated: 'Parents may be free to become martyrs themselves. But it does not follow that they are free in identical circumstances to make martyrs of their children before they have reached the age of full and legal discretion when they can make that decision for themselves.'[21]

The slogan 'My child, my choice' is thus attractively simple, but it is also evidently and deeply mistaken. Interestingly, it may echo a familiar maxim employed by pro-choice feminists, 'My body, my choice'. This was intended to give expression to the idea that woman have reproductive autonomy and may justifiably decide to terminate a pregnancy. However, most philosophical accounts of personal autonomy do not speak about the body,[22] and the idea of personal autonomy seems distinguishable from that of bodily ownership.[23] Moreover, those opposed to abortion can easily respond that any putative rights to ownership of one's own body are constrained by the rights of others, in this case that of the unborn child within a woman's body. Parents do not have rights over their children as they do over their own bodies. Moreover, parents do not own their children. This is so even if the 'proprietarian' view of parents as owners of their offspring can be found in Roman law[24] and has found some favour with a few philosophers.[25] Yet, the emergence of a recognition that children are independent persons with rights has been correlate with a decline in parental rights.[26] In sum, a parent cannot choose for a child simply because that child is the parent's. 'This is my own child' does not mean, nor does it imply 'This is a child that I own.'

The harm principle and best interests

The foregoing sketch of the liberal model of the family in which the harm standard is the basis of the limits of permissible parenting might suggest the following. That standard should be the means of adjudicating disagreements between doctors and parents. In other words if parents lose their right to parent only if they cause or risk serious harm to their children, then their decisions as to the treatment their child receives should be respected so long as these do not infringe the harm principle.

To show that this implication is mistaken and to defend the view that it is a best interest principle that should operate to adjudicate medical disagreements, I will argue the following. First, I distinguish how and why the harm standard differs from the best interest standard. Second, I critically evaluate the reasons that have been given for favouring the harm standard over the best interest standard in cases of disagreement.

The harm principle is a threshold trigger principle that licenses legal intervention into the lives of citizens. Its canonical expression in respect of adults is to be found in John Stuart Mill's *On Liberty* where it is stated that the state may only interfere with the actions

21 321 US [1944] 158, 170.

22 Sarah Buss and Andrea Westlund, 'Personal Autonomy' *The Stanford Encyclopedia of Philosophy*, Edward N Zalta (ed) (Spring 2018 edn, Stanford University) <https://plato.stanford.edu/archives/spr2018/entries/personal-autonomy>.

23 David Archard, 'Informed Consent: Autonomy and Self-ownership' (2008) 25(1) Journal of Applied Philosophy 19–34.

24 W L Lacey, '*Patria Potestas*' in B Rawson (ed), *The Family in Ancient Roma: New Perspectives* (Croom Helm 1986) 120–44.

25 Jan Narveson, *The Libertarian Idea* (Temple University Press 1998) 272–4; Edgar Page, 'Parental Rights' (1984) 1(2) Journal of Applied Philosophy 187–203; B Hall, 'The Origin of Parental Rights' (1999) 13(1) Public Affairs Quarterly 73–8.

26 John Eekelaar, 'What are Parental Rights?' (1973) 89 Law Quarterly Review 210–34; Susan Maidment, 'The Fragmentation of Parental Rights' (1981) 40(1) Cambridge Law Journal 135–58.

of individuals 'to prevent harm to others'.[27] Mill was clear, as others have been subsequently, that children need to be protected against the injurious actions of others as well, unlike adults, as their own actions.

Thus, the harm principle specifies a level of parental care, the falling below of which sets into operation measures of child protection. When, but only when, parents cause or risk causing serious harm to their children, can state agencies intervene into the family and take appropriate measures to protect the child from further actual or risked harm. What measures are subsequently judged appropriate may then be determined by a best interests principle. The best interests principle is not then, as Douglas Diekema understands it, a 'threshold principle for intervention' in the same way as a harm principle.[28]

The best interests principle and a harm principle do not conflict or offer themselves as alternative standards, since they are used to make essentially different decisions: whether there shall be intervention into the life of a family to protect a child and how, afterwards and in the wake of that intervention, the child shall be cared for.

It should be added that the temporal language used in the making of the distinction should not suggest that there is a simple chronological order by which an initial intervention is then succeeded by a disposal of the child. One and the same intervention could be triggered by an occasioning of harm and be directed to the promotion of the harmed child's best interests.

This important distinction in the way that the two standards function can be justified as follows. We should not hold parents in their quotidian care of any child to a duty of providing only such care that is in the best interests of a child. Parents must provide a reasonable level of care. They are not required always and only to do what maximises the welfare of any child in their care. They need not be held liable for not choosing the best education, best leisure activities, food, and so on. Such a requirement would be unreasonably and unfeasibly demanding. At the very least, it would involve parents self-sacrificially failing to consider their own interests.[29]

However, no one who outlines and defends what has been termed the liberal model of parenthood and the associated liberal standard of justified intervention into family life believes that parents *are* required to do what is best for their children; indeed, they may do considerably less. Yet, when they do significantly harm their children (or risk doing so), then, but only then, may the state and its agencies interfere to protect the child. Bearing in mind the statement made at the outset that judges are cited not to the end of showing their legal judgment to be correct, but rather as providing good expressions of underlying principles, the following is a wonderfully clear and eloquent statement of the view defended here. Hedley J, who, in turn, had quoted Lord Templeman's view that, 'It matters not whether the parent is wise or foolish, rich or poor, educated or illiterate, provided the child's moral and physical health are not in danger',[30] comments:

27 John Stuart Mill, *On Liberty*, Gertrude Himmelfarb (ed with introduction) (Penguin 1974 [1859]) 'Introductory'.

28 Douglas Diekema, 'Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention' (2004) 25 Theoretical Medicine 243–64.

29 E Salter, 'Deciding for the Child: A Comprehensive Analysis of the Best Interest Standard' (2012) 33 Theoretical Medicine and Bioethics 179–98.

30 *Re KD (a Minor Ward) (Termination of Access)* 1 AC 806, [1988] 2 FLR 139, 812 and 141.

> There are those who may regard that last sentence as controversial but undoubtedly it represents the present state of the law in determining the starting point. It follows inexorably from that, that society must be willing to tolerate very diverse standards of parenting, including the eccentric, the barely adequate and the inconsistent. It follows too that children will inevitably have both very different experiences of parenting and very unequal consequences flowing from it. It means that some children will experience disadvantage and harm, while others flourish in atmospheres of loving security and emotional stability. These are the consequences of our fallible humanity and it is not the provenance of the state to spare children all the consequences of defective parenting. In any event, it simply could not be done.[31]

Yet, Hedley J is also explicit that the law should intervene when it is satisfied that the child is subject to or at risk of significant harm.

The general basic point is worth re-emphasising. The law should acknowledge that it is on the whole and on balance best that parents should rear children, whilst also accepting that parents will differ greatly in their abilities to do so. Most if not all will fail to do what is best for their child. Yet, the state may only intervene into family life to protect a child when parental standards of care fall below a threshold of significant harm.

The crucial difference between a harm and a best interests standard should be spelled out. To harm another, on a familiar and generally endorsed view within moral philosophy, is to 'set back' a person's interests from what they would otherwise be or should be in the normal course of events.[32] It is essentially to make someone worse off. By contrast, to act in another's best interests is to promote those interests to the greatest degree possible. It is essentially to ensure that someone is as well off as they can be.

There may yet be a gap between not harming a child and doing enough or providing a reasonable level of care. Thus, Jeffrey Blustein defends a 'satisficing parentalism' as opposed to the maximising version required of a best interests principle strictly construed.[33] Nevertheless, doing enough or what is reasonable or as much as one can may still be more than simply avoiding harm. This means that we may only intervene to protect a child if a parent harms that child (or risks doing so), yet hold parents to a moral duty to do more than simply not harm their offspring. It would be a further question as to what measures, short of intervention, might be appropriate to ensure that parents discharge that duty.

This distinction between the scope and functional role of a best interests and a harm principle is clear. Various writers do recognise the difference. Loretta Kopelman, for instance, argues that the best interests standard may be used in at least three different ways, one of which is as a threshold principle for intervention into family life.[34] In fact, as she acknowledges, whilst the standard may then be used as a means of determining what shall subsequently be done, it is the occasioning of harm that in standard child protection procedures in fact triggers intervention. Again, Charles Foster sees the harm

31 *Re L (Care: Threshold Criteria)* [2007] 1 FLR 2050.

32 Joel Feinberg, *Harm to Others*, vol 1 of *The Moral Limits of the Criminal Law* (Oxford University Press 1984).

33 Jeffrey Blustein, 'Doing the Best for One's Child: Satisficing Versus Optimizing Parentalism' (2012) 33 Theoretical Medicine and Bioethics 199–205.

34 Loretta Kopelman, 'The Best Interests Standard as Threshold, Ideal and Standard of Reasonableness' (1997) 22 Journal of Medicine and Philosophy 271–89.

principle as useful for 'triage' in the sense of that term as used in medical emergencies, namely as determining where resources are best devoted, namely to the most urgent cases. In the case of child protection, the principle of triage means attending first to those children suffering or at risk of serious harm.[35]

Others writing in this area simply fail to see this essential difference between the contexts in which the harm and best interest principles operate. They are thus disposed to see them as competing alternative standards for evaluating the choices to be made of how children should be treated medically. In adjudicating that competition, there is then much discussion of whether the charge of indeterminacy applies equally to both principles or more obviously, and fatally, to that of best interests. Giles Birchley, for instance, sees it as important, in defending the best interests principle against the harm principle as a standard of medical decision-making, to respond to the charge often made that best interests but not harm is vulnerable to indeterminacy.[36]

This is all beside the point if the two standards do not in fact offer themselves as principled means of answering the same question. Equally beside the point, and for all the same reasons, is any attempt to favour one principle over the other by demonstrating that its full normative specification, but not that of the other, cannot be made given the existence of deep-lying moral disagreements or the fact of moral pluralism. Here, the thought is that what can be understood by 'best interests' but not, by contrast, what is meant by 'harm' broaches significant and ultimately irresolvable moral disputes.

There is also no point in arguing that using a harm principle to resolve medical agreement is to be preferred to a best interests principle because such use is consistent with the employment of the harm principle in child protection.[37] There is no point, to labour the basic truth, because the harm principle functions in the latter context, that of child protection, as a trigger for intervention into the family. 'Best interests' is then employed as the standard for determining what shall be done once the need for child protection has been triggered.

The context of medical disagreement

However, the context within which medical disagreement must be adjudicated is not analogous to that in which child protection – the initial intervention into the life of a family – is triggered. In the first place, there is a difference between a case in which parents have failed to bring their sick child to the attention of doctors and that in which they have done so but have come to disagree about what treatment is appropriate. The first kind of case is arguably one in which the parents are guilty of neglect or abuse and thus in which child protection measures may be appropriate.[38] Three of the four cases cited at the outset are of the second kind, inasmuch as disagreement about treatment can include one about whether or not life-preserving treatment should be continued.

The fourth, that of Ashya King, was one in which a disagreement about treatment led the parents to remove him from the care of the treating hospital and to seek treatment

35 Charles Foster 'Harm: As Indeterminate as "Best Interests", but Useful for Triage' (2016) 42 Journal of Medical Ethics 121–2.

36 Giles Birchley, 'Harm is All You Need? Best Interests and Disputes about Parental Decision-making' (2016) 42 (2) Journal of Medical Ethics 111–15.

37 D Wilkinson and M Nair, 'Harm isn't All You Need: Parental Discretion and Medical Decisions for a Child' (2016) 42(2) Journal of Medical Ethics 116–18.

38 Kathleen Knepper, 'Withholding Medical Treatment from Infants: When is It Child Neglect' (1994–1995) 33 University of. Louisville Journal of Family Law 1–53.

abroad. On the liberal child protection model such an action could be viewed as equivalent to a failure to treat and thus as meriting child protection measures. To be clear, the merits or otherwise of the legal judgment in that case are not being considered here. Rather, it is important to recognise the critical distinction between harming a child by failing to make treatment possible and acting in the best interests of a child by choosing the best possible treatment.

Second, parents who bring their child to the attention of and care by doctors need not be thought on the liberal model of parenthood as surrendering all their rights to act in the first instance as their child's guardians. Indeed, parents can act as proxy choosers for their children by giving consent to proposed treatment options. Nevertheless, it is important to acknowledge that a proxy decision-maker is morally obligated to make those decisions on behalf of another that accord with the other's known wishes or, as would be the case with an infant who cannot be thought of as having made known any wishes, what is in the other's best interests.[39]

Third, if and when any final determination of what treatment the child should receive has been made that goes against the parents' wishes, such a determination differs from how the liberal model of parenthood understands an intervention into the family to protect a child against serious harm. No general suspension of the rights of the parents is involved. No judgment need be made as to the causing by the parents of harm to their children. It is not the case that others – foster or adoptive parents, temporary guardians or carers – now do what the parents would otherwise do. Rather, doctors provide treatment for a child whose parents remain its primary guardians. Finally, the decision to overrule the parents' wishes is in a limited and specific domain, namely medical treatment of the child for such time as the child needs medical care.

In sum, the harm principle is relevant in the context of medical treatment in requiring that a sick child should be treated and in ruling out those initial interventions and treatments that occasion harm. Should it then be used when there is disagreement between doctors and parents as to what that treatment should be? The argument here is that the best interests principle alone should determine what is done. To think otherwise – and to represent the harm principle as the only basis on which parental views as to treatment should be overruled – is, once again, to confuse the threshold function of the harm principle with the standard of appropriate care.

If the choice is between the conflicting preferences of doctors and parents, it is unclear why one should not adjudicate by means of a best interests principle.

In front of us lies a sick child. Why is it not obvious that we should do the best we can for that child? It seems patently odd to say simply that we should do whatever does not harm the child. Consider how the liberal model of child protection understands what the state should do. A child is removed from the care of her parents because in that care she is being harmed or exposed to the significant risk of harm. What shall we now do? We should surely make arrangements for that subsequent care of the child that promotes her best interests, whether, for example, this is with adoptive parents, one of the original parents, or with members of the extended family. How would a harm principle help with a decision as to her future care? One obvious reason it may not help is that, whilst it will rule out some future care arrangements (for instance, by a parent who has proved to be

39 Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (5th edn, Oxford University Press 2001) 99–103; Allen E Buchanan and Dan W Brock, *Deciding for Others: The Ethics of Surrogate Decision-making* (Cambridge University Press 1990) 93–126.

abusive or neglectful), it will not of itself serve to adjudicate between others (adoptive parents or other family members, for example). But what will help is a best interests principle. What is the best available care that can be provided for this child who cannot continue safely to be cared for as before by her original guardians?

Now of course the analogy of child protection is here of limited use. We are speaking of the making of permanent arrangements for the subsequent upbringing of a child. In the medical context we are talking about time- and scope-limited care. Moreover, and most importantly, the disagreement between doctors and parents may not be resolvable by appeal to the harm principle, as it would be if the abusive parents in a child protection case wished to continue caring for their child. Indeed, we need carefully to spell out the features of the kind of case of medical disagreement that causes problems. Two are crucial.

First, it is a case in which the child is incapable of expressing a view as to the treatment he or she wishes. Article 12 of the UN Convention on the Rights of the Child states that:

> States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.[40]

The cases that have provoked most heated debate and discussion have been those of severely ill babies. These are not children capable of forming their own views.

Equally, these are children who fall well below the required threshold of 'Gillick competence'. This is the capacity – of understanding and intelligence – that legal minors may demonstrate in respect of some matter affecting their interests such that 'parental right yields to the child's right to make his own decisions'.[41] The fact that the child does not have a voice that should be taken into account means that the disagreement that needs to be resolved is a simple one between doctors and parents. I assume that the parents speak with one voice, an assumption that I make for the purposes of further argument, but not without acknowledging that in at least some cases parents may disagree.

Second, the disagreement in question as to what is best for the child is allowed to be a reasonable one and not one that can be adjudicated simply by dismissing the preferences or views of either party as harmful for the child or as unreasonable. That is to say that both parties have good reasons for their views and that those views do not run afoul of the harm principle. Of course, what a parent wants might cause the child harm or risk doing so. However – as was made clear earlier – there is a difference between harming and not maximally promoting the interests of another. So, if we do have such a disagreement, why should we give a particular weight or importance to the parents' views?

Giving weight to parental views

Against the view defended here that in such cases of disagreement there should be a determination of what is best for the child is a claim that the parents' views should be favoured over the doctors'. I will outline the most interesting version of the claim and then consider various arguments as to why the views of parents should outweigh those of doctors. These – in sum – are that parents know best what is best for their children, that their interests should be taken into account, and that we are deciding within a context of value pluralism.

40 UN Convention on the Rights of the Child 1989 <www.ohchr.org/en/professionalinterest/pages/crc.aspx>.

41 *Gillick v West Norfolk Health Authority* [1986] 1 AC 112, 186 (Lord Scarman).

One influential, thoughtful and intelligently designed proposal in the case of disagreement between parents and doctors is captured by the idea of a zone of parental discretion.[42] The zone in question is 'the ethically protected space where parents may legitimately make decisions for their children, even if their decisions are sub-optimal for those children (i.e. not absolutely the best for them)'. They may be sub-optimal, but they do not harm the child. Nevertheless, inasmuch as the choices are sub-optimal, they are not what is best. So, if parents choose what the doctors judge is not optimal, why should their choice be acted upon?

Lynn Gillam as the author of this 'ethical tool' for dealing with doctor–parent disagreement argues that it 'accords appropriate moral weight to parents as the decision-makers for the child'.[43] This provokes the question, what is this 'appropriate moral weight', and what is its normative basis? Gillam does not make explicit why such a weighting is appropriate. It cannot be that opting for what is the parents' choice of treatment is the route of least resistance, and chosen inasmuch as the avoidance of disagreement, so long as the child is not harmed, has benefits or at least forestalls certain costs. Disagreement is indeed problematic, and it can lead to conflict, litigation and unresolved animosities. Yet, what is at stake is the future of a child. Moreover, requiring of doctors that they do what they do not think is best for the child has its own evident burdens, namely requiring them to do something other than what they are professionally obligated to do, namely do the best they can for their patient.

Parents are also not being asked to discharge a parental duty of care that is defined as maximising the child's interests. A best interests standard for all forms of parental care is open to familiar damaging criticisms, not least its over-demanding nature. As we have already argued, the presumption is that parents vary in their standards of care.

Moreover, the choice of the best medical care does not as such normally impose unreasonable costs on a parent. It is time limited and domain specific. It may well be that what the doctors commend as best for the child has costs for the parents who must subsequently care for the child. Preserving or prolonging a child's life may, for instance, be at the expense of significant disabilities that require an enormous devotion of time and resources to the life-long care of the child. In such a case it is appropriate to take account in making a decision not just of what is in the child's interests, but what is in the parents' interests. However, it does not change the appraisal of what is best *for the child* and, as such, the subject of the disagreement between parents and doctors.

A determination that what is objectively best for the child is not what his or her parents wish for is not equivalent to a loss of the right to parent. Parents are not thereby losing their general right to make choices for the child. It is only their choice in respect of medical care that might be overruled. It is thus not denied that the parents are, and will likely remain, the decision-makers for the child. The significance of that is not denied. After all, it is they – and not some other third party – who make up one side of the disagreement.

It is worth adding the following from, as it were, the other side. That parents have the right to make choices in the everyday life of their children and, in doing so, can legitimately exclude others from making these choices, does not give the choices of parents a special weight outside these normal quotidian contexts.

42 Lynn Gillam, 'The Zone of Parental Discretion: An Ethical Tool for Dealing with Disagreement between Parents and Doctors about Medical Treatment for a Child' (2006) 11(1) Clinical Ethics 1–8.

43 Ibid 2.

What then remains of the 'appropriate moral weight' that the parents' views should have in cases of medical decision-making? It is important to distinguish between the weight that might be accorded to parents' choices just because and for no other reason than that they are the child's parents and the weight that might be accorded to parents' choices for some other reason that is in some way related to their status as the child's parents.

Here are some important instances of this latter kind of reason. The first is essentially epistemic and concerns who it is that is best placed to judge what is in a child's interests. A parent may plausibly claim that she knows better what is best for her child because she is a parent. She stands in a superior position to that of the doctor to gauge how the child feels or what the child wants. A parent is epistemically better placed than doctors to judge what is in her child's interests.

Yet, the crucial normative work in this claim is done by the interests of the child and not by the parental relation. This relation serves to explain a position of privileged knowledge and not as such to ground a moral entitlement to choose for the child. Thus, the assertion 'I am her parent and should choose' needs to be expanded to the following statement: 'As her parent I know her better than others, and given that it is whatever is best for her that should determine what is chosen I, as her parent, am better placed to judge what, all things considered, will be best for her.' Put in another and more concise way, there are two normative principles in play. The first is that the best should be done for a child. The second is that whosoever is best placed to judge what is best for the child should choose what is done. Conjoined with the further premise that the parent is so best placed, it follows that the parent should choose.

This is a valid argument, but everything turns on the epistemic premise. Parents, it is claimed, know their children better than anyone else. Why? Perhaps it is that they are close in every sense to their charges. Loving parents are moved to do what is best for their child. There is no better defender of this motivational claim than the seventeenth-century English philosopher, John Locke. He maintained that God:

> . . . has in all the parts of creation taken a peculiar care to propagate and continue the several species of creatures, and makes the individuals act so strongly to this end, that they sometimes neglect their own private good for it, and seem to forget that general rule, which nature teaches all things, of self-preservation; and the preservation of their young, as the strongest principle in them, over-rules the constitution of their particular natures.[44]

This is a powerful claim. However, there are good reasons not to give this fact too much weight in the case of medical decision-making. Being motivated to do what is best for someone does not make one the best or even a better judge of what is in fact best. Love can indeed be blind. Even as a general rule, the claim that parents are better placed than others to judge what is best for the child is a defeasible one. The best medical decision may not rely on knowledge about a child's welfare that a parent alone has access to or is better placed to know. Doctors may – and indeed if they are conscientious should – take account of all relevant information, including that which can be best or only provided by parents.

Finally, a claim about superior epistemic access must always be carefully distinguished from other claims a parent might make on behalf of the child. A parent's claim that the child should continue to receive life-prolonging treatment may not express a view about what is best for the child, but rather what a parent wishes for. Such wishes may not simply

44 John Locke, *Two Treatises of Government*, critical edition with an introduction and *apparatus criticus* by Peter Laslett (Cambridge University Press 1963 [1698]) I.vi.§56.

be an expression of what the parent sees as in her interests and thus be open to the charge of a failure to disengage parental from a child's interests. The wishes in question may be the expression of a general view about, for instance, the value of life as such rather than of the value of *this* life. Whether it is important to this child to carry on living is distinct from the question of whether it matters to keep anyone alive.

However, it is important to acknowledge the interests of any parent. Indeed, Wilkinson and Nair give this as one reason to favour the harm principle over the best interests principle when deciding between parents and doctors. They think that if there is little to choose between doctor and parent in respect of what is best for the child then we should favour the parents' view so long as this is not harmful to the child. Indeed, the doctors' choice may be better for the child. Yet, 'where the benefit to child [*sic*] is statistically unlikely or small in magnitude it is reasonable to give parents' interests (or rights) some weight'.[45] The suggestion is that the weight of parental interests might suffice to outweigh the putatively negligible or minor superior weight of the doctors' choice over the parents.

Now, how might the parents' interests count? There must be what Lainie Friedman Ross terms 'intra-familial trade-offs'.[46] One cannot simply demand what is best for a child by giving no weight to the interests of other family members, including, but not exclusively, those of the parents. Thus, for instance and as acknowledged earlier, a medical decision for the child may have burdensome consequences for the parents. These must be factored into any overall decision as to what is best, and not just what is best for the child.

But acknowledging that a parent's interests in the outcome of any decision should be counted is not the same thing as giving an 'appropriate moral weight' to a parent's choices. For what a parent might choose for her child is thought to have a weight *whatever* the consequences for the parent herself. Moreover, those consequences enter into an all-things-considered judgment of what is best for the child. It is not that her interest in any outcome shows the parent to be the better chooser of what is best for the child or to have a greater moral claim to make the relevant choice. Rather, it supplies one significant consideration that should enter into in any full and nuanced judgment of what is the best choice for the child.

Value pluralism and moral dilemmas

Wilkinson and Nair argue that doctors and parents may disagree because of 'value uncertainty': that is, the relevant parties may appeal to distinct values in defence of their respective views about what is best for the child. They conclude: 'Where there are a range of different reasonable views about whether or not a particular treatment is in a child's best interests, it is unfair to impose one set of values on all parents.'[47] They do so in the context of a defence of the harm principle as that which should order deliberations about any choice of treatment.

The first thing then to say is that, presumably, they view that principle as not beset by the problem of value uncertainty. Doctors and parents can reach normative agreement on what counts as harm, even if they might disagree as to whether, as a matter of empirical fact, something is harmful. The 'uncertainty' in question concerns what is best for the child.

45 Wilkinson and Nair (n 37) 117.

46 Lainie Friedman Ross, *Children, Families and Healthcare Decision-making* (Clarendon Press 1998) 44.

47 Wilkinson and Nair (n 37) 117.

Second, some disagreements between doctors and patients may not be about values (say, about the quality of a life), but rather be about factual matters (whether this treatment will work, for instance). And if it is the latter it is unclear why medical expertise should not be decisive.

Third, an appeal to the special knowledge a parent has of his or her child is not, as might be implied, relevant in this context.[48] Such privileged knowledge as they have need not be of a sort that disposes to a better medical understanding of their child's condition. Nor, crucially, need it be one that shows their value claims to be more likely to be true.

Fourth, if, as argued here, we must adjudicate the disagreement by reference to best interests, then we should aim to make an objective determination of what is best. This may be difficult to do. But those who insist that an interpretation of what is meant by 'best interests' is impossibly arbitrary[49] need to show why such a problem does not afflict the concept of 'harm'. It also needs to be shown why courts should not, as they do in many analogous situations, attempt to spell out how a critical standard should be construed and applied.

Perhaps the 'uncertainty' in question is meta-ethical, there being an irreducible plurality of values in play and no possible means of ordering these values or weighting them by means of some single foundational value.

This is, of course, possible. But it is also a substantive and controversial philosophical claim. There is a great difference between the claim, consistent with a denial that values are plural or that they cannot be rank ordered, that people reasonably disagree on moral matters, and the claim that such moral disagreement may reflect an underlying plurality of incommensurable values. It needs to be shown why the courts should not proceed on the presumption that they can make an objective determination of what is best for the child. Simply invoking the fact of reasonable disagreement does not suffice to show it.

The final thing to say is this. Even if there is an irresolvable disagreement of values between doctors and parents – irresolvable because the respective values cannot be measured against one another – it is far from clear why we should decide in favour of the parents. It is said that so deciding would be 'unfair' inasmuch as it would mean imposing one set of values – presumably those of the doctors – on the parents. Yet, why would it not be unfair to impose the parents' values on the doctors? After all they, as doctors, have a professional duty to do what they see as best for their patients, and they could not discharge that duty as they understand it if they must do what they do not believe to be the best for their patient.

Another way of expressing this point is by saying that each party to the disagreement has an interest in seeing their view prevail. The parents have an interest as the parents of this child; the doctors have an interest in doing what they view as their professional duty, indeed what they understand as their clearly defined legal duty of care. We can surely reasonably disagree about whose is the greater interest. But, even if we could say which was the greater, it is far from evident that these interests should play any role in determining which view prevails. For what matters, and all that matters, is that the best is

48 Dominic Wilkinson and Julian Savulescu, *Ethics, Conflict and Medical Treatment: From Disagreement to Dissensu* (Elsevier 2019) 89–91.

49 Robert H Mnookin, 'Foster Care: In whose Best Interests?' in Onora O'Neill and William Ruddick (eds), *Having Children: Philosophical and Legal Reflections on Parenthood* (Oxford University Press 1979) 179–213; Jon Elster, *Solomonic Judgments: Studies in the Limitations of Rationality* (Cambridge University Press) Part III 'Solomonic Judgements: Against the Best Interests'.

done for the child. That someone has an interest in seeing that what is done is what they wish to be done is beside the point.

More generally, there are fair and unfair ways to resolve disagreements by settling upon one of two (or more) preferred outcomes. We might simply toss a coin. Whilst in one sense fair, that method seems arbitrary. Another is by means of a democratic vote. Yet, in the current context it is unclear who should be permitted to vote. Moreover, if the relevant suffrage is extended to the disputing parties, and we discount numbers on either side, we simply end up with a tie. A final method is that of an impartial, independent decision-maker. This is precisely what the court is.

There is a stronger version of the 'value uncertainty' claim that is defended by Raanan Gillon. This is that the disagreement between doctors and parents is a moral dilemma and that the parents' and doctors' views represent two horns of that dilemma.[50] However, a moral dilemma is properly understood as a necessitated choice between two courses of action each of which has moral reasons in favour of it, such that the choice involves some kind of moral loss. The loss in question is the failure to do that which is not chosen and yet which we should have done.[51]

This is not a claim that the choice is between morally equivalent outcomes. That is extremely unlikely in the present context, but, if it was, nothing would be lost by choosing either one. The claim that we are dealing with a moral dilemma is stronger and other than the claim that the choices are morally incommensurable. The identification of a moral dilemma is such that, even if the choices can be compared and ranked, nevertheless, *something* is lost by choosing one outcome over the other.

However, it is not clear that the choice between the doctors' and parents' views of what is best for the child is a dilemma in this sense. We ought to do what is best for the child and the determination of one course of action as the best (whosoever's view that follows) does not leave a moral remainder. The other course of action is thereby characterised as inferior, but not one that still has moral reasons in its favour. We do have moral reason to do what is best for the child; we do not have a moral reason to do what is not best.

Perhaps it is thought that, nevertheless, something of value is lost, namely the choice of one of the two parties. Yet, it is strange to think that the choice as such has value. What is valuable is that which is chosen. Parents and doctors make choices of what is best for the child, and it is what is in fact best for the child that is valuable.

Conclusion

The slogan 'My child, my choice' is an evocative, emotive and understandably powerful battle cry and *cri de coeur*. It gives expression to an almost visceral sense of parental entitlement to determine what shall happen to one's child. Yet, at the end of the day, the disagreement between doctors and parents is about what is best for the child, not what is best for doctors or parents. It is about what is best, and not just about what does not harm the child. The best interests and harm principles have different domains of application, and it is important to distinguish them. Once we recognise that important distinction, we must proceed to adjudicate these disagreements in terms of what is best for the child.

50 Raanan Gillon, 'Why Charlie Gard's Parents should have been the Decision-makers about their Son's Best Interests' (2018) Journal of Medical Ethics 104.

51 Terrence McConnell, 'Moral Dilemmas' in Zalta (ed) (n 22) <https://plato.stanford.edu/archives/sum2018/entries/moral-dilemmas>.

Some think that favouring the views of the parent gives these an 'appropriate moral weight'. Yet, it has been argued here that there are no good reasons – grounded in the claim that parents know best, in the interests of the parents, in consistency with the use of the principles elsewhere, or in value uncertainty – to grant the views of parents a special and trumping moral weight over the views of doctors. We should continue objectively to determine what is best for the child, and do so by making use of an independent adjudicator. The courts fulfil such a role even if it is to be regretted that disagreements between doctors and patients must, as was so with the cases cited at the outset, be resolved through legal means.

NILQ 70(1): 111–129

Healthcare resource allocation in the English courts: a systems theory perspective

PROFESSOR KEITH SYRETT*

Centre for Health, Law, and Society, University of Bristol Law School

Abstract

Engagement with sociological perspectives can enrich an understanding of medical law and provide a basis for critique of certain of its key premises. Since both law and healthcare are frequently conceptualised and analysed as systems, the theoretical frameworks developed by Niklas Luhmann and Gunther Teubner would seem to offer particular promise in this regard. This article explores a particular area of medical law to which an understanding of the social (and political-economic) context of decision-making is of clear importance – adjudication upon the allocation of scarce resources – in order to identify what insights may be gained from an approach grounded in systems theory.

Keywords: judicial review; healthcare; resource allocation; systems theory.

Introduction: medical law and the uses of sociology

There appears little room for argument today that medical law 'has achieved an enduring place at the pedagogical table', alongside more traditional subjects of academic legal study.[1] Yet, notwithstanding its status as a 'vigorous, dynamic and eclectic field of cross-disciplinary and international scholarship',[2] the relative youthfulness of the sub-discipline means that there remains ample scope for innovative investigation of synergies with other fields of inquiry. Such an exercise may serve several valuable goals, including deepening comprehension of emerging and evolving norms, identifying new modes of addressing problems, and illuminating potential pathways for future development.

A related, but arguably distinct, rationale for embarking upon such exploration might be located in a sense of discomfiture with certain of the foundational tenets of medical law, the objective being the critical reassessment of the validity of these in light of the understandings which may be gleaned from beyond its boundaries. One such matter which has been subject to such analysis is the centrality accorded to bioethical principles as yardsticks by means of which the normative structures of medical law may be understood and evaluated.

This critique of 'bioethics-centrism' has emerged from various quarters. From the social sciences, the argument is posited that the 'highly rational, formal, largely deductive mode of

* keith.syrett@bristol.ac.uk.

1 I Freckleton, 'The Emergence and Evolution of Health Law' (2013) 29 Law in Context 74, 97.

2 Ibid.

argumentation' which bioethics embodies cannot readily be translated into practical scenarios:[3] hence, that 'applied ethics' rests upon the naive and mistaken premise that 'social reality cleaves down neat philosophical lines, with theoretical categories matching those in social reality: i.e. that what a philosopher says is the doctor–patient relationship actually represents the relationship between doctors and their patients in all settings'.[4]

Comparable voices can be heard emanating from within the legal academy. For Montgomery, the traditional conception of 'medical law [as] a species of applied ethics, implying a staged process of applying ethical principles to a problem and deriving the necessary legal rules from that application'[5] has resulted in a disjuncture between theory and practice. He therefore calls for a 'new paradigm' for medical (or healthcare) law,[6] in which medical law is set in its 'institutional context',[7] and which makes use of norms created by and within the medical professions and the NHS, rather than viewing these as 'forces to be constrained' by the application of external rules.[8] Similarly, Veitch argues that it is:

> . . . essential to complement the existing, and dominant, critical form of analysis within the academic medical law literature – one based on ethics and the ethical supportability of court decisions and laws – with one whose critical eye is directed towards the more mundane, though by no means less important, institutional apparatus that structures aspects of how the courts function in this area.[9]

Most recently, Harrington has proposed a rhetorical analysis of medical law, challenging the perceived orthodoxy that 'ethics is held to be the truth of the law in this area: that which the law must strive for, though often failing in doing so'.[10] He focuses instead upon legal speech as 'a site of struggle between rival common-sense notions of the nature of society and its values, and the relationship of both to the law'.[11]

There are important differences between these accounts, but what unites them is both an attentiveness towards the social and political context in which medicine – and medical law – sit,[12] and, relatedly, a critical posture towards the apparent hegemony of bioethics, which is regarded as too detached from lived experience to properly account for practice in the clinic (or the courtroom). This appears to create a distinct space in which understandings drawn from sociology might prove of particular utility. The focus of the latter upon the manner in which 'institutions provide procedures through which human conduct is patterned'[13] allows us better to comprehend, inter alia, 'how ethical questions are not separable from the relations of powers in which ethical dilemmas emerge and are resolved', and 'how individuals draw on existing cultural resources which are embedded

3 R Fox, 'Is Medical Education Asking too much of Bioethics?' (1999) 128 Daedelus 1, 10.

4 A Hedgecoe, 'Critical Bioethics: Beyond the Social Science Critique of Applied Ethics' (2004) 18 Bioethics 120, 130.

5 J Montgomery, 'Time for a Paradigm Shift? Medical Law in Transition' (2000) 53 Current Legal Problems 363, 363.

6 See J Montgomery, *Health Care Law* (2nd edn, Oxford University Press 2003) 4.

7 Montgomery (n 5) 408.

8 Ibid 407.

9 K Veitch, *The Jurisdiction of Medical Law* (Ashgate 2007) 5.

10 J Harrington, *Towards a Rhetoric of Medical Law* (Routledge 2017) 162.

11 Ibid.

12 See Montgomery (n 5) 363, 408; Veitch (n 9) ch 2; Harrington (n 10) 2.

13 P Berger, *Invitation to Sociology: A Humanistic Perspective* (Penguin 1962) 104.

in their everyday experiences as a way of tackling ethical questions'.[14] However, with limited exceptions (including aspects of the work of two of the legal scholars identified above),[15] this disciplinary intersection between medical law and sociology has been sparsely explored.

Considerations of space necessarily preclude this article from undertaking a *comprehensive* exploration of the contribution which sociology can make to a better understanding – perhaps, a thoroughgoing reconceptualisation – of the fundamental tenets of medical law. Rather, it seeks to offer an illustration of the insights that work in this field can offer by focusing upon a discrete subcategory: judicial scrutiny of the allocation of scarce healthcare resources. For at least two reasons, this would appear to be a topic which especially lends itself to being viewed through a sociological lens. First, perhaps more visibly than in any other context within medical law, decisions which fall to be scrutinised by the courts in this field are structured by the *institutional* context in which they are taken: whether funding is made available for a particular treatment sought by a patient will turn upon a series of organisational choices which are reflective of the relations of power both within, and external to, the allocative decision-making body. Secondly, the propensity to resort to litigation regarding allocative choices is explicable, at least in part, by reference to broader *social* trends such as: enhanced health literacy, especially in relation to the introduction of new technologies; the rise of patient pressure groups (supported in some cases by pharmaceutical companies seeking enhanced return on research and development costs); a more consumerist approach to healthcare as a commodity, and so on.

For similar practical reasons, this article will limit its consideration of sociological approaches to those of the 'system theorists', in particular Niklas Luhmann and Gunther Teubner. It is submitted, however, that these contributions are especially apposite to the subject-matter surveyed here. Adjudication of healthcare allocation questions is a practice which sits at the intersection of two forms of social organisation which both can be, and have been, profitably analysed in systemic terms: law and healthcare.[16] As will be discussed more fully below, systems theory provides us with particular insights into the manner in which communication can occur between these ostensibly dissimilar ways of ordering and perceiving the world and, correspondingly, an explanation of the dynamics

14 J López, 'How Sociology Can Save Bioethics . . . Maybe' (2004) 26 Sociology of Health and Illness 875, 881. For further discussions of the relationship between bioethics and sociology, see R DeVries and P Conrad, 'Why Bioethics Needs Sociology' in R DeVries and J Subedi (eds), *Bioethics and Society: Constructing the Ethical Enterprise* (Prentice Hall 1998); R Zussman, 'The Contributions of Sociology to Medical Ethics' (2000) 30 Hastings Center Report 7; R DeVries, 'How Can We Help? From "Sociology in" to "Sociology of" Bioethics' (2004) 32 Journal of Law, Medicine and Ethics 279.

15 Veitch (n 9) 33 argues that 'the sociological type of inquiry allows for reflection on how some changes in the underlying structure of society might relate to aspects of medical law', developing this primarily in chapter 2 of his book, while Harrington (n 10) 21–8 draws upon systems theory to analyse the 'indeterminacies and perplexities' of medical law. Elsewhere, it is the work of Foucault which has been most widely utilised: see e.g. A Sharpe, *Foucault's Monsters and the Challenge of Law* (Routledge 2010); M Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Hart 2015); J Fanning, 'Continuities of Risk in the Era of the Mental Capacity Act' (2016) 24 Medical Law Review 415.

16 For discussion of law as a social system, see further below. Amongst an extensive literature of healthcare as a system, see e.g. L Gilson (ed), *Health Policy and Systems Research: A Methodology Reader* (World Health Organization 2012); M Britnell, *In Search of the Perfect Health System* (Palgrave 2015); J Johnson, C Stoskopf and L Shi (eds), *Comparative Health Systems: A Global Perspective* (2nd edn, Jones & Bartlett 2018).

of change which is referable to social and organisational factors,[17] rather than premised upon adoption of a universalist worldview. It therefore promises a distinctive theoretical framing which may function as a corrective to a bioethics-centred approach to the analysis of legal norms and their ongoing development.

The goal of this article, therefore, is to explore judicial decision-making on allocation of scarce healthcare resources in English courts in light of the understandings provided by systems theory, with a view to identifying the insights which the latter may bring to analysis of the former. In order to pursue this, it is necessary first both to outline how the law has evolved in this field, and the manner in which that evolution has 'traditionally' been framed.

A narrative of judicial scrutiny of resource allocation

This section presents a tripartite categorisation of the activity of the English courts in relation to adjudication upon allocative questions in healthcare.[18] While admittedly somewhat crude – especially as there are not neat chronological boundaries between the categories (in particular, the second and third) – such classification is, it is submitted, valuable in directing attention away from the particularities of individual cases, thus facilitating consideration of the broader social and political trends within which the decisions are set, while simultaneously allowing examination of the evolution of relevant jurisprudence.

As Newdick notes, the first judicial review of an allocative decision made within the NHS 'surprisingly' did not occur until 1980;[19] this fact in itself may be framed within a sociological lens, as discussed subsequently. These early cases, up to the decision of the Court of Appeal in *R v Cambridge Health Authority, ex parte B* in 1995,[20] were characterised by judicial deference or 'passivity'.[21] Judges did not consider allocative questions to be wholly non-justiciable, since they retained the capacity to intervene on *Wednesbury* grounds, but this test was applied in a very strict manner with the consequence that allocative decisions were, in effect, insulated from any meaningful judicial scrutiny, even on procedural grounds. This position is perhaps best captured by *R v Central Birmingham Health Authority, ex parte Collier*,[22] where access to intensive care facilities were denied to a child with a life-threatening condition who had been placed at the top of a waiting list for treatment. Here, Stephen Brown LJ stated that:

> . . . it is not for this court, or any court, to substitute its own judgment for the judgment of those who are responsible for the allocation of resources . . . The courts of this country cannot arrange the lists in the hospital, and, if it is not evidence that they are not being arranged properly due to some unreasonableness

17 Although systems theory might be viewed as taking a 'macro' perspective on society, nonetheless 'in Luhmann's grand theory of societal evolution organizations are of pivotal importance . . . Today, most societal systems are represented by specific organisations, and, vice versa, most organizations are related to a societal system': R Hasse and G Krücken, 'Systems Theory, Societal Contexts, and Organizational Heterogeneity' in R Greenwood et al (eds), *The Sage Handbook of Organizational Institutionalism* (Sage 2008) 539, 548.

18 This analysis therefore differs from that of Wang, who offers a two-stage account: see D Wang, 'From *Wednesbury* Unreasonableness to Accountability for Reasonableness' (2017) 76 Cambridge Law Journal 642, 644–52. See further below.

19 C Newdick, *Who Should We Treat?* (2nd edn, Oxford University Press 2005) 95, referring to *R v Secretary of State for Social Services, ex parte Hincks* (1980) 1 BMLR 93.

20 [1995] EWCA Civ 49.

21 Newdick (n 19) 98.

22 [1988] Lexis Citation 1301.

> in the *Wednesbury* sense on the part of the authority, the courts cannot, and should not, be asked to intervene.

A different approach to the judicial role in this field may be traced to the decision of the High Court in *ex parte B*,[23] with the principles which were articulated by the courts in a series of subsequent cases eventually being placed upon a statutory footing by secondary legislation accompanying the publication of the *NHS Constitution* in 2009.[24] Here, judicial scrutiny is of a considerably more intensive quality than was previously the case: Newdick labels it 'hard look'.[25] However, while the 'trigger' for review remains the most substantive of the grounds of judicial review – irrationality – the obligations imposed upon the allocative decision-maker by law (whether common law, or statute/*NHS Constitution*) are procedural in character. These take two forms. First, the decision-maker is required – in the words of Laws J in *ex parte B* – to 'explain the priorities which have led them to decline to fund the treatment':[26] that is, in effect, to provide reasons for the decision not to fund a particular intervention. Secondly, a procedure must be in place whereby an individual can put forward factors which constitute their particular case as exceptional, thereby warranting departure from a general policy not to provide access to a treatment or service.[27] This provides for a mode of participation in the process of allocation, understood in a Fullerian sense as the presentation of proofs and reasoned argumentation for a decision in favour of the patient.[28]

In both of the preceding instances, the approach adopted by the courts is relatively unambiguous, but there is a further category of case in which the position is less clear-cut. Here, the basis of challenge lies in the application and interpretation of the evidential base upon which allocative choices are premised. The NHS Constitution includes a right, said to be rooted in administrative law, 'to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence'.[29] In this context, however, rationality is framed by some courts in a more substantive manner than in the cases previously discussed, turning upon the relevancy of considerations, the existence of evidence reasonably capable of supporting the decision, and the analysis and application of that evidence. Hence, in *R (Otley) v Barking and Dagenham NHS Primary Care Trust*,[30] the refusal to provide funding for a cancer drug was held to be unlawful, inter alia, on the basis of a misapplication of evidence on clinical effectiveness contained in guidance produced by (what was then) the National Institute for Health and Clinical Excellence (NICE); in *R (Ross) v West Sussex Primary Care Trust*,[31] the Trust had acted unlawfully because it had failed 'to understand the strength of the evidence in favour of treating [the patient]' in light of a 'fundamental misunderstanding

23 [1995] 1 FLR 1055. This decision was overturned by the Court of Appeal (n 20), but it nonetheless laid the basis for future jurisprudence in the area: see K Syrett, 'Institutional Liability' in J Laing and J McHale (eds), *Principles of Medical Law* (4th edn, Oxford University Press 2017) [7.71].

24 See now National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, SI 2012/2996, regs 34, 35.

25 Newdick (n 19) 100.

26 Above (n 23) 1065.

27 The process is known (in England) as the Individual Funding Request. For an example, see NHS England, *Commissioning Policy: Individual Funding Requests* (NHS England 2017).

28 See L Fuller, 'The Forms and Limits of Adjudication' (1978) 92 Harvard Law Review 353, 364.

29 Department of Health, *The NHS Constitution for England* (Department of Health 2015) 7.

30 [2007] EWHC 1927 (Admin).

31 [2008] EWHC 2252 (Admin).

of the results' of randomised controlled trials of the treatment;[32] and because it 'fell into error when considering [the] cost-effectiveness' of the drug;[33] and, in *R (Rose) v Thanet Clinical Commissioning Group*,[34] albeit *obiter*,[35] Jay J considered that departure from (non-binding) NICE guidelines in respect of the strength of the clinical evidence base for a treatment amounted to 'an irrational conclusion and, in particular, one whose reasoning is without foundation'.[36]

However, in other cases, courts have taken a more deferential stance towards the allocative decision-maker's analysis and application of evidence. Thus, in *R (AC) v Berkshire West Primary Care Trust*,[37] the Court of Appeal ruled that the Trust was entitled to take the view that the evidence of clinical effectiveness was insufficiently strong to warrant funding breast augmentation surgery for transsexual patients, while in *R (British Homeopathic Association) v NHS Commissioning Board*[38] (a case turning on the fairness of a consultation process rather than rationality), it was held that 'it would not be appropriate for the court to pass judgment on the legitimacy or otherwise of the view that homeopathy works', notwithstanding acceptance by the Board 'that there is a body of opinion, to which some practicing clinicians adhere, that homeopathy works (and that there is evidence to that effect)'.[39] It should be noted, also, that three challenges to recommendations made by NICE turned on procedural grounds relating to the accessibility of the economic models on which NICE decisions rested and on the provision of adequate reasons, rather than on the Institute's understanding and application of evidence and the selection and weighing of data.[40] Yet, even within this small subcategory of allocation case, there is judicial ambivalence regarding adoption of a substantively deferential position.[41] Albeit *obiter*, the Court of Appeal in *R (Servier Laboratories Limited) v NICE* 'was by no means convinced' that the Institute's rejection of post-clinical trial subgroup data in its evaluation of clinical effectiveness of a drug was rational, attaching particular weight to the fact that the European Medicines Agency had taken account of such data when carrying out its regulatory functions.[42]

32 Ibid [83].

33 Ibid [88].

34 [2014] EWHC 1182 (Admin).

35 The claimant lost the case on the basis that her challenge was not to the general funding policy, but rather to the 'legally unobjectionable' decision not to reopen her individual funding request on grounds of exceptionality, given that she had presented no new clinical information to justify such reopening: ibid [78]–[80].

36 Ibid [104].

37 [2011] EWCA Civ 247.

38 [2018] EWHC 1359 (Admin).

39 Ibid [61].

40 *R (Eisai Ltd) v NICE* (2007) EWHC 1941 (Admin)/(2008) EWCA Civ 438; *R (Servier Laboratories Ltd) v NICE* (2009) EWHC 281 (Admin)/[2010] EWCA Civ 346; *R (Bristol-Myers Squibb Pharmaceuticals Ltd) v NICE* [2009] EWHC 2722 (Admin). For discussion, see K Syrett, 'Health Technology Appraisal and the Courts: Accountability for Reasonableness and the Judicial Model of Procedural Justice' (2011) 6 Health Economics, Policy and Law 469.

41 A stance which is best captured by the following *dictum* of Holman J: 'It is important to stress at the outset that NICE is the specialist, expert body, charged with making appraisals and decisions of this type. The court is not. I have neither the right, still less the expertise, to review the decisions as to their substance.': *R (Servier Laboratories Ltd) v NICE* [2009] EWHC 281 (Admin), [6].

42 *R (Servier Laboratories Ltd) v NICE* [2010] EWCA Civ 346, [51].

Ways of seeing:[43] analysing the narrative

How might this narrative be interpreted? A standard framing is to view it as reflective of evolving jurisprudence: developments and modifications in the selection and application of grounds of judicial review understood within the broader context of English public law.[44] This is the approach taken by Newdick,[45] who considers the case law on access to hospital care under the three main heads of review articulated by Lord Diplock in the *GCHQ* case,[46] and within the category of irrationality (under which most of the cases discussed above fall), outlines a trend – noted above – from 'judicial passivity' to 'the hard look'. He attributes the latter shift to changing understandings of the meaning of the irrationality ground, citing a *dictum* of Lord Woolf MR, in which the judge identified 'two faces' of irrationality: 'the barely known decision which simply defies comprehension' (which underpins the passive stance) and 'a decision which can be seen to have proceeded by flawed logic' (which underpins the more interventionist 'hard look' form of scrutiny).[47]

This interpretation satisfies some of the criteria outlined in the work of the legal academics cited in the first section of this article – for example, it provides a response to Veitch's questions: 'If some judges are willing to be more proactive, then how, precisely, have they been so? What techniques have they used to assert their power . . . ?'[48] It is notable, however, that Newdick attributes the change in the judicial approach to irrationality to broader doctrinal developments in public law – especially a greater emphasis on the requirement for administrative bodies to give reasons for decisions[49] – rather than to any changes in the social and political context of allocative decision-making. Furthermore, this account stops short of analysing the developing law in terms of the ethical principles which might be said to underpin it, as much medical law scholarship tends to do.[50]

In this regard, the work of the present author provides an alternative reading, although in a manner which is somewhat distinct from the ethically informed analyses offered in respect of other topics in the field of medical law. Hence, it is argued that the shift towards a procedural form of review, post-*ex parte B*, can be understood as a way of judicially enforcing the 'accountability for reasonableness' model developed by Norman Daniels and James Sabin.[51] This model is ethically informed in so far as it centres upon

43 See J Berger, *Ways of Seeing* (BBC and Penguin 1972).

44 See further the discussion of the work of Daniel Wang below, especially (n 59) and accompanying text.

45 Newdick (n 19) 94–109.

46 *CCSU v Minister for Civil Service* [1985] AC 374.

47 *R v North & East Devon Health Authority, ex parte Coughlan* [1999] EWCA Civ 1871, [65]. Note, however, that Arvind and Stirton argue that the first reading of *Wednesbury*, which is generally taken to reflect the orthodox judicial position, was inconsistent with the 'juristic consensus' of the 1960s, 'in which it was taken for granted that the legal system must provide redress going to the merits of the case', and that it only became dominant with the influence of Lord Diplock over the evolution of English public law in the 1970s and 1980s: T Arvind and L Stirton, 'The Curious Origins of Judicial Review' (2017) 133 Law Quarterly Review 91, 95–6.

48 Veitch (n 9) 4.

49 Newdick (n 19) 97.

50 Of course, this is not to say that Newdick is oblivious to such principles: merely that they do not form part of the account he presents in this specific context. For discussion elsewhere in his book, see ibid, especially chs 1 and 2.

51 See e.g. N Daniels and J Sabin, *Setting Limits Fairly: Learning to Share Resources for Health* (2nd edn, Oxford University Press 2008) discussed in K Syrett, *Law, Legitimacy and the Rationing of Health Care: A Contextual and Comparative Perspective* (Cambridge University Press 2007) 100–8; also K Syrett, 'NICE and Judicial Review: Enforcing "Accountability for Reasonableness" through the Courts?' (2008) 16 Medical Law Review 127. See also Wang (n 18).

(distributive) *justice*, but it is purportedly neutral as to the ethical *substance* of allocative choices – for example, whether these seek to give effect to utilitarian or egalitarian considerations.[52] This is because there appears to be no societal consensus upon the appropriate ethical basis for allocating scarce healthcare resources,[53] and thus the best that can be achieved is a fair process for making such decisions which will ensure that they are publicly regarded as legitimate.

Those critics of 'bioethics-centrism' whose work was outlined earlier in this article might feel some discomfiture with an analysis which understands legal developments in the light of one of Beauchamp and Childress' famous four principles of biomedical ethics (albeit one which, being procedural in orientation, lacks the absolute, universal quality of other ethical principles which may be at play in medical law cases).[54] However, the present author has sought additionally to situate the 'accountability for reasonableness' thesis within the socio-political context of a changing NHS. In particular, a shift from implicit to explicit modes of priority-setting has been viewed as the backdrop for the evolution from judicial passivity to procedural scrutiny, with the judicial stance serving to reinforce the legitimacy of the prevailing form of allocation.[55]

More recently, a further reading of the development of the case law has been offered by Wang. This also attaches strong weight to judicial compliance with 'accountability for reasonableness' as an underlying driver for the evolving jurisprudence. However, it seeks to distinguish itself from the work of the present author in that it confers primacy upon the legal norms, rather than regarding these as having been shaped by the surrounding socio-political environment. Arguing against the latter position, on the basis that 'correlation is not causation',[56] Wang claims that 'it is actually the rigorous judicial scrutiny of rationing decisions that has driven the NHS to be more explicit about the reasons and procedures leading to the denial of treatment, rather than the other way round',[57] drawing attention also to the need for NHS decision-makers to make decisions 'judge-proof', that is 'to avoid, respond to, and comply with judicial review'.[58] He regards the broader development of English public law, especially 'the affirmation of the language of rights' and a growing tendency to require reasons to be presented for decisions,[59] as a 'better . . . explanatory variable' for the evolving law in this field than a shift from implicit to explicit rationing.[60]

Wang's critique of the conflation of correlation and causation appears somewhat at odds with his opinion that judicial scrutiny is the driving force underpinning increasingly explicit decision-making within the NHS, although elsewhere he is more guarded, noting that isolating the impact of litigation upon bureaucracies which are subject to multiple pressures is problematic, and claiming more modestly 'that courts interacted within a

52 It might be argued that the 'relevance' condition of the 'accountability for reasonableness' model, which requires that decisions be based upon criteria which fair-minded people will accept as pertinent to allocation of scarce healthcare resources, has a substantive character: see e.g. Syrett (n 51) (2007) 104–5; Syrett (n 40) (2007) 481.

53 For a critical perspective on this position, see R Ashcroft, 'Fair Process and the Redundancy of Bioethics: A Polemic' (2008) 1 Public Health Ethics 3.

54 T Beauchamp and J Childress, *Principles of Biomedical Ethics* (7th edn, Oxford University Press 2012) ch 7.

55 See K Syrett, 'Impotence or Importance? Judicial Review in an Era of Explicit NHS Rationing' (2004) 67 Modern Law Review 289, especially at 297.

56 Wang (n 18) 644.

57 Ibid 652–3.

58 Ibid 668.

59 Ibid 654–5. Cf Newdick (n 49) and accompanying text.

60 Ibid 656.

"soup of influences" that created a context that made rationing more explicit'.[61] What is most interesting about his analysis, however, is that it demonstrates both the ample scope which remains for debate as to the nature of the interaction between the law and the surrounding socio-political environment in this field, and the continuing primacy of bioethical understandings (in this instance, manifested in the framing of the evolving case law as a shift towards 'accountability for reasonableness').

As argued in the first section of this article, adoption of a systems theory perspective carries the potential to further illuminate these matters, as well as another issue mentioned only passingly by Wang: the (tentative) emergence of a third category of review which is more substantive in character.[62] The remainder of this article will accordingly seek to explore the insights which systems theory can provide in this context.

Applying systems theory to allocative case law

Mele, Pels and Polese have provided a helpful definition of a system as 'an entity, which is a coherent whole such that a boundary is perceived around it in order to distinguish internal and external elements and to identify input and output relating to and emerging from the entity'.[63] A systems approach is holistic, not reductionist: it 'analyses a phenomenon seen as a whole and not as simply the sum of elementary parts'.[64] This makes it a valuable perspective for the analysis of the deeper-rooted causes of broad-ranging shifts that occur over time, such as those analysed in this article. The following discussion will therefore offer an explanation of the salient points of systems theory and will seek to apply these to the developments in allocative jurisprudence outlined above.

(i) Functional differentiation, operational closure and judicial passivity

While originating in biology, systems theory rapidly came to be applied within the social context, with the concept of autopoiesis forming a central organising principle. This connotes 'the process of a system that produces "itself from itself"',[65] that is one in which elements of the system interact with each other to produce and reproduce the system without direct reference to the external environment. Such systems are thus operationally closed: the system defines its own boundary which separates itself from the environment, this giving rise to its autonomous character.

For Luhmann, this autopoietic reproduction takes place by means of communication,[66] the 'core of social systems'.[67] 'What is essential for an autonomous social autopoiesis is the conceptualization of society as a system of meanings, developed through a process of differentiation':[68] that is, the emergence of functionally

61 Ibid 658.

62 Citing *Otley* (n 30) and *Ross* (n 31), Wang merely remarks that 'based on divergent expert opinions, the courts also challenged the health authorities' analysis of the scientific evidence and the conclusion that the claimant's case was not exceptional': (n 18) 650. This seems to understate the distinctiveness of the form of scrutiny exercised by the courts in these cases.

63 C Mele, J Pels and F Polese, 'A Brief Review of Systems Theories and their Managerial Applications' (2010) 2 Service Science 126, 127.

64 Ibid.

65 Ibid 128.

66 See N Luhmann, 'The Autopoiesis of Social Systems' in F Geyer and J Van d Zeuwen (eds), *Sociocybernetic Paradoxes: Observation, Control and Evolution of Self-Steering Systems* (Sage 1986) 174.

67 M Schwaninger and S Groesser, 'Operational Closure and Self-Reference: On the Logic of Organizational Change' (2012) 29 Systems Research and Behavioral Science 342, 344.

68 A Lourenço, 'Autopoietic Social Systems Theory: the Co-Evolution of Law and the Economy' (Centre for Business Research, University of Cambridge Working Article No 409 2010) 3.

differentiated social subsystems,[69] such as law, politics, the economy and religion, which operate to reduce the complexity of the world through the absorption, processing and return of information through their own particular, distinct ways of 'seeing' and 'understanding'. The boundaries of these systems are formed by way of binary codes such as (in the case of law), 'legal/illegal', which serve therefore both to identify the subsystem and to distinguish it from its environment,[70] that is to effect its operational closure. Put differently, those participating in the making of legal communications 'operate on the basis of shared assumptions about "boundary conditions" which demarcate the legal order from other forms of communication: what counts as a legal rule, and what does not'.[71] Meanwhile, elsewhere (for example, in the realms of politics or religion), there exist other shared understandings based around different demarcations of those subsystems from their environment (the legal system then forming part of *that* environment).

While Luhmann did not write as extensively on medicine or healthcare as he did on other fields such as law, with the consequence that 'sociological systems theory has been applied to analyses of health only marginally',[72] he assumed "'treatment of disease", "treatment of ill persons" or "medicine"' to have evolved into a functional social subsystem.[73] The binary code applicable to this context might be obvious – ill/healthy – or might be more complex, for example hindering/promoting health, suboptimal/optimal physical and mental health or, in the public health context, presence/absence of pathogenic factors.[74] As for the medium of communication which applies within the system, Pelikan disputes Luhmann's claim that there is none,[75] and argues that this resides in the science-based system of medical terminology for differential diagnostics, and for the related system of therapies, defined in medical textbooks, handbooks, journals and reviews.[76] This latter point will be revisited below.

An acceptance that medicine/healthcare can be viewed, alongside law, as a social subsystem allows us a means of framing both the non-involvement of the courts at all prior to 1980, and the subsequent highly deferential judicial stance towards allocative challenges in early case law on the topic. The consequence of functional differentiation between operationally closed subsystems, effected through distinctive coding, is that 'the highly specialised types of communication developed within the subsystems of society are no[t] . . . interconnected or interchangeable, and attempts to artificially impose one type of systemic communication on another fail'.[77] Law and medicine (or healthcare) are distinct and autonomous social subsystems, defining themselves with regard to their environment in terms of differing binary codes. The two subsystems 'see things

69 Differentiation on a functional basis is a characteristic of modernity. In previous eras, differentiation took the form of segmentation (e.g. by reference to tribes or families), or stratification (i.e. hierarchical).

70 See N Luhmann, 'Operational Closure and Structural Coupling: The Differentiation of the Legal System' (1991) 13 Cardozo Law Review 1419, 1428.

71 S Deakin and F Carvalho, 'System and Evolution in Corporate Governance' (Centre for Business Research, University of Cambridge Working Article No 391 2009) 11.

72 J Pelikan, 'Understanding Differentiation of Health in Late Modernity by Use of Sociological Systems Theory' in D McQueen, I Kickbusch, L Porvin et al (eds), *Health and Modernity: The Role of Theory in Health Promotion* (Springer 2007) 74, 75.

73 Ibid 88.

74 Ibid 88–9, 92.

75 Ibid 89.

76 Ibid 89–90.

77 H G Moeller, *Luhmann Explained: From Souls to Systems* (Open Court 2006) 33.

differently and there is no possibility of one system being able to internalise the world-view of another'.[78]

In this sense, there is a profound problem of judicial (in)competence:[79] courts are quite simply not suited to determine questions of this type because they do not fit with the manner in which the legal system sees the world. This is well captured by the dictum of Ralph Gibson LJ in *Collier*.[80] The judge bemoans the deficiencies of the allocative decision-making process undertaken by the health authority, but acknowledges that law is utterly impotent to address them:

> If I were the father of this child, I think that I would want to be given answers about the supply to, and use of, funds by this health authority. No doubt the health authority would welcome the opportunity to deal with such matters so that they could explain what they are doing and what their problems are. But this court and the High Court have no role of general investigator of social policy and of allocation of resources.

The existence of functionally differentiated, operationally closed social subsystems, the boundaries of which are defined by codes, gives rise to what Luhmann has described as a 'paradox'. The system is what it is because of what it is not, and every determination of legality within the legal system contains within it the possibility that it might have 'gone the other way'.[81] But this paradox must be managed by the system, since to expose it would result in a form of existential paralysis: as Luhmann writes, 'one can neither ask nor answer the question (because it would lead to a paradox) as to whether the distinction between legal and illegal itself is legal or illegal'.[82] Such management (or 'deparadoxification') takes place through a process of concealment, which will commonly take the form of a 'mix of distinctions within the law and displacements to other decision-makers'.[83]

This process can be seen in operation in the early judicial review case law. The differentiation between law and healthcare is not manifested in *complete* abdication by the courts of any form of adjudicative role whatsoever, since this would amount to an acknowledgment of the (arbitrary) distinction between law and non-law and thus exposure of the 'paradox'. Rather, a strategy of concealment is adopted, beneath the 'ample cloak' of the *Wednesbury* principle.[84] This enables judges to define such matters within the terms of the system's binary coding of legal/illegal and, simultaneously, to displace decision-making in practice to those operating within the healthcare system by adopting the most restrictive reading of this ground of review, which in effect divests the courts of the task of reaching a determination on the issues of allocation.

(ii) Structural coupling and judicial interventionism

Systems theory thus provides an alternative perspective which can assist in explaining a phenomenon which is relatively well understood – the standpoint of judicial passivity, and

78 M King and C Thornhill, *Niklas Luhmann's Theory of Politics and Law* (Palgrave Macmillan 2005) 25.

79 For a discussion of the various forms of judicial (in)competence, see Syrett (n 51) (2007) 128–34.

80 Above (n 22).

81 Harrington (n 10) 22.

82 N Luhmann, L*aw as a Social System* (K Ziegert trans) (Oxford University Press 2004) 177.

83 Harrington (n 10) 23.

84 The phrase derives from J Jowell and A Lester, 'Beyond Wednesbury: Substantive Principles of Administrative Law' [1997] Public Law 368, 371.

the rationales for this position.[85] However, the particular value of adopting a sociological approach to medical law surely lies primarily in its capacity to cast fresh light on issues which are less settled, such as the basis for a shift to a more interventionist judicial stance on allocation questions. In order to explore its contribution in this regard, it is necessary to outline additional elements of the theory.

As a starting point, it is important to note Luhmann's statement that 'closure must not be misunderstood as isolation'.[86] While social subsystems are operationally closed, they are cognitively open – they have ongoing contact with the external environment and can receive information from it, but (as discussed in the preceding section) this information is processed in forms which are specific to its own 'way of seeing' (its code), and is then returned to the environment as a communication from, and in the terms of, that subsystem (such as a legal ruling).

Central to processes of interaction between a social subsystem and the other social subsystems which constitute its environment is the notion of 'structural coupling', which captures the 'idea of highly selective connections between systems and environments'.[87] 'This designates that different systems may co-evolve over time and systematically communicate about the same themes and within specific contexts, but in their specific and different codes.'[88] Some examples may be of assistance in understanding this concept. A structural coupling between the distinct subsystems of law and politics is effected through constitutions: 'a constitution is the paradox that brings together law and politics precisely by keeping them separate (namely, by allowing both law and politics to restrict the influence on each other)',[89] structural coupling between the subsystems of law and the economy is effected through mechanisms such as contract and property;[90] and structural coupling between politics and the economy through mechanisms such as taxes and tariffs.[91]

It should be noted that, in each of these cases, notwithstanding the coupling, the different subsystems are and remain separate, with the information emanating from the external environment being 'sorted' into the subsystem's distinct code. Thus, external pressures generated from the environment do not operate as direct inputs into the subsystem – Luhmann writes that 'the twin concepts of closure and structural coupling exclude the idea of information "entering" the system from the outside'.[92] Rather, structural coupling 'can only trigger irritations, surprises and disturbances',[93] which may

85 It is highly possible that systems theory can also offer an additional explanatory framework for the wider pattern of judicial deference to medical judgement characteristic of medical law in the *Bolam* era, but this is beyond the limited scope of this article. For a well-known critique of the position adopted by the courts, see The Right Honourable the Lord Woolf, 'Are the Courts Excessively Deferential to the Medical Profession?' (2001) 9 Medical Law Review 1.

86 Luhmann (n 82) 80.

87 Luhmann (n 70) 1432.

88 I-J Sand, 'The Interaction of Society, Politics and Law: The Legal and Communicative Theories of Habermas, Luhmann and Teubner' (2008) 53 Scandinavian Studies in Law 45, 53.

89 A Philippopoulos-Mihalopoulos, *Niklas Luhmann: Law, Justice, Society* (Routledge 2010) 143. See also Luhmann (n 70) 1436.

90 Luhmann (n 70) 1435.

91 N Luhmann, *Theory of Society* vol 2 (R Barrett trans) (Stanford University Press 2013) 111.

92 Luhmann (n 70) 1432.

93 Luhmann (n 82) 383.

(or may not) eventuate in *internally constructed* processes of adaptation and mutation.[94] Mechanisms of structural coupling thus provide spaces through which 'perturbation' from the environment is experienced, providing the subsystem with a 'chance to learn and transform its structures'.[95] Hence, as Teubner notes, 'co-evolving systems exert an indirect influence on each other'.[96]

These further features of systems theory provide a framework through which it is possible to interpret a number of aspects of the evolving jurisprudence on allocative matters.

First, they suggest that 'legal and social changes are . . . related but distinct processes. Legal change reflects an internal dynamic which, nevertheless, is affected by external stimuli and, in turn, influences the external environment.'[97] An autopoietic approach 'does not rule out causation: it assumes a complex causal relationship between subsystems, thus rejecting the view of *linear* causation in favour of one based on mutual influence'.[98] This tends to support Wang's more modest claim relating to the 'soup of influences',[99] in which law and the health system interact with each other to construct an environment in which allocative decisions are more explicit in character. The two subsystems underwent a process of *co-evolution* and thus attempts to locate the 'drivers of change' either in the shift to explicit rationing processes in the NHS (a position which is attributed by Wang to the present author), or the development and articulation of public law principles (Wang's claim) are equally misplaced, premised as they both are on an input/output model. It is simply not possible, in Luhmannian social systems theory, for a change in the character of resource allocation to directly modify the legal approach (or, correspondingly, for a change in the legal regime to directly alter the manner in which rationing takes place): 'only the law decides on this'.[100]

However, as we have seen, a social subsystem is far from isolated from its environment and can (although not necessarily *will*) be affected by 'perturbations in the other social system [which] will trigger there some changes governed by the internal logics of this world of meaning'.[101] In the context explored here, this raises a second issue: that is, the mechanisms through which the subsystems of law and medicine/healthcare are structurally coupled, such coupling being the locus of perturbation which may 'provoke change on the other side'.[102] In particular, given that the initial period surveyed here was analysed as characterised by closure, rather than coupling, we might ask whether structures of coupling have emerged over the period dating from the *Hincks* case in 1980.

Epistemological developments in the field of medicine appear to provide the key here. In recent decades, both in the UK and elsewhere, the practice of 'evidence-based

94 Deakin and Carvalho (n 71) 21 define 'mutation' as that which 'occurs by "rearranging" the available components and coupling them with the "new" informational components that represent the "new facts" that caused the pressure for mutation'.

95 Luhmann (n 70) 1433.

96 G Teubner, *Law as an Autopoietic System* (Blackwell 1993) 61.

97 G Teubner, 'Substantive and Reflexive Elements in Modern Law' (1983) 17 Law and Society Review 239, 249.

98 Lourenço (n 68) 10. Emphasis in original.

99 Above (n 61) and accompanying text.

100 Harrington (n 10) 24 discussing *Gillick v West Norfolk and Wisbech Health Authority* [1986] 1 AC 112: 'a change in medical opinion regarding the need for teenage contraception could not of itself have changed the corresponding legal regime'.

101 G Teubner, 'Legal Irritants: Good Faith in British Law or How Unifying Law Ends up in New Divergences' (1998) 61 Modern Law Review 11, 28.

102 Ibid.

medicine' (EBM) has secured hegemonic status, gradually (albeit not wholly) supplanting a more experiential approach of clinical judgement, rooted in trial and error, and personal observation. EBM, defined as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients',[103] is, in principle, scientific, objective and data-driven (as discussed further below). When initially applied to the allocative context in the NHS during the early 1990s, EBM facilitated the elimination of 'waste' on clinically ineffective treatments.[104] Subsequently, stimulated by the development of the sub-discipline of health economics[105] and the emergence of 'the first cousin of EBM',[106] health technology assessment (HTA) (in which regard the UK was a pioneer through the establishment of NICE in 1999), it additionally afforded a basis for prioritising certain treatments and services over others on grounds of cost-effectiveness.

Of course, evidence and its attendant discourse has always been central to the 'world of meaning' of law. EBM thus opened up a distinct space for structural coupling between this subsystem and that of medicine/healthcare. A particular mechanism by which such coupling was realised was the clinical guideline, a specialised form of the science-based medium of communication identified by Pelikan.[107] Guidelines, regarded as the 'main vehicle for implementing EBM',[108] function within the medicine/healthcare subsystem as statements of recommended best practice with a view to enhancement of the quality of healthcare and the minimisation of clinical variation; this was especially the case following the establishment of NICE in 1999 given that these were stated as the Institute's primary objectives.[109] Within the legal subsystem, in accordance with its distinct coding, they provide presumptive evidence of what constitutes a lawful standard of care or, in the allocative context, of a rational exercise of administrative discretion.[110]

This brings us to a third issue, which is to identify the manner in which the legal subsystem responded, by means of its own processes and operations, to the perturbation in the medical/healthcare subsystem caused by the shift to this new basis for clinical practice. Here, it is important to understand EBM, and latterly HTA, as rationalist forms of activity in so far as they seek to determine 'the one best option' in a given situation, following an identification of the issue, an analysis of the alternative means of addressing it, an evaluation of the consequences of adopting each of the alternatives, and a

103 D Sackett, W Rosenberg, J Muir Gray et al, 'Evidence Based Medicine: What It is and What It isn't' (1996) 312 British Medical Journal 71, 71.

104 See e.g. NHS Management Executive, *Improving Clinical Effectiveness* (NHS Management Executive (EL (93)115) 1993).

105 For discussions, see e.g. J Hurst, 'The Impact of Health Economics on Health Policy in England, and the Impact of Health Policy on Health Economics, 1972–1997' (1998) 7 Health Economics S47; J Coast, 'A History that Goes Hand in Hand: Reflections on the Development of Health Economics and the Role Played by Social Science & Medicine, 1967–2017' (2018) 196 Social Science and Medicine 227; E MacKillop and S Sheard, 'Quantifying Life: Understanding the History of Quality-Adjusted Life-Years (QALYs)' (2018) 211 Social Science and Medicine 359.

106 M Kelly and T Moore, 'The Judgement Process in Evidence-based Medicine and Health Technology Assessment' (2012) 10 Social Theory and Health 1, 2.

107 Above (n 76) and accompanying text.

108 M Field and K Lohr (eds), *Clinical Practice Guidelines: From Development to Use* (National Academy Press 1992) 2.

109 For discussion, see K Syrett, 'NICE work? Rationing, Review and the "Legitimacy Problem" in the New NHS' (2002) 10 Medical Law Review 1.

110 For a general discussion of the relation between clinical guidelines and the law, see J Tingle and C Foster (eds), *Clinical Guidelines: Law, Policy and Practice* (Cavendish 2002).

comparison of the consequences with the objectives.[111] Priority-setting decisions in healthcare which are explicitly premised upon these approaches can therefore be seen as manifestations of rationalist policy-making.[112]

The social subsystem of law also obliges decision-making to be characterised by rationality, through the mechanism of judicial review. Hence, although guidelines may constitute the primary *mechanism* through which coupling is brought about, the underpinning of that coupling resides in a shared commitment by both subsystems to the value of rationality. Unsurprisingly, therefore, the perturbation in the legal subsystem, experienced through forms of coupling centred upon the collection and application of evidence, manifests itself in an adaptation of law's construction of the ground of irrationality as the basis of what it regards as an inappropriate (and therefore unlawful) mode of decision-making. Thus, as the earlier narrative outlines, there has been a shift in the law's stance on what constitutes an irrational decision in the healthcare allocation context, from an egregious decision which is 'outrageous in its defiance of logic',[113] to the more frequently witnessed one which is seen to be based upon 'flawed logic'. But this evolution takes place within the terms and processes established by the legal subsystem, not as a direct input from the medicine/healthcare subsystem. Hence, if (following Newdick) we take Lord Woolf's dictum in *Coughlan* as expressive of this evolution,[114] it is notable that 'the second face' of irrationality is justified on the basis of (admittedly imprecise) legal precedent ('as it has developed in modern public law') and of existing – not novel – jurisdictional reach ('another aspect of the decision which is equally the concern of the law').[115] This fits with Teubner's notion of 'self-referential closure' as characterising an autopoietic system of law, signifying:

> . . . the circular relation between legal decisions and normative rules: decisions refer to rules and rules to decisions . . . references to external factors, e.g. politics or religion, are replaced by references to legal rules (stemming from court decisions, doctrinal inventions, or legislative acts).[116]

The preceding account offers a way of comprehending the broad shift from judicial deference to interventionism and the legal means by which this is achieved, but it does not specifically enable us to distinguish between, and understand, the variants of 'hard look' scrutiny which, as outlined above, range from the procedural to the much more substantive. However, deeper investigation of the nature of EBM as a rationalist activity can be of assistance in this regard.

EBM may be understood, in Weberian terms, as an illustration of instrumental rationality, 'that is determined by expectations as to the behaviour of objects in the

111 See C Lindblom, *The Policy-Making Process* (Prentice Hall 1968) 12. The close correlation to EBM can be seen from the description of the core of the practice of the latter as consisting of five steps: (i) formulation of clinical questions; (ii) searching for the best evidence; (iii) critically appraising this evidence; (iv) applying this evidence to patients; and (v) evaluating the impact of this application: R Upshur and C Tracy, 'Legitimacy, Authority, and Hierarchy: Critical Challenges for Evidence-based Medicine' (2004) 4 Brief Treatment and Crisis Intervention 197, 198.

112 See J Russell and T Greenhalgh, 'Being "Rational" and being "Human": How National Health Service Rationing Decisions are Constructed as Rational by Resource Allocation Panels' (2014) 18 Health 441; T Tenbensel, 'Health Prioritisation as Rationalist Policy Making: Problems, Prognoses and Prospects' (2000) 28 Policy and Politics 425.

113 *CCSU* (n 46) 410 (Lord Diplock).

114 See above (n 47) and accompanying text.

115 *Coughlan* (n 47) [65] (Lord Woolf MR).

116 G Teubner, 'Autopoiesis in Law and Society: A Rejoinder to Blankenburg' (1984) Law and Society Review 291, 295.

environment and of other human beings; these expectations are used as "conditions" or "means" for the attainment of the actor's own rationally pursued and calculated ends'.[117] As Schwandt argues:

> [This form of] rationality is monological and a matter of having the correct procedure for constructing descriptive, interpretive, and/or evaluative statements, assertions or claims about various kinds of "objects" that are evaluated. This approach, in turn, is wedded to a model of strategic political action aimed at "solving problems" in social programming. Administrators and policymakers seek to manage economic and social affairs "rationally" in an apolitical, scientized manner.[118]

Hence, under this approach, the focus is upon the gathering of 'better evidence of "what works" in terms of policy intervention':[119] the best such evidence being 'that which is derived through quantitative methodologies, empirically-tested and validated'.[120] In the case of EBM, this is manifested in a hierarchy of evidence reflective of the propensity of the method to avoid bias, in which epidemiological evidence derived from systematic reviews and meta-analyses of randomised controlled trials sit at the top, and unsystematic clinical observations lie at the foot.[121]

With this analysis in mind, we might plausibly read contentious judgments such as *Ross* and *Otley* and *obiter dicta* in *Rose* and *Servier Laboratories*, where judges connect irrationality with a misunderstanding or misapplication of, or departure from, evidence, merely as further instances of law's adaptation to the external stimulus of EBM through its own internal processes for 'seeing' and 'understanding' the environment. These judges articulate a 'legal construction of social reality',[122] through continued invocation of the ground of irrationality, but they choose to do so in a way which explicitly foregrounds EBM's objective, quantitative and rationalist forms of knowledge as the bases of logical – and therefore lawful – decisions. It might, perhaps, be said that there is evidence of especially close structural coupling between the subsystems of healthcare and law in these cases.

However, this particular filtering of the external pressures of EBM into the normative structures of the law is far from unproblematic. Drawing on the notion of the self-referential closure of a system,[123] Deakin and Carvalho observe that:

> . . . the essential characteristic of the order of the legal system as a system of communication is the importance of its internal congruence . . . the agents who participate in the making of legal communications do so on the basis of a set of shared understandings about the nature of the legal system. It is on this basis that the legal system can be said to "reproduce itself" over time.[124]

The question which arises, therefore, is whether the approach taken in these cases complies with 'shared understandings'. Of course, in one sense it does so, since it falls under the head of irrationality and, as noted above, Lord Woolf's explanation of the

117 M Weber, *Economy and Society: An Outline of Interpretive Sociology*, G Roth and C Wittich (eds) (Berkeley University of California Press 1978) 24.

118 T Schwandt, 'Evaluation as Practical Hermeneutics' (1997) 3 Evaluation 69, 74

119 I Sanderson, 'Getting Evidence into Practice: Perspectives on Rationality' (2004) 10 Evaluation 366, 368.

120 I Sanderson, 'Evaluation, Policy Leaning and Evidence-Based Policy Making' (2002) 80 Public Administration 1, 6.

121 G Guyatt, D Sackett, J Sinclair et al, 'Users' Guides to the Medical Literature. IX. A Method for Grading Health Care Recommendations' (1995) 274 Journal of the American Medical Association 1800.

122 The phrase is that of Teubner (n 97) 249.

123 See above (n 116) and accompanying text.

124 Above (n 71) 9.

'second face' of this ground may be viewed as an exercise in self-reference. From another standpoint, however, the more expansive reading of the ground, which (as argued previously) appears more substantive in orientation than is usual, does not appear wholly consistent with a broadly shared understanding permeating most of the remainder of the case law on allocation of scarce healthcare resources – from the decision of the High Court in *ex parte B* onward – that the focus of review should lie with the *process* of decision-making. This lack of congruence affords an explanation for the ambivalent stance of the courts in the third category of allocative case identified previously in this article: other judges do not share the same understandings as to the nature and scope of the irrationality ground as their brethren presiding in these cases.

This connects closely to a further, and final, question about the possible future direction of judicial activity in this decision-making context. What might insights from systems theory tell us about the likelihood of judges continuing to cleave to the 'traditional' approach to allocative choices, in which the emphasis is primarily upon procedural aspects of the decision, as against a more substantive reading in which the understanding and application of evidence is much more closely scrutinised?

As we have seen, since the legal system is cognitively open to its environment, it possesses the capacity to adapt to external stimuli experienced via mechanisms of structural coupling. But systems theory teaches us that such adaptation is neither automatic nor complete, since 'the scope for legal variation is constrained by the need to maintain the legal system's autonomy and internal consistency'.[125] It follows that there is no inevitability that a more substantive reading of irrationality in this context will eventually secure hegemonic status, even though it may constitute a 'better fit' with the environment (at least so long as EBM retains *its* hegemonic status). The key, rather, is 'how far [the revised reading] operate[s] consistently with the internal categories of legal analysis'.[126] Here, it is pertinent to remind ourselves that, while judicial scrutiny of healthcare allocation has been analysed in this article as if it were a discrete, autonomous field, it functions in reality merely as a subset of the broader law of judicial review.[127] Both congruence, and the scope of adaptation, can therefore only fully be understood by reference to that wider jurisprudential context. This is because:

> . . . it is a feature of legal orders that the meaning which they create refers to a shared perception that individual legal communications are linked together to form a coherent body of norms. In other words, for the agents who operate within and by reference to it, an understanding of the legal system cannot be obtained from an analysis of isolated elements, but derives from the process of self-observation of the system as a 'whole'.[128]

Accordingly, it is necessary to look beyond the law on healthcare allocation to ascertain whether that which has been identified here as a more substantive reading of the irrationality ground links coherently with norms elsewhere; if it does so, then there is much greater likelihood of future development in this direction. The position here is somewhat unclear. Historically, close scrutiny of the evidential basis for a decision has not

125 S Deakin, 'Legal Evolution: Integrating Economic and Systemic Approaches' (Centre for Business Research, University of Cambridge Working Article No 424 2011) 17.

126 S Deakin, 'Juridical Ontology: The Evolution of Legal Form' (2015) 40 Historical Social Research 170, 177.

127 See further above (n 44) and accompanying text.

128 Deakin and Carvalho (n 71) 9.

formed an important part of the court's role in a judicial review case.[129] However, there are indications that this may be changing, in particular because of the increased use of the proportionality standard. Since this test can be seen to 'reflect appropriate means-end rationality',[130] it is inevitable that 'judicial assessments of proportionality often depend upon complex empirical questions'.[131] A growing (albeit incomplete) convergence between this standard and the ground of irrationality, which has support from some academics and judges,[132] would point to the potential for increasing coherence between the more substantive mode of judicial interventionism grounded upon close scrutiny of the evidential basis for decisions, and broader systemic norms: but there remains some distance to travel. Consequently, the ambivalent judicial stance outlined previously seems likely to persist for the time being.

Conclusion

The last point serves as a valuable reminder that an approach to the understanding of medical law (or any other field of law) which is informed by understandings drawn from systems theory need not, and should not, render 'traditional' doctrinal legal analysis redundant. This is unsurprising, because Luhmann considers legal argumentation, which includes the reasoning of judges deciding a case in a particular way, to amount to one of the principal ways in which communication – which lies at the heart of his theory – occurs within the legal system.[133]

That said, systems theory adds an important dimension to a purely doctrinal approach, in the form of its attentiveness to the social context in which law sits. Superficially, this seems paradoxical given the emphasis of the theory upon the autonomy of systems, including law, but it must be remembered that the autonomous nature of a system comes about by way of *differentiation from a surrounding environment*, and that systems are cognitively open to that environment. This provides a means of comprehending legal change, which is triggered through structural coupling. The argument posited in this article is that an increased focus upon evidence as the basis for decisions in healthcare, manifested in particular in clinical guidelines and founded upon instrumental rationality, coupled the systems of medicine/healthcare and law together and simultaneously operated as a perturbation to the legal system.

However, systems theory also rejects a straightforward 'input–output' (or 'stimulus–response') model of interaction with the environment. This casts doubt upon analyses which seek to explain developments in legal norms as *caused* by external pressures (or vice versa), such as shifting approaches to allocative decision-making in the NHS. Rather, the pressures from the environment (such as those created by the rise of EBM) are received within and constructed by the legal system's own normative criteria, since 'the legal system models the environment in its own terms'.[134] In the field surveyed here, this is

129 See J Tomlinson and K Sheridan, 'Judicial Review, Evidence, and Systemic Unfairness in the UK' (*IACL-AIDC Blog*, 3 September 2018) <https://blog-iacl-aidc.org/blog/2018/9/3/judicial-review-evidence-and-systemic-unfairness-in-the-uk>.

130 M Cohen-Eliya and I Porat, *Proportionality and Constitutional Culture* (Cambridge University Press 2013) 126.

131 A Carter, 'Constitutional Convergence? Some Lessons from Proportionality' in M Elliott, J Varuhas and S Stark (eds), *The Unity of Public Law?: Doctrinal, Theoretical and Comparative Perspectives* (Hart 2018) 373.

132 See e.g. P Craig, 'The Nature of Reasonableness Review' (2013) 66 Current Legal Problems 131; *Kennedy v Charity Commission* [2014] UKSC 20, [54] (Lord Mance JSC); *Pham v Home Secretary* [2015] UKSC 19, [94] (Lord Mance JSC), [104]–[109] (Lord Sumption JSC).

133 See King and Thornhill (n 78) 45.

134 R Lempert , 'The Autonomy of Law: Two Visions Compared' in G Teubner (ed), *Autopoietic Law: A New Approach to Law and Society* (Walter de Gruyter 1988) 153.

manifested in developments in the ground of irrationality in respect of questions of healthcare allocation, but the consistency of certain of these developments with the wider body of norms is questionable, giving rise to some uncertainty as to the future pattern of evolution in view of the importance of internal congruence to the effective operational performance of the legal system.

In sum, this article has sought to demonstrate that a systems theory perspective can assist in building an enhanced understanding of this area of medical law. However, the utility of this approach surely extends well beyond this particular context. To illustrate this, a final point may be considered:

> For Luhmann . . . 'truths', which assume the existence of some external, objective arbiter of rightness . . . stand in the way of any 'sociological' understandings of the contingent nature of society. They are remnants of the Enlightenment notion of 'perfection' through which precise external causes could be identified for each evident imperfection in society, and 'naturally good' and 'naturally bad' explanations and solutions could be readily distinguished from one another.[135]

Systems theory therefore teaches us, through its foundation in the functional differentiation of society, that no single 'view of the world' predominates. Here lies the basis of a further challenge to a view of medical law which takes bioethics as central.[136] It is through a capacity to yield insights of this type that systems theory demonstrates its value, and it is submitted, therefore, that it is worthy of careful consideration by anyone seeking to analyse and explicate the present terrain, or to map the future trajectory, of medical law.

135 King and Thornhill (n 78) 3.

136 It is perhaps pertinent to note here that Luhmann regarded the systems of *morality* and law as functionally differentiated: see N Luhmann, 'Politicians, Honesty and the Higher Amorality of Politics' (1994) 11 Theory, Culture and Society 25, 29.

NILQ 70(1): 131–153

Reproductive loss and disposal of pregnancy remains+

LOUISE AUSTIN* AND SHEELAGH MCGUINNESS**

Centre for Health, Law, and Society, University of Bristol Law School

Abstract

In this paper we examine the legal framework which governs the management of pregnancy remains in the context of reproductive loss; specifically pregnancies which reach an unwanted end prior to 24 weeks' gestation. It is important to consider the role for law as it is clear that law has the capacity to shape the nature of the care that people receive and their experience of bereavement at the time of reproductive loss. The unwanted end of a desired pregnancy can have profound consequences for those who experience it. How we respond to the needs of these individuals will have important consequences not just for their well-being, but it can also impact their future reproductive experiences. Furthermore, the original empirical research on which this paper is based demonstrates how healthcare practice in this area is problematic in its inconsistency, and in failures to account for the particular needs of the person who has suffered an unwanted end to pregnancy. Because appropriate healthcare is properly determined in this context by the perspective of the individual, we argue that healthcare professionals should, as a matter both of good practice and of law, follow the individual's lead when seeking to understand their needs. Accordingly, we advocate for the importance of all legal options for disposal of pregnancy remains being discussed when a person who has suffered reproductive loss wants that information and present practical measures that can be introduced to ensure this happens.

Keywords: reproductive loss; miscarriage; human tissue; Human Tissue Authority; pregnancy remains; informed consent; *Montgomery*.

+ We are grateful to John Coggon, Danielle Fuller, Judy Laing, Jeannette Littlemore, and two anonymous reviewers for their helpful comments on earlier drafts. We are also grateful to audiences at the 2018 Socio-Legal Studies Association Annual Conference and the Centre for Social Ethics and Policy Seminar Series, University of Manchester.

* Mrs Louise Austin, PhD Candidate in Law, Centre for Health, Law and Society and Centre for Ethics in Medicine, University of Bristol Law School, UK; louise.austin@bristol.ac.uk. I would like to acknowledge the support of ESRC through my 1+3 Scholarship (1653376).

** Dr Sheelagh McGuinness, Centre for Health, Law, and Society, University of Bristol Law School UK; sheelagh.mcguinness@bristol.ac.uk. I would like to acknowledge the support of the ESRC, ES-N008359–1.

1 Introduction

The loss of a pregnancy, either through miscarriage or stillbirth, affects many people each year.[1] In addition to this, each year pregnant people will end a much-wanted pregnancy for many reasons, e.g. following a diagnosis of fetal abnormality.[2] The unwanted end of a desired pregnancy can have profound consequences for those who experience it. How we respond to the needs of these individuals will have important consequences not just for their well-being, but it can also impact their future reproductive experiences.[3] It is now accepted that appropriate care at the time of loss should be responsive not just to clinical but also emotional needs.[4] In particular, care that facilitates the ability to grieve, if necessary, can reduce the need for longer-term follow-up psychological care and improve future reproductive outcomes.[5] As such, the care and support provided to affected people and their families can help to mediate how they experience the loss and significantly impact their on-going health and well-being, including future reproductive decision-making.

In this paper we examine the legal framework which governs the management of pregnancy remains[6] in the context of reproductive loss; specifically pregnancies which reach an unwanted end prior to 24 weeks' gestation.[7] We do not focus on stillbirth because, as we will explain in more detail below, there is ambiguity about the status of pregnancy remains after miscarriage which does not exist in stillbirth, and often pregnant people are not aware of the legally permissible options for disposal of miscarried pregnancy remains. The medico-legal framework that governs miscarriage and stillbirth has not been the subject of sustained academic critique, notwithstanding the burgeoning

1 It is estimated 1 in 8 pregnancies end in miscarriage amongst those who know they are pregnant: *NHS, Overview: Miscarriage* <www.nhs.uk/conditions/miscarriage/#how-common-are-miscarriages>.

2 The most recent statistics show that 3314 abortions were performed under this ground: Department of Health and Social Care, *Abortion Statistics, England and Wales: 2017 Summary Information from the Abortion Notification Forms Returned to the Chief Medical Officers of England and Wales* (DHSC, 2018).

3 See, for example: Dimitrios Siassakos, 'All Bereaved Parents are Entitled to Good Care after Stillbirth: A Mixed-methods Multicentre Study (INSIGHT)' (2018) 125(2) BJOG: An International Journal of Obstetrics and Gynaecology 160–70; Sarah Cullen, Barbara Coughlan, Anne McMahon, Brenda Casey, Sheila Power and Mary Brosnan, 'Parents' Experiences of Clinical Care during Second Trimester Miscarriage' (2018) 26 British Journal of Midwifery <www.magonlinelibrary.com/doi/abs/10.12968/bjom.2018.26.5.309>.

4 The emotional and psychological impacts of miscarriage have been identified as a priority area for future research: see Matthew Prior et al, 'Priorities for Research in Miscarriage: A Priority Setting Partnership between People Affected by Miscarriage and Professionals following the James Lind Alliance Methodology' (2017) 7(8) BMJ Open 1–8. There is evidence that miscarriage can have psychological and emotional impacts and that these are often under-recognised: see Ingrid Lok et al, 'Psychological Morbidity following Miscarriage' (2007) 21(2) Best Practice and Research Clinical Obstetrics and Gynaecology 229–47.

5 Siassakos (n 3); NHS North Bristol NHS Trust, *PARENTS Study* <www.nbt.nhs.uk/www.nbt.nhs.uk/WCHResearchPARENTS>; Aleena Wojcieszek, 'Care in Subsequent Pregnancies following Stillbirth: An International Survey of Parents' (2018) 125 BJOG 193–201.

6 Here we follow the language of the HTA guidance. The Authority explains its use of this term, and why it doesn't distinguish between fetal tissue and other products of conception as follows: 'Women define their pregnancy according to their own circumstances, values, understanding and beliefs. The HTA and professionals in the field consider that any attempt to categorise the pregnancy may result in health professionals viewing the pregnancy differently from the woman involved. Furthermore, if the mode of disposal were to be linked to types of pregnancy or pregnancy loss, some women may find themselves being denied certain choices. Acting in response to the needs and wishes of the women first and foremost helps avoid such problems.' <www.hta.gov.uk/faqs/disposal-pregnancy-remains-faqs>.

7 We adopt the categorisation of reproductive loss provided by Sarah Earle, Pam Foley, Carol Komaromy and Cathy Lloyd, 'Conceptualizing Reproductive Loss: A Social Sciences Perspective' (2008) 11(4) Human Fertility 259–62. However, we wish to emphasise that situations where an unwanted pregnancy is ended with the consent of the pregnant person can constitute a reproductive gain, for more on this see Erica Millar, *Happy Abortion: Our Bodies in an Era of Choice* (Zed Books 2017).

social science literature.[8] However, it is important to consider the role for law, as it is clear that law has the capacity to shape the nature of the care pregnant people receive and their experience of bereavement at the time of reproductive loss. Our analysis draws from the findings of the Death Before Birth (DBB) project – on which the first author provided research assistance and the second author was a co-investigator – in order to support the arguments that we make.[9]

DBB was a socio-legal, linguistic study of how people in England who have experienced miscarriage, termination and stillbirth reach decisions concerning the disposal of the remains of pregnancy, how their perceptions of the law impact their decision-making, and how they communicate their experiences and choices to those who support them.[10] The options for disposal are set out in key guidance documents: cremation (shared or individual); burial (shared or individual); sensitive incineration (incineration separate to other clinical waste); burial at home or at some other site subject to certain limitations.[11] The first stage of the DBB project involved an examination of hospital documentation to find out what options were being offered or discussed with those who experience reproductive loss. The next stage of the project involved semi-structured interviews with a range of stakeholders including bereavement care providers in hospitals within NHS England; professionals in the funerary industry; those who worked with relevant bereavement support organisations; and women who experienced stillbirth, miscarriage, or termination following a diagnosis of fetal anomaly. These interviews bore out a key finding of the DBB project: that those who experience miscarriage are offered information about some (usually cremation), but not all of the legally permissible options for disposal.[12] It was also clear that individuals who miscarried outside of the hospital setting were not always fully informed about what to expect or how to manage the pregnancy remains they passed.

In order to remedy the gap in information disclosure, we argue that the test for informed consent as laid out in *Montgomery v Lanarkshire Health Board* provides a legal basis for requiring that pregnant people be given information on all legally permissible options for disposal.[13] Legally, pregnancy remains prior to 24 weeks' gestation are regarded as the person's tissue. Ensuring that the person has a choice in what is done with those remains once they cease to be physically connected to them forms part of their interest in their own physical integrity which the law of informed consent seeks to protect. In addition, options for disposal may have important implications for the acceptability of different

8 See, for example, Linda Layne, *Motherhood Lost: A Feminist Account of Pregnancy Loss in America* (Routledge 2003); Sarah Earle, Carol Komaromy and Linda Layne (eds), *Understanding Reproductive Loss: Perspectives on Life, Death, and Fertility* (Routledge 2016); Roseanne Cecil, *The Anthropology of Pregnancy Loss: Comparative Studies in Miscarriage, Stillbirth, and Neonatal Death* (Berg 1996).

9 Death Before Birth: Understanding, Informing and Supporting Choices made by People who have Experienced Miscarriage, Termination and Stillbirth <https://deathbeforebirthproject.org> (ESRC, ES-N008359–1).

10 Death Before Birth, 'About the Project' <https://deathbeforebirthproject.org/about>.

11 See: HTA, *Guidance on the Disposal of Pregnancy Remains following Pregnancy Loss or Termination* (HTA 2015); Royal College of Nursing, *Managing the Disposal of Pregnancy Remains* (RCN 2015); Institute of Cemetery and Crematorium Management, *The Sensitive Disposal of Fetal Remains: Policy and Guidance for Burial and Cremation Authorities and Companies* (ICCM 2015); Sands Stillbirth and Neonatal Death Charity, 'Chapter 20. Funerals and Sensitive Disposal', *Pregnancy Loss and the Death of a Baby: Guidelines for Professionals* (4th edn, Tantamount 2016) 323–53.

12 For a detailed summary of the key findings, see: Sheelagh McGuinness and Karolina Kuberska, *Report to the Human Tissue Authority on Disposal of Pregnancy Remains (less than 24 weeks' gestational stage)* (2017) <https://deathbeforebirthproject.org/research/htareport2017>.

13 *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [108].

treatment options to the pregnant person. As such, disposal of pregnancy remains should be discussed as part of the care and management of miscarriage.

The legal question in *Montgomery* related to risk disclosure when seeking informed consent to medical treatment, and whether a doctor had breached her duty of disclosure by failing to warn a pregnant patient of the risk of shoulder dystocia occurring during vaginal delivery, and the alternative option of delivering the baby by way of a caesarean section instead. The Supreme Court concluded that the doctor's duty was:

> . . . to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would attach significance to it.[14]

Thus, information disclosure in healthcare goes beyond information about risk to include variant or alternative treatments, and should be tailored to individuals.[15] In adopting this approach, the court endorsed the approach to consent set out in General Medical Council (GMC) guidance which also focuses on the need to tailor information to individual patients.[16] In keeping with this, we argue in section 3 of this paper that in accordance with Human Tissue Authority (HTA) guidance, healthcare staff should advise pregnant people of all disposal options, including those not available through the hospital, and details of whom to approach if the person's preferred method of disposal is not offered by the hospital.[17]

Prior to that legal argument, in section 2 we provide an overview of the conceptual framework that grounds our arguments. We endorse a feminist person-centred approach to understanding pregnancy loss. The strength of this approach is that it acknowledges the range of views that different people may have with regard to pregnancy remains. The remainder of the section details the practical implications which management of pregnancy remains has for treatment for miscarriage. As we detail below, alternative approaches to the management of miscarriage will have consequences for the physical experience of miscarriage and may also impact the options for disposal available to the pregnant person. As indicated, in section 3 we detail the legal basis for ensuring that pregnant people are provided with appropriate information on disposal options. We argue that disposal of pregnancy remains should be discussed as part of the explanation of different options for the management of miscarriage. Disposal options are part of the information necessary to ensuring that a pregnant person knows what to expect from treatment and the relationship between treatment and disposal may influence the acceptability of different approaches to management of miscarriage. The final part of our paper makes some specific recommendations about the possibility of using standardised policies, consent forms and information leaflets to promote consistency in

14 Ibid [87].

15 Ibid [87] and [90].

16 Ibid [93]. GMC, 'Consent: Patients and Doctors making Decisions Together' (GMC 2008) [4] <www.gmc-uk.org/-/media/documents/consent---english-0617_pdf-48903482.pdf>. This guidance is in the process of being revised post-*Montgomery*, but the current draft revised guidance still focuses on the need to tailor information disclosure to the individual patient: GMC, 'The Main Principles of this Guidance', *Decision Making and Consent: Supporting Patient Choices about Health and Care: Draft Guidance for Consultation* (GMC, 2018) 6 <www.gmc-uk.org/-/media/ethical-guidance/related-pdf-items/consent-draft-guidance/consent-draft-guidance.pdf>.

17 HTA (n 11) [9].

information provision and thus facilitate better care in this area. Clearly defined information provision pathways will be extremely important. It is our intention in this paper to identify practical solutions, with a clear foundation in law, which can improve healthcare in this area.

2 Reproductive loss and remains of pregnancy

2.1. Understanding pregnancy loss

Earle et al describe how 'reproductive loss may not be experienced and understood in the same way by different groups of people'.[18] The DBB Project findings echo this and evidence heterogeneous attitudes towards the end of a pregnancy, towards the remains, and towards options for treatment and disposal. In order to accommodate this diverse range of views, we advocate a person-centred approach to understanding pregnancy and reproductive loss.[19] In particular we highlight the embodied nature of reproductive experience and detail the implications of this for how we understand the relationship between the pregnant person and the pregnancy remains and for the care and management of miscarriage. In the opening to *Mass Hysteria: Medicine, Culture, and Mothers' Bodies*, Rebecca Kukla states:

> the fetus and with it the pregnant woman are not objects that come with ready-made stable boundaries . . . the maternal body incarnates one human being at the beginning of pregnancy and two at the end of it, and it is by no means clear how to tell a coherent story about this passage.[20]

For those who experience reproductive loss, particularly prior to 24 weeks, this lack of coherence continues, or indeed can be exacerbated, as once the pregnancy ends there are not two. One of the DBB project participants describes the situation as follows:

> There's only me that knew that I was ever pregnant. You know. There's only me that knows I ever had a baby well obviously my family knows but um there is nothing to say that she existed okay she never made it into this world but she existed.[21]

As such the fetus and subsequently the remains occupy a liminal category. Some parents will perceive this material as their child and want it to be afforded all the respect, dignity and ceremonial disposal as that of a formerly living person.[22] Others, perhaps most obviously those ending an unwanted pregnancy, may not view the tissue in this way and would not want ceremonial disposal.[23]

Isabel Karpin has influentially argued for the importance of reconceptualising the maternal–fetal relationship to counter-narratives that frame the pregnant person in

18 Earle et al (n 7) 260

19 Layne (n 8); For an excellent recent contribution to this call, see Abigail McNiven, '(Re)collections: Engaging Feminist Geography with Embodied and Relational Experiences of Pregnancy Losses' (PhD thesis, Durham University 2014) <http://etheses.dur.ac.uk/10786>.

20 Rebecca Kukla, *Mass Hysteria: Medicine, Culture, and Mothers' Bodies* (Rowman & Littlefield 2005) 4.

21 This was someone who had themselves experienced reproductive loss and now supported others in this situation. WP3–05/2017. Some of the quotations in this paper have been edited to ensure they are intelligible to the reader. These edits have been minimal and have not impacted the substance of the quotations.

22 Here we use ceremonial disposal to describe cremation or burial as often these are accompanied by a ceremony with features similar to a truncated funeral. See further, Karolina Kuberska, 'Unwitnessed Ceremonies: Funeral Services for Pre-24-week Pregnancy Losses in England' in S Kilshaw and K Borg (eds), *Negotiating Miscarriage: A Social, Medical and Conceptual Problem* (Berghahn Books forthcoming).

23 Amanda J Myers, Patricia A Lohr and Naomi Pfeffer, 'Disposal of Fetal Tissue following Elective Abortion: What Women Think' (2014) Journal of Family Planning and Reproductive Health Care 84–9.

opposition to the fetal subject.[24] Using the frame of 'not one but not two', she suggests we recuperate the maternal–fetal connection:

> . . . to place the woman in control of her body/self and the fetus and not, as she was constructed in the pre-technological era, as subject to her body nor, as she might otherwise be constructed in the age of technology, as subject to the fetus.[25]

We suggest that a similar recuperation of the interest a person might have in their pregnancy remains is important to meeting the needs of those who have experienced reproductive loss. Peel and Cain note:

> It is hard to locate pregnancy loss in the lexicon of feminism: Feminists have been well taught to mistrust the concept of the 'pre-born' child, the now ubiquitous foetal image which threatens to take over the mother's subjectivity and agency.[26]

The lack of opportunity to acknowledge the status of the remains poses a challenge to the pregnant person's agency and subjectivity different to that traditionally identified in the abortion debate; in this case the 'strangeness' that the remains are not recognised as 'a child'. Linda Layne argues that:

> It is time for feminists to move pregnancy loss from 'a private space of shame' to a 'public space of solidarity . . . Feminists must frankly acknowledge the frequency and import of such events in women's lives and create a woman-centred discourse of pregnancy loss.[27]

We agree and argue that such an approach provides a nuanced framework for how we might understand the relationship between the person and the remains. Such an approach is driven by the needs and interests of the pregnant person rather than fear or suspicion of fetal personification. By placing the person in control of defining the boundaries of their interests in pregnancy remains it is possible to accommodate a range of views and experiences from those who view the material as their future child, to those who attach no significance to it at all.

In her study of reproductive loss amongst white middle-class American women, Layne highlights the way in which those who experience pregnancy loss often find themselves caught between two contradictory cultural forces. First, is the power of medical and reproductive technologies which (i) make the fetus increasingly visible and public and (ii) increase expectation of a 'successful' reproductive outcome. Home use tests facilitate people finding out they are pregnant before they have even missed a period. In addition to this, medical and reproductive technologies have increasingly facilitated the entry of the fetus into 'public life' and mean that pregnant people get to 'see' their child at earlier

24 See Isabel Karpin, 'Legislating the Female Body: Reproductive Technology and the Reconstructed Woman' (1992) 3(1) Columbia Journal of Gender and Law 325–49.

25 Ibid 330.

26 Elizabeth Peel and Ruth Cain, 'Chapter 6. "Silent" Miscarriage and Deafening Heteronormativity: A British Experiential and Critical Feminist Account' in Earle et al (eds) (n 8) 87 drawing on the work of Petchesky. For a discussion of the relationship between the pregnancy loss movement and anti-abortion politics, see Layne (n 8).

27 Layne (n 8) 239.

gestational stages.[28] Van der Sijpt describes the dominant linearity of reproductive narratives:

> Current thinking and theorizing about pregnancy and childbirth often take a linear time frame as a starting point. Dominant biomedical embryological notions trace the development of a fertilized ovum into an embryo and eventually, a foetus that is believed to be viable at a specific gestational age. Consequently, pregnancies are conceptualised as a gradual process evolving over time and expressible in days, weeks, months and trimesters.[29]

Furthermore, there is the perception that a pregnancy, particularly one which is medically managed, will progress along a trajectory that gives rise to a living child. Layne argues that this combination of 'earlier and more intensive social construction of fetal personhood' and increasingly unrealistic expectations about the possibilities of biomedicine can exacerbate experiences of reproductive loss.[30] The Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guideline No 17 defines miscarriage 'as the spontaneous loss of a pregnancy before the fetus reaches viability', taken to be 24 weeks' gestation.[31] They provide the following statistics on occurrence of miscarriage:

> If this happens in the first 3 months of pregnancy, it is known as an early miscarriage. Unfortunately, early miscarriages are common, with 10–20 in 100 (10–20%) pregnancies ending this way. Late miscarriages, after 3 months of pregnancy but before 24 weeks, are less common: 1–2 in 100 (1–2%) pregnancies end in a late miscarriage.[32]

Miscarriage, particularly early miscarriage, is therefore a relatively common experience. Notwithstanding this, it is usually unplanned and unexpected. Discourses of pregnancy commonly focus on positive birth outcomes and future living children, often overlooking potential negative experiences.[33] As Peel and Cain summarise:

> Pregnancy loss is an example of the cultural silence around reproductive 'malfunction': statistically common it remains shrouded in secrecy.[34]

---

28 The role of ultrasound in pregnancy has been subject to sustained and varied critique, see for example, Rosalind Petchesky, 'Fetal Images: The Power of Visual Culture in the Politics of Reproduction' (1987) 13(2) Feminist Studies 263–92; Janelle Taylor, *The Public Life of the Fetal Sonogram: Technology, Consumption, and the Politics of Reproduction* (Rutgers University Press 2008). For a succinct overview of these arguments and a fascinating account of the role of ultrasound in the context of termination of pregnancy, see Sian Beynon-Jones, 'Revisioning Ultrasound through Women's Accounts of Pre-abortion Care in England' (2015) 29 Gender and Society 694–715.

29 Erica Van der Sijpt, 'Chapter 8. Focusing on Force and Forms in Cameroon: Reproductive Loss Reconsidered' in Earle et al (eds) (n 8) 79. See also Erica van der Sijpt and Catrien Notermans, 'Perils to Pregnancies: On Social Sorrows and Strategies Surrounding Pregnancy Loss in Cameroon' (2010) 24(3) Medical Anthropology Quarterly 381–98.

30 Layne (n 8) 29.

31 Royal College of Obstetricians and Gynaecologists, *The Investigation and Treatment of Couples with Recurrent First-trimester and Second-trimester Miscarriage* (Green Top Guideline No 17) (RCOG, 2011) <www.rcog.org.uk/globalassets/documents/guidelines/gtg_17.pdf>.

32 Royal College of Obstetricians and Gynaecologists, *Information for You: Recurrent and Late Miscarriage: Tests and Treatments of Couples* (RCOG 2012) <www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-recurrent-and-late-miscarriage---tests-and-treatment-of-couples.pdf>.

33 For example, pregnancy support books rarely include information about reproductive loss, and if they do it is minimal and tends to focus on the risks of early miscarriage. This is indicative of a broader glossing over of positive negative outcomes to pregnancy: see, for example, in relation to pre-natal testing, Pam Lowe et al, '"Making it All Normal": The Role of the Internet in Problematic Pregnancy' (2009) 19(10) Qualitative Health Research 1476–84.

34 Peel and Cain (n 26) 79.

This taboo leads to the second cultural force Layne identifies. The experience of reproductive loss is often met with silence or by attempts to minimise the significance of the experience.[35] Samantha Murphy states 'by creating this foetus, this unborn child as a social being, we turn this woman into "its mother" – defining her in terms of the foetus'.[36] Yet, in situations of reproductive loss where there is no living child existing in the world:

> [T]he very people who have encouraged the mother-in-the-making to take on this role and may have participated with her in the social construction of her 'baby' often withdraw their support for these interrelated projects and act as if nothing of any significance took place.[37]

When reproductive loss is mediated through the cultural taboo surrounding it, the experience can be made worse through lack of recognition or acknowledgment of what the person has been through. For example, some of the DBB project participants pointed to lack of acknowledgment of reproductive loss from colleagues once they returned to work.[38]

In addressing the cultural taboo surrounding reproductive loss we need to acknowledge the complexity of the relationship that people may have with their pregnancy remains, as is clear from the following account from one of the DBB project participants:

> Obviously mine was, um, so mine stopped growing at six weeks but I was twelve to thirteen weeks pregnant cause my body hadn't realised that nothing was happening. Um so so he said your only options are a cremation and that has to be on site erm and it's up to it whether you want to be there or not and then if you want but the remains to remain on site. And I was like right okay that makes no sense bothering to uh. I just thought oh why wouldn't it just go in with general like clinical waste if it's – if they're not deeming it as a thing? So it sort of made no sense I was like is it a thing? Cause one minute it is a thing and the next it's not a thing?[39]

This quotation emphasises the importance of information provision being context-specific and sensitive to the needs of the individual. For this woman, the fetus did not constitute a baby at this point, but rather, 'a thing'. The offer of a cremation diverges with this perception and elevates the status of the remains in a way which does not accord with her perception. We are thus sensitive to the fact that the way in which options for disposal are offered can have implicit meaning for the status of pregnancy remains: by placing a particular value on the remains, we may be transforming the pregnant person into a role or a relationship they do not yet identify with.[40] As this quote emphasises, we must also be careful of imposing narratives or scripts on grieving individuals by assuming that a

35 Alice Lovell, 'Some Questions of Identity: Late Miscarriage, Stillbirth and Perinatal Loss' (1983) 17(11) Social Science and Medicine 755–61; Claudia Malacrida, 'Complicating Mourning: The Social Economy of Perinatal Death' (1999) 9 (4) Qualitative Health Research' 504–19.

36 Samantha Murphy, 'Chapter 9. Bereaved Parents: A Contradiction in Terms?' in Earle et al (eds) (n 8) 118.

37 Layne (n 8) 17.

38 This may be because people are unsure what to say. See Jeannette Littlemore et al, 'Pregnancy Loss: How to Find the Right Words to Talk about it' (*The Conversation,* 25 August 15 2018) <https://theconversation.com/pregnancy-loss-how-to-find-the-right-words-to-talk-about-it-100915>.

39 WP4–10/2017.

40 For a similar, but sharper, account of dissatisfaction in a similar situation see Leslie J Reagan, 'From Hazard to Blessing to Tragedy: Representations of Miscarriage in Twentieth-Century America' (2003) 29(2) Feminist Studies 356–78.

much-wanted pregnancy means an automatic preference for ceremonial disposal.[41] Nor should we assume that because a someone has elected to have a termination they have no interest in the remains.[42] Instead, we argue that healthcare professionals should take the lead from pregnant people about their needs.

Montgomery, whose application to this area is explained below, endorsed a patient-centred approach to information disclosure in healthcare.[43] Consistent with that, our critical reasoning here, and the findings from the DBB Project, we advocate for the imperative of a person-centred approach to care in the area of disposal of pregnancy remains; one that acknowledges the heterogeneity of views that individuals might have about their pregnancy remains and the range of feelings they may have about the status of those remains. In order to ensure that someone is prepared for what to expect from the experience of miscarriage, and also to allow them to make an informed choice about different treatment options. We argue for the importance of all options for disposal being discussed unless, in response to the healthcare professional advising there are different options available, the pregnant person indicates they do not want that information. We will now detail the legal framework that sets the contours for the permissibility for the management of fetal remains.

2.2 Miscarriage and stillbirth – definitions, registration and disposal

Legally, pregnancy losses that occur prior to 24 weeks' gestation are treated differently from those that occur after this time. A pregnancy that ends before 24 weeks' gestation is a miscarriage; after this time it will be defined as a stillbirth and subject to different rules regarding registration and burial.[44] In England and Wales, the Births and Deaths Registration Act 1953, s 41 (as amended by the Stillbirth (Definition) Act 1992, s 1(1)) defines stillbirth as 'a child which has issued forth from its mother after the 24th week of pregnancy and which did not at any time after being expelled from its mother breathe or show any other signs of life'. A stillbirth must be registered and, upon registration, the parents will be issued with a certificate which permits burial or cremation.[45] There is no legal requirement to register a miscarriage and, while a very clear set of legal rules surrounds the disposal of the body of a baby born dead after 24 weeks, the law governing the disposal of remains prior to this gestational age is much less clear.[46]

As mentioned in the introduction to this paper, prior to 24 weeks' gestation the remains are treated as the person's tissue, or, in the language of the Human Tissue Act 2004, 'relevant material'.[47] The HTA Code of Practice summarises the situation as follows:

> The law does not distinguish between fetal tissue and other tissue from the living; fetal tissue of less than 24 weeks gestation is considered to be the mother's tissue, as are non-fetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid). Consequently, fetal tissue and non-fetal products of

41 For a critical reflection on the transforming meanings of miscarriage and the growth of grief narratives, see Reagan (n 40).

42 See, for example, the diversity of views identified by Myers et al (n 23).

43 *Montgomery* (n 13) [87].

44 NHS, 'What Happens if your Unborn Baby Dies: Stillbirth' <www.nhs.uk/conditions/stillbirth/what-happens>.

45 Births and Deaths Registration Act 1953, s 11(2) or (3); Births and Registrations Act 1926, s 5.

46 For a discussion of this, see 'Management of Miscarriage: Your Options' <www.miscarriageassociation.org.uk/wp-content/uploads/2016/10/Management-of-miscarriage-2016.pdf>.

47 Human Tissue Act 2004, s 53.

> conception are subject to the same consent requirements under the HT Act as all other tissue from the living (see section on tissue from the living, paragraphs 108–112). However, because of the sensitivity surrounding pregnancy loss, consent should always be sought, even where it might not be lawfully required.[48]

Alluded to in this quotation is the fact that disposal of relevant material does not normally fall within the remit of the HTA; rather the Authority has a statutory function to regulate removal, storage, or use of human tissue through a system of licensing and inspection. Thus, when an individual miscarries, the pregnancy remains are regarded as their tissue. If that tissue is to be stored or used for the purposes of a histological or post mortem examination to ascertain the cause of the miscarriage, 'appropriate consent' must be sought.[49] Disposal of human material is not subject to the same statutory rules as removal, storage and use; most importantly for our purposes, specific consent is not required for disposal. It is not our purpose in this paper to provide an argument for specific consent to disposal. Instead we argue that in order to give fully informed consent to management of the miscarriage, pregnant people need to be informed about what to expect during the experience of miscarriage and how to manage the remains subsequently, as part of the discussion of different management options.

As already noted, while the law makes no distinction between pregnancy remains and other tissue, the HTA recognises that pregnancy remains are different as their nature is 'particularly sensitive'.[50] The Authority has therefore sought to address this sensitivity by issuing specific guidance entitled 'Guidance on the Disposal of Pregnancy Remains following Pregnancy Loss or Termination'.[51] This sets out the disposal options which should be offered, and requires that all those options be discussed.[52] The guidance was developed between 2014 and 2015 following a request from the Chief Medical Officer. Caroline Brown, then Head of Regulation at the HTA, summarises the background to the guidance as follows:

> During 2014, miscarriage and the disposal of fetal remains had been the subject of increased levels of media controversy and public scrutiny: there had been scandals regarding the disposal of fetal ashes by crematoria in Scotland and the disposal of fetal remains by hospitals across the UK, followed by a call for a change in the legal status of fetal remains.
>
> It was the Channel 4 Dispatches programme aired in March 2014 that exposed the poor practices of some hospitals, which were routinely disposing of fetal remains by incineration without any reference to the wishes of the parents. A ministerial statement stating that incineration was not an acceptable method of disposal prompted the Chief Medical Officer to ask the Human Tissue Authority (HTA) to develop new national guidance and to consider how compliance with it might be monitored.[53]

The problematic practice that Brown mentions was the use of incineration as a method of disposal of pregnancy remains in the absence of parental consent. The documentary led to headlines such as 'Thousands of Unborn Foetuses Incinerated to Heat UK

48 HTA, *A: Guiding Principles and the Fundamental Principle of Consent: Code of Practice* (HTA 2017) [141] <www.hta.gov.uk/sites/default/files/files/HTA%20Code%20A.pdf>.

49 Human Tissue Act 2004, s 1(1).

50 HTA guidance (n 11) [4].

51 Ibid.

52 Ibid [5], [8].

53 Caroline Browne, 'Foreword' in McGuinness and Kuberska (n 12).

Hospitals'.[54] In the subsequent fallout there was confusion between normal incineration practices and the practice of 'sensitive incineration'; that is, incineration separate to other clinical waste. Sensitive incineration was recommended at the time in the HTA Code of Practice and in guidance issued by the Royal College of Nurses.[55] Brown states that one of the key debates was whether sensitive incineration should continue to be considered an appropriate disposal option.[56] Guidance issued in Scotland in 2012 had indicated that incineration was no longer appropriate in that jurisdiction.[57] Ultimately the HTA decided that sensitive incineration would continue to be an acceptable disposal option. We suggest that sensitive incineration does form an important choice for some people. Amanda Myers et al undertook research with people who elected to have a termination and their findings show that many in this situation, i.e. ending an unwanted pregnancy, would not find ceremonial disposal acceptable.[58] The DBB Project findings highlight that such an option may also be important for those experiencing the loss of a wanted pregnancy, as illustrated in the quote above.

Despite the guidance from the HTA emphasising that 'the wishes of the woman, and her understanding of the disposal options open to her, are of paramount importance',[59] the DBB project found that many pregnant people are not given full information about the disposal options available to them. In the same way that the HTA has turned to the common law to address the validity of what is 'appropriate consent' for the storage and use of pregnancy remains,[60] we will argue in section 3 that consent and the test in *Montgomery* can be used to provide a legal basis to ensure that people are given information about all disposal options, in accordance with the HTA guidance. In order to make this case we suggest that information about disposal and management of pregnancy remains is a necessary aspect of information disclosure as part of the informed consent to treatment process. We will now explain the relationship between disposal and management of pregnancy remains and variant treatments that form part of miscarriage care.

2.3 Treatment for miscarriage

Guidance from the National Institute for Health and Care Excellence (NICE) notes that with regard to variant treatment for miscarriage:

> [T]here is a lack of research into the effects of these different approaches from the woman's perspective, in particular their psychological and emotional impact. Miscarriage is distressing for most women, and the type of management itself might affect women's need for counselling, with a resulting cost to the NHS.[61]

54 Adam Withnall, 'Thousands of Unborn Foetuses Incinerated to Heat UK Hospitals' *The Independent* (London, 24 March 2014) <www.independent.co.uk/life-style/health-and-families/health-news/thousands-of-unborn-foetuses-incinerated-to-heat-uk-hospitals-9212863.html>. This is a headline which re-emerges from time to time in relation to broader anti-abortion editorial agendas, see, for example: Sarah Knapton, 'Aborted Babies Incinerated to Heat UK Hospitals' *The Telegraph* (London, 24 March 2014) <www.telegraph.co.uk/science/2016/03/15/aborted-babies-incinerated-to-heat-uk-hospitals>.

55 Royal College of Nursing, *Managing the Disposal of Pregnancy Remains* (RCN 2007).

56 Browne, 'Foreword' in McGuinness and Kuberska (n 12).

57 'Disposal of Pregnancy Loss up to and Including 23 Weeks and 6 Days Gestation' (Scottish Government 2015) <www.sehd.scot.nhs.uk/cmo/CMO(2015)07.pdf>

58 Myers et al (n 23).

59 HTA guidance (n 11) [4].

60 See (n 48) [19] and [20].

61 NICE, '2. Research Recommendations. 2.4. Management of Miscarriage', *Ectopic Pregnancy and Miscarriage: Diagnosis and Initial Management* (Clinical Guideline [CG154], NICE 2012) <www.nice.org.uk/guidance/cg154/chapter/2-Research-recommendations>.

Interviews conducted as part of the DBB Project suggest the lack of information and variation in practice does have an impact on people's experience of pregnancy loss.[62] This lack of clarity and choice can have long-term impacts on the grieving process as noted by one participant:

> [The lack of choice] can complicate people's grief if they found afterwards, you know, 'I would have liked to have done this thing that someone else has done but I never had that choice.'[63]

When a miscarriage does occur, there are three main treatment options: natural or expectant management; medical management; or surgical management. Natural or expectant management does not involve medical intervention, instead letting 'nature take its course'.[64] Medical management of miscarriage involves administering misoprostol to soften the cervix and thus speed up the process.[65] Surgical management involves removal of the fetal and pregnancy-related tissue, either by manual vacuum aspiration under local anaesthetic or in the operating theatre under general anaesthetic.[66]

NICE guidance recommends expectant management as the first-line management strategy for 7–14 days from confirmation of diagnosis of miscarriage with some exceptions, such as previous negative reproductive outcomes, or where there is a risk of haemorrhage, or evidence of infection.[67] Medical management is recommended if expectant management is not successful or where expectant management is *not acceptable* to the pregnant person.[68] Finally, it is recommended that surgical management should be offered where clinically indicated, although there is no elaboration on what the clinical indications might be.[69] The RCOG information for patients states: '[t]he risk of infection is the same if you choose medical or surgical treatment'.[70] Given this explicit preference for expectant management, it is clear that the majority of people will experience the physical process of miscarriage outside of a clinical setting.

The NICE guidance does not consider disposal of pregnancy remains as part of the treatment process. However, it does state that pregnant people should be appropriately informed about what to expect during treatment, including expectant management.[71] We argue that if it is important that people are informed about 'what to expect' this should include being provided with information about what to expect with regard to pregnancy remains and options for management of these remains.

Research undertaken by Abigail McNiven also evidences how the variation in physical experiences can impact on a person's perception of the acceptability of different forms of management of miscarriage.[72] McNiven details how '[u]ncertainty regarding the distinction between "normal" and "worrying" experiences within miscarriage, including

62 McGuinness and Kuberska (n 12).

63 WP3–06/2017.

64 Royal College of Obstetricians and Gynaecologists, *Information for You: Early Miscarriage* (RCOG 2016) 3 <www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-early-miscarriage.pdf>.

65 NICE, 'Recommendations. 1.5. Management of Miscarriage' (n 61).

66 Ibid.

67 Ibid.

68 Ibid emphasis added.

69 Ibid.

70 Royal College of Obstetricians and Gynaecologists (n 64) 3.

71 NICE, 'Recommendations. 1.5. Management of Miscarriage' (n 61).

72 McNiven (n 19) 63.

both bleeding and pain, emerged in a number of participants' narratives'.[73] Within the DBB Project, we found similar evidence of uncertainty, including uncertainty about what to do with the remains, as detailed in this account from one of the support workers whom we interviewed:

> I get quite a few calls about that: 'how much blood should I be losing?', 'these pains that I'm having, is that normal?', 'I've been getting these pains' and I'll be saying to them, 'well, the pains you are getting are labour pains because your body has got to go into labour for the cervix to open and for the baby to go away.' So the pains that you are experiencing can be really quite severe and they didn't realise they were gonna have these pains. They're told it's like a period pain . . . – it's nothing like a period pain.[74]

Lack of information was a common theme in these interviews, as was guilt or dissatisfaction on the part of the woman with the decisions she made in the absence of full information or preparedness. The lack of information about the physical experience of miscarriage can be exacerbated by confusion as to what to do with the remains once passed. The following quote from one of the DBB Project participants starkly illustrates this:

> And I didn't know what to do. I didn't know how to to cope with what was happening. I was in pain. So it sounds awful but the baby ended up falling into the toilet. And I couldn't I couldn't stay in the bathroom so I I went back into the bedroom and my husband who who was in the bathroom with me the whole time and helping me to pass the baby he he had a look at the baby and tried to get it out of the toilet so that we could do something with the body. Um, but he came back in the bedroom a couple of minutes later and just said the the baby had sort've disintegrated. The body'd split apart and um there was nothing much he could do about getting it out of the toilet.
>
> [A]nd then we, we had a terribly awful practical talk about what did we do next so we ended up flushing the toilet.[75]

This participant was deeply upset by the experience and deeply regretted that she was not better prepared about what to expect, and also about the steps that would have preserved her options for what to do with the remains. Clear and comprehensive information provision about what the physical experience of miscarriage entails, what to expect with regard to the remains, and information on the legally permissible options for disposal are therefore vital for '[i]mprovement in the diagnosis and management of early pregnancy loss . . . in order to reduce the incidence of the associated psychological morbidity'.[76]

Similar findings are reflected in the work of Myers et al who interviewed people undergoing termination of pregnancy about the options they would want for disposal of pregnancy remains.[77] The authors note managing the process at home, where disposal by professionals was not an option, caused feelings of anxiety for some people, whilst not being problematic for others. Some of the Trust documentation, examined as part of the DBB project, did not address options for those who miscarry at home. And for those that did, the advice varied from being told to bring the remains to hospital for disposal to

73 Ibid 118.

74 WP3–05/2017.

75 WP4–11/2017.

76 NICE, 'Recommendations. 1.5. Management of Miscarriage' (n 61).

77 Myers et al (n 23) 86.

being advised to flush the remains down the toilet.[78] One interviewee, a volunteer with a support organisation, describes how the lack of information and understanding about the physicality of the remains, and permissible disposal options, can lead to confusion and feelings of guilt about choices made:

> Some mums will come and say oh I collected it in a in a Tupperware box or whatever and then others will be really against like I didn't think I just flushed the toilet I didn't think there'd be anything and then they've got that guilt as well you know that they just flushed it while somebody else has buried it and made made a memorial you know and because they didn't know 'cause they were never told that there would be something and also some people get a phone call after an ARPC and are told we've got the remains what do you want us to do with them and they never knew there would be remains.[79]

In this section we have argued that the pregnant person has an interest in their pregnancy remains, including an interest in how the remains are disposed of. In addition, we have discussed the heterogeneity of views that different people hold following loss of pregnancy. Finally, we provided an overview of the proximate relationship between different treatment options for miscarriage and the embodied experience of loss both in terms of pain and also in terms of the management of disposal of pregnancy remains. The acceptability of different treatment options may be influenced by the physical experience that attaches to each option, including what it means for the management of pregnancy remains. In the next section we will explain how the law on informed consent grounds the obligation to take seriously the person's interests in disposal of their pregnancy remains, as part of the process of care and management of miscarriage.

3 *Montgomery*: closing the information gap

Montgomery is now the leading case on the standard of disclosure when seeking informed consent to medical treatment.[80] This paper does not explore the history of the law relating to informed consent leading up to this decision as that has been written about extensively elsewhere.[81] Instead, we focus on the ruling in *Montgomery* and how that can be utilised to close the legislative gap around information provision on disposal options for people experiencing miscarriage prior to 24 weeks.

As has been stated above, by the time of the Supreme Court hearing in *Montgomery*, the key question for the court concerned risk disclosure and the correct test for determining whether or not a particular risk should have been disclosed to the patient.[82] Mrs Montgomery had been under the care of the defendant Health Board during her pregnancy. Due to her small stature and diabetes, she was more likely to have a large baby, which was associated with an increased risk of shoulder dystocia occurring during vaginal delivery. Shoulder dystocia involves the baby's shoulders becoming stuck behind the

78 The possibility of passing remains in the toilet arose in several of our interviews. While for some there was concern about this possibility, and they took steps to avoid this taking place, for others this was deemed an acceptable or desirable outcome. A key theme in these accounts was lack of preparedness and lack of information and understanding about what to do.

79 WP3–06/2017.

80 *Montgomery* (n 13).

81 See, for example, Margaret Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law?' (1987) 7(2) Legal Studies 169; Michael A Jones, 'Informed Consent and Other Fairy Stories' (1999) 7(2) Medical Law Review 103; José Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2009) 17(1) Medical Law Review 76.

82 The initial claim included a claim for negligent management of the labour. This was unsuccessful at first instance and was not pursued on appeal: *Montgomery* (n 13) [2]–[4].

pelvis during delivery. The medical evidence in *Montgomery* suggested that 70 per cent of such cases are resolved without further complications but, where that is not the case, there can be high perinatal mortality and morbidity and an increased risk of maternal morbidity.[83] Despite Mrs Montgomery expressing concerns during her pregnancy about her ability to deliver the baby vaginally, her treating doctor did not disclose the risk of shoulder dystocia to her, or discuss the alternative option of delivering the baby by way of caesarean section.[84] Unfortunately for Mrs Montgomery and her child, shoulder dystocia did occur during vaginal delivery causing the baby to suffer cerebral palsy affecting all four limbs and a brachial plexy injury resulting in paralysis of one arm.[85] Mrs Montgomery asserted that she should have been told of the risk of shoulder dystocia and the alternative method of delivery by way of caesarean section and, had this occurred, she would have elected to undergo a caesarean section and her child would have been born unharmed.[86]

At first instance and on appeal, the courts concluded that, applying *Sidaway v Board of Governors of the Bethlem Royal Hospital*[87] which had taken the *Bolam* standard[88] as the starting point for determining the adequacy of disclosure, there was no obligation for the risk of shoulder dystocia and alternative method of delivery by way of caesarean section to be discussed as other doctors would not have done so.[89] The Supreme Court overturned those decisions, rejecting the application of *Bolam* as the standard for determining whether information about medical treatment should be disclosed.[90] Instead, the court held:

> An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.[91]

The court also held that there were exceptions where doctors would not be held to this standard. These were: (1) when information was withheld from a patient on the grounds that the doctor reasonably believed its disclosure would be seriously detrimental to the

83 *Montgomery* (n 13) [9]–[10].

84 Ibid [17], [29].

85 Ibid [22].

86 Ibid [13], [18] and [22].

87 [1985] AC 871.

88 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, 587, per McNair J: 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'.

89 *Montgomery* (n 13) [3].

90 Ibid [86].

91 Ibid [87].

patient's health (termed the 'therapeutic exception');[92] (2) where treatment was necessary (for example, treatment was required urgently and the patient was unconscious and so unable to consent); and (3) if the patient did not wish to be informed of attendant risks and alternative or variant treatments.[93]

The court went on to find that applying the correct standard, Mrs Montgomery should have been advised of the risk of shoulder dystocia occurring and the alternative method of delivery by way of caesarean section and, had she been given that information, she would have elected to undergo a caesarean section and her child would have been born uninjured.[94]

3.1 Protecting bodily integrity: interests in fetal tissue

In *Montgomery*, Baroness Hale stated that the interest informed consent seeks to protect 'is a person's interest in their own physical and psychiatric integrity, an important feature of which is their autonomy, their freedom to decide what shall and shall not be done with their body'.[95] As has been noted above, the HTA guidance regards pregnancy remains that result from a miscarriage as the person's tissue.[96] It is, therefore, part of their body, such that ensuring they have a choice in what is done with those remains once they cease to be physically connected to them forms part of their interest in their physical integrity, which, as stated by Baroness Hale, the law of informed consent seeks to protect. It is also important to ensure that a pregnant person is fully informed about what to expect from the experience of miscarriage and to minimise confusion and upset regarding what can be done with the pregnancy remains. As we have detailed, people respond to pregnancy loss differently and thus healthcare professionals, when considering what information to offer about disposal, should take their lead from the person experiencing the miscarriage. This requires healthcare professionals to advise that there are different methods of disposal available and then asking if the person would like information about these. This is consistent with the emphasis in *Montgomery* on patients having a right not to know, as well as the right to have information if they want it. It is also consistent with *Montgomery*'s focus on tailoring information provision to the needs of the individual patient in order to ensure the right to decide what is done to your own body is protected.[97]

3.2 Tailoring information to the individual

Whilst *Montgomery* was primarily concerned with the question of risk disclosure, it also addressed the wider question of what information patients should be given and the extent to which that should be driven by the needs of the individual patient. That information should be tailored to the individual is suggested not only by the reference to risks the particular patient would be likely to attach significance to in the test for materiality, but also by the reference to the need to discuss the individual patient's condition and the

92 We return to the application of the therapeutic exception later in this section, but the scope and need for the therapeutic exception has been called into question, see Rob Heywood and Jose Miola, 'The Changing Face of Pre-operative Medical Disclosure: Placing the Patient at the Heart of the Matter' (2017) 133 Law Quarterly Review 296; Emma Cave, 'The Ill-informed: Consent to Medical Treatment and the Therapeutic Exception' (2017) 46(2) Common Law World Review 140. It is notable that, despite *Montgomery*'s approval of the therapeutic privilege, in the GMC's proposed revised consent guidance (n 16), the therapeutic privilege has been referenced in a footnote only on the basis it is not seen as necessary in medical practice.

93 *Montgomery* (n 13) [85], [88], [91].

94 Ibid [94] and [104].

95 Ibid [108].

96 HTA (n 48) [141].

97 *Montgomery* (n 13) [85], [87].

alternative treatments available in light of that.[98] It is given further support by the court noting that in endorsing this standard, it was reflecting 'a broadly similar approach'[99] to that taken in the guidance issued by the GMC. The guidance in question sets out the standards expected of doctors in the context of seeking informed consent to medical treatment and had long required doctors to 'tailor' information provision according to the patient's 'individual circumstances'.[100] We have explained the importance of tailoring discussions around the management of miscarriage and options for disposal to the individual patient in keeping with the HTA guidance.

The court also said that the obligation to disclose information is not dependent upon the patient asking questions. If it is information a patient could be expected to need to know, it should be disclosed whether they have asked for it or not, unless one of the exceptions identified above applies, such as the person indicating they do not want information about a particular disposal option.[101] Therefore, those Trusts identified in the DBB project which make disclosure contingent upon women asking questions about particular disposal options[102] are in breach of *Montgomery*'s explicit rejection of this requirement.

In tailoring discussions to the individual, the court in *Montgomery* said that doctors should engage in dialogue with patients in order to ensure they understand what treatment is proposed and alternatives.[103] Thus, disclosure of disposal options should not be a 'tick-box process' but a two-way discussion between the patient and the healthcare professional aimed at identifying what information the pregnant person wants and ensuring that, where they do want information about disposal options, they are informed of all options, including those not available at the hospital but available elsewhere. Otherwise, disclosure of disposal options may negatively impact a person's experience, as is illustrated by the following quote from one of the participants in the Myers et al study:

> From an emotional side, I wouldn't like to hear the options, because it would make things really difficult . . .[104]

The information should also be provided in a sensitive way that is responsive to the needs of the person at the time. One of the DBB Project participants highlighted how, although patient was provided with information, it was not in a manner which was helpful at that time:

> *Interviewer:* Can I ask if you got any leaflets?
>
> *Interviewee:* Errm. We did in the EPU. Errm Just about what missed missed miscarriage is. She did start saying about what happens with the remains. And I ran out and threw up in the toilet because it was just it was so clinical the way she talked about it. And what happens. They asked what what happens afterwards once they've done the DNC. Do we want to keep them or what they do with them? It made me feel physically sick and I ran out and I threw up in the toilet.[105]

It could be argued that these quotes give rise to the possibility of non-disclosure as part of the therapeutic exception, i.e. healthcare professionals may consider disclosure of

98 Ibid [87] and [90].

99 Ibid [93].

100 GMC (2008) (n 14)

101 *Montgomery* (n 13) [58]–[59].

102 McGuinness and Kuberska (n 12).

103 *Montgomery* (n 13) [90].

104 Myers et al (n 19) 88.

105 WP4–09/2017.

disposal options would cause significant harm.[106] However, although the exact threshold for significant harm has not been explicitly defined, it is accepted that it must go beyond anxiety or distress; specifically, in *Montgomery* the court said it must not be used to 'prevent the patient from making an informed choice'.[107] The quotation above illustrates distress as a response to the *way* in which information provision was provided, and had the healthcare professionals established what the woman wanted to know and addressed matters sensitively, those reactions may not have occurred.

Tailoring information to individuals not only acts to protect a person's interest in their bodily integrity, it is also reflective of good healthcare practice in the management of miscarriage. Baroness Hale was clear in *Montgomery* that the law protects both physical and psychiatric integrity.[108] Whilst *Montgomery* concerned the appropriate standard of disclosure in cases involving informed consent to medical treatment, it also has a wider application to healthcare.

3.3 *MONTGOMERY* AND ITS WIDER APPLICATION TO HEALTHCARE

In *Montgomery*, the court noted that, whilst the judgment was primarily concerned with doctors, as 'a wider range of healthcare professionals now provide treatment and advice . . . it is also relevant, *mutatis mutandis*, to other healthcare providers'.[109] We suggest that the reference to the need to protect physical and psychiatric integrity, as well as its broader application to healthcare providers, supports the notion that the need for information provision is not confined to the provision of medical treatment but extends to all of a patient's healthcare needs where those needs have the potential to impact their physical and psychiatric integrity. As spelled out above, the NICE guidance requires all options for the management of miscarriage to be discussed with the pregnant person in order for them to decide how to proceed. NICE does not include discussion of the disposal of pregnancy remains within that and, on the face of it then, disposal of pregnancy remains is not part of the medical treatment of miscarriage. What amounts to 'medical treatment' is contested and can vary between contexts.[110] These debates are outside the scope of this paper,[111] but we argued in section 2 that disposal of pregnancy remains should be considered as part of the discussion of different treatment options. The choice of approach to management of miscarriage can impact the disposal options available with consequential effects on the person's psychological health. Therefore, disposal of pregnancy remains forms part of the person's wider healthcare needs in the management of miscarriage.

Furthermore, case law post-*Montgomery* lends support to the argument that the requirement of informed consent to medical treatment set out in *Montgomery* encompasses events which, even if not regarded as part of the treatment itself, arise as a consequence of that treatment. In *Spencer v Hillingdon Hospital NHS Trust*,[112] nursing staff failed to

106 See Cave (n 92) who highlights information arguments about the scope and need for the therapeutic exception.

107 *Montgomery* (n 13) [91].

108 Ibid [108].

109 Ibid [75].

110 John Coggon, 'Comments and Reflections on "Proper Medical Treatment": A Case for Coherent Inconsistency' in Sara Fovargue and Alexandra Mullock (eds), *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge 2016) 229. Fovargue and Mullock's collection illustrates the range of interpretations that can exist as to what amounts to 'proper medical treatment'.

111 For an example of these debates and discussions, see Fovargue and Mullock (110).

112 [2015] EWHC 1058 (QB).

advise a patient on discharge of the risk of developing post-operative deep vein thrombosis or pulmonary embolism. Collender HHJ found in favour of the patient, concluding that the need to disclose this information fell within the scope of *Montgomery* and commenting 'that the basic principles – and resulting duty of care – defined in *Montgomery* are likely to be applied to all aspects of the provision of advice given to patients by medical and nursing staff'.[113] Therefore, in addition to our argument that disposal of pregnancy remains forms part of healthcare in the management of miscarriage, its proximity to such treatment justifies our conclusion that the need to disclose information about disposal options falls within the scope of the test for informed consent as clarified in *Montgomery*.

3.4 The benefit of applying *Montgomery*

When setting out the correct standard of disclosure that applied in the context of informed consent, the court in Montgomery noted this reflected the standard set out in medical professional guidance but felt imposition of the standard at law was necessary to ensure compliance.[114] The DBB project findings illustrate that, despite the HTA guidance being explicit that all disposal options should be discussed with people who miscarry, the extent to which this occurs in practice varies.[115] However, with regard to 'storage and use' of pregnancy remains for the purposes of further clinical examination, e.g. histology, findings suggest that people were provided with very detailed information, not just on how slides would be prepared for the purposed of examination but also about how they would be disposed of subsequently.[116] As such it is clear that this is an area where legal obligations can help achieve consistency in practice between healthcare settings and professionals.

That the HTA guidance should be the starting point for determining what the common law requires is supported by *O'Hare v Coutts*.[117] In this case, when considering the application of *Montgomery* in the context of financial advice, Kerr J said that a professional regulatory regime should be treated as strong evidence of what the common law requires.[118] The HTA guidance then is evidence that the common law should require disclosure of all disposal options in order to protect the patient's physical and psychiatric integrity as part of good healthcare, and *Montgomery* provides the legal basis for this. The following section explores how the argument we make in this paper can be translated into practice.

4 Facilitating better care in the context of reproductive loss

4.1 An integrated care pathway

If, as we have argued, consent and the test laid out in *Montgomery* provide a legal basis for the need to disclose information about all options for the disposal of pregnancy remains following miscarriage, then standardised policies, forms and information could be encompassed within a miscarriage care pathway. Pregnancy loss can occur within different departments, for example, A&E, Gynaecology, Early Pregnancy Assessment Units etc. In order to ensure comprehensive care, we argue for one policy to cover

113 *Spencer*, ibid [32].

114 *Montgomery* (n 13) [93].

115 McGuinness and Kuberska (n 12).

116 Ibid 13.

117 [2016] EWHC 2224 (QB).

118 *O'Hare*, ibid [207].

disposal of pregnancy remains across hospital departments as part of an integrated care pathway.[119] The need for such a pathway is stark, given the inconsistent nature of provision of treatment for miscarriage, which is summarised as follows:

> [T]he care of those experiencing miscarriage has developed in the UK in a much more patchy manner, despite the development of national guidelines; this type of reproductive loss has no obvious specialty to call home within the current National Health Service (NHS) structures, and can be housed in a range of organizational locations. Even limiting consideration to secondary care, people experiencing miscarriage might be cared for within a dedicated early pregnancy unit, a maternity or gynaecology ward.[120]

This patchiness, borne out in the DBB Project findings, shows different experiences of care depending on the clinical environment where the miscarriage took place. The use of standardised forms could help to overcome this patchiness by providing reliable resources that are easily accessible to health practitioners in a number of contexts. These resources will need to be supported by appropriate training. A standardised document on disposal options could be integrated into a miscarriage care pathway and could encompass those experiencing pregnancy loss at home, as well as those experiencing pregnancy loss within a hospital setting.

Sands (the Stillbirth and Neonatal Death charity) has led a coalition of organisations to develop a National Bereavement Care Pathway with a view to ensuring bereaved parents are all offered 'equal, high quality, individualized, safe and sensitive care'.[121] This was developed in conjunction with the Department of Health and several other baby loss charities and medical professional bodies.[122] Miscarriage care forms part of this national pathway and if comprehensively adopted will hopefully lead to improved care for all those who experience reproductive loss.

4.2 Standardised forms

In Scotland, guidance issued by the Chief Medical Officer and Chief Nursing Officer on disposal of pregnancy remains of less than 24 weeks' gestation incorporates advice on information to be included in drafting patient information leaflets, and sample wording for a consent form.[123] Although we disagree with the Scottish rejection of sensitive incineration as an acceptable disposal option, we suggest that a similar approach to standardisation of information provision could be taken in England. We are aware that advocating for the use of a standardised information document could be criticised as

119 McGuinness and Kuberska (n 12) 21.

120 Ruth Graham et al, 'Experiences of Reproductive Loss: The Importance of Professional Discretion in Caring for a Patient Group with Diverse Views' in Earle et al (eds) (n 8) 210–11 (references omitted).

121 Sands, *Projects to Improve Bereavement Care* <https://sands.org.uk/professionals/projects-improve-bereavement-care/national-bereavement-care-pathway>.

122 Charities: ARC (Antenatal Results and Choices), Bliss, Lullaby Trust, Miscarriage Association; Professional Bodies: Institute of Health Visiting, NHS England, Neonatal Nurses Association, Royal College of Midwives, Royal College of Nurses, Royal College of Obstetricians and Gynaecologists, Royal College of General Practitioners: Sands, 'National Bereavement Care Pathway' <www.sands.org.uk/professionals/projects-improve-bereavement-care/national-bereavement-care-pathway>.

123 Chief Medical Officer and Chief Nursing Officer (Scotland), *Revised Guidance on the Disposal of Pregnancy Losses up to and Including 23 Weeks and 6 Days Gestation* (April 2015) <www.sehd.scot.nhs.uk/cmo/CMO(2015)07.pdf>.

risking de-individualising care.[124] For example, some research indicates that patients who are asked to sign consent forms see such forms as protecting the hospital from litigation, rather than making their particular wishes known.[125] Similarly, use of standardised forms is often criticised for failing to take account of persons with poor literacy skills, or who do not read or write English.[126] *Montgomery* emphasises that the duty of information disclosure is not fulfilled by 'bombarding the patient with technical information'.[127] Instead, the healthcare professional's 'advisory role involves dialogue'.[128] We argue here for the use of standardised forms to *support* active verbal discussion of options for management and disposal of pregnancy remains, not as a substitute for such dialogue. Recent research on consent conducted on behalf of the GMC suggests healthcare professionals find standardised information useful to ensure that everything that should be addressed is covered when seeking a patient's consent.[129] One interviewee in the DBB Project, a volunteer with a support organisation, summarised how absence of information can lead to confusion about what options are available, or a feeling that there is a lack of choice as to what they can do:

> I've heard people say well what seems to be on offer is this kind of group cremation. They've said 'I don't know if we've got the choice to do anything different and maybe we'll want to do something different.' People don't always seem very clear on their options.[130]

Thus, standardised forms should not simply be distributed to those experiencing pregnancy loss in fulfilment of the obligation to discuss options for disposal of the pregnancy remains. Instead, they should be used to frame the dialogue between the pregnant person and the healthcare professional, to ensure the person's choices are accurately recorded, and that the they can leave the hospital with the information that they require. Standardised forms can provide a reliable resource that is easily accessible to health practitioners in a number of contexts. In accordance with HTA guidance, such forms should inform healthcare staff of the need to advise patients of *all* disposal options, including those not available through the hospital, and details of whom to approach if the person's preferred method of disposal is not offered by the hospital.[131]

The DBB project found that people's perceptions of time are sometimes skewed by the experience of miscarriage and that people needed to take time to reflect on their decisions, rather than being rushed through the decision-making process.[132] Therefore people experiencing miscarriage should be given time to reflect upon their options for disposal and discussion should happen in a quiet place, with the opportunity to ask

124 Community Research, *Doctors' Attitudes to Consent and Shared Decision-Making: Full Research Report for the GMC* (June 2017) 32 <www.gmc-uk.org/Doctors_attitudes_to_consent_and_shared_decision_making_FINAL_research_report.pdf_72137875.pdf>.

125 Andrea Akkad, Clare Jackson, Sara Kenyon, Mary Dixon-Woods, Nick Taub and Marwan Habiba, 'Patients' Perceptions of Written Consent: Questionnaire Study' BMJ (31 July 2006) 2 <www.bmj.com/content/bmj/333/7567/528.full.pdf>; Peter Neary, Ronan A Cahill, W O Kirwan, E Kiely and H P Redmond, 'What a Signature Adds to the Consent Process' (2008) 22 Surgical Endoscopy 2698, 2699.

126 Ibid 3.

127 *Montgomery* (n 13) [90] per Lord Kerr and Lord Reed.

128 Ibid.

129 Community Research (n 125) 31–2.

130 WP3–06/2017.

131 HTA (n 11) [9].

132 Sarah Turner and Jeannette Littlemore et al, 'The Production of Time-related Metaphors by People who have Experienced Pregnancy Loss' in A Gargett and J Barnden (eds), *The Production of Metaphor* (John Benjamins forthcoming).

questions, and to read the patient information leaflets.[133] There may be practical issues with provision of such facilities; for example, finding a quiet place in a busy A&E department. This could be explored through a pilot study of the use of such forms. People should also be made aware of what will happen in the event of no decision being made. Adopting this approach to standardised forms as part of an integrated bereavement care pathway can facilitate person-centred care in the context of reproductive loss, utilising consent and the test laid out in *Montgomery* as the legal basis for such an approach acts to respect physical and psychiatric integrity in the management of miscarriage.

5 Conclusion

Reproductive loss is a relatively common experience and yet a cultural silence exists around it, despite the recognition that such loss can have a profound impact on a person's psychological and physical well-being and future reproductive experiences. Appropriate care at the time of loss which responds to the person's emotional and clinical needs, and facilitates grieving, can reduce the need for long-term psychological care and improve future reproductive outcomes.[134] This paper provides a legal argument for the importance of ensuring that information about different options for disposal of pregnancy remains should be discussed as part of this care. NICE recognises that all options for management of miscarriage should be discussed. We argue that details of the options for disposal should form part of this discussion as part of the information disclosure necessary to ensure informed consent to treatment.

The empirical research on which this paper is based demonstrates how healthcare practice in this area is problematic in its inconsistency and fails to account for the particular needs of the person who has suffered an unwanted end to pregnancy. Despite the existence of HTA guidance aimed at overcoming the legislative ambiguity around the need to discuss disposal options with individuals who miscarry prior to 24 weeks, the DBB project revealed that this guidance is not being consistently followed.

We recognise that people will view the pregnancy remains from miscarriage in different ways according to their experience, attitudes and beliefs. Some may want ceremonial disposal, whilst others will not. In recognition of this, we have advocated for a person-centred approach which recuperates the maternal–fetal relationship. Healthcare professionals should follow the pregnant person's lead in the management of miscarriage by providing information about all disposal options where they want this information. By placing the pregnant person at the centre of care, and facilitating their control over these remains, healthcare professionals should, as a matter both of good practice and of law, be responsive to needs of the individual.

We have advocated for the importance of all legal options for disposal of pregnancy remains being discussed. Adopting the approach outlined in *Montgomery*, we have suggested that a person's bodily interest in their tissue should be protected by disclosure and discussion of all information options, unless they have explicitly stated they do not want such information. Such discussions should be tailored to individuals in accordance with *Montgomery*'s patient-centred approach and our person-centred approach, which acknowledges that people have different embodied experiences of, and attitudes towards, miscarriage.

133 McGuinness and Kuberska (n 12) 22–3.

134 See (n 3), (n 4) and (n 5).

Reproductive loss will usually be unexpected and unplanned for, and people in this situation will need clear and accessible information about the options available to them. The medico-legal framework that governs miscarriage and stillbirth has important consequences for the care received by persons experiencing reproductive loss. As such, it is important that this framework is subject to scrutiny and critique; and it is extremely important that this critique acknowledges the embodied nature of pregnancy. To date, reproductive loss and disposal of pregnancy remains has been an underexplored area of legal scholarship, yet it is an area which is profoundly significant. *Montgomery*'s requirement of patient-centred care in the context of informed consent to medical treatment should be echoed in the management of miscarriage and disposal of pregnancy remains, ensuring a person-centred approach to the care and management of miscarriage.

LEGISLATION, TRENDS AND CASES

NILQ 70(1): 157–162

Cases

Extraterritorial corporate liability for environmental harm: *Okpabi v Royal Dutch Shell*

JANE ROONEY*

Lecturer in Law, Centre for Health, Law, and Society, University of Bristol Law School

Introduction

On 14 February 2018 the Court of Appeal confirmed in *Okpabi v Royal Dutch Shell*[1] that English courts could not exercise jurisdiction over the matter of whether the parent company, Royal Dutch Shell (RDS), owed a duty of care towards the people of the Ogale Community affected by the contamination of waterways by oil spills, as a result of deep-water oil exploration in the Niger Delta by its subsidiary, Shell Petroleum Development Company of Nigeria Ltd (SPDC).

This case note considers how *Okpabi* establishes a curtailment of the precedent set in *Lungowe v Vedanta*[2] for ensuring accountability of home corporations in English courts. *Okpabi* provides further evidence of the ineffectiveness of tort law to ensure that English domiciled parent companies take measures to prevent against harm to the health, safety, and environment of communities affected by the extraterritorial operations of their subsidiaries.

1 The facts

In *Okpabi*, the claimants alleged that RDS was negligent in failing to maintain the oil pipeline operated by its subsidiary SPDC in the Niger Delta to acceptable standards and failing to protect it from interference by third parties engaging in bunkering – the unlawful siphoning-off of oil.[3] The oil 'contaminated the land, swamps, groundwater and waterways', and the water could not be used for 'drinking, agricultural, washing or recreational purposes' affecting over 40,000 people.[4] RDS argued that English courts could not exercise jurisdiction because there was 'no real issue' to be tried between the claimants and the parent company,[5] and that the claimants were merely using proceedings against the parent company as a device to exercise jurisdiction over SPDC.[6] Therefore, in

* jane.rooney@bristol.ac.uk.

1 *Okpabi v Royal Dutch Shell plc* [2018] EWCA Civ 191.

2 *Lungowe v Vedanta Resources plc and Konkola Copper Mines plc* [2017] EWCA Civ 1528.

3 *Okpabi* (n 1) para 8.

4 Ibid para 9.

5 Civil Procedure Rules, Part 11(1).

6 *Okpabi* (n 1) para 5.

order to decide whether English courts had jurisdiction over the case, the court had to determine whether there was an arguable case of a duty of care owed by RDS to the claimants based upon the preliminary evidence.[7]

2 The judgment

The court examined whether there was foreseeable damage, a relationship of proximity, and whether it was 'fair, just and reasonable' to impose a duty of care to establish whether there was jurisdiction over the parent company.[8] While the court found the damage foreseeable, the main focus of the judgment was proximity. The court confirmed[9] that the test for proximity was *Chandler v Cape*,[10] which concerned a parent company's liability for its subsidiary's treatment of its employees. In order for liability to arise, the parent company must have taken 'direct responsibility for devising a material health and safety policy, the adequacy of which is the subject of the claim' or 'control . . . the operations which give rise to the claim'.[11]

Lord Justice Simon acknowledged RDS's mandatory health and safety standards and policies,[12] the imposed system of mandatory design and engineering practices,[13] the imposed system of supervision and oversight in implementing RDS's standards,[14] RDS's financial control over SPDC in relation to the allegations of negligence,[15] and centralisation of security matters.[16] However, in the case of RDS, the concern had been 'to ensure that there were proper controls and not to exercise control', thus falling short of the proximity requirement in *Chandler* to 'control operations'.[17] Further, a distinction had to be made 'between a parent company which controls, or shares control of, the material operations of a subsidiary, on the one hand, and a parent company which simply issues mandatory policies as group-wide operating guidelines for its subsidiaries'.[18] A duty of care would not arise as a result of the parent company merely establishing health and safety guidelines to which all subsidiaries had to conform. If mandatory policies were directed towards a particular subsidiary, then a duty of care was more likely to arise.[19] Despite the fact that RDS had specific concerns regarding SPDC in Nigeria, as evidenced in its 2014 Sustainability Report,[20] RDS did not take 'direct responsibility' for the practices and failures of SPDC.[21] In response to the claimant's argument that it was fair, just and reasonable to require RDS to take reasonable care to mitigate foreseeable harm created by SPDC – as it would not subvert or compromise the Nigerian statutory scheme and RDS had made billions of pounds of profit from SPDC's operations[22] – Lord Justice

7 Ibid 84.
8 *Caparo Industries plc v Dickman* [1990] 2 AC 605.
9 *Lungowe* (n 2) para 83.
10 *Chandler v Cape* [2012] EWCA Civ 525, para 80.
11 *Okpabi* (n 1) para 49.
12 Ibid paras 90–9.
13 Ibid paras 100–08.
14 Ibid paras 109–13.
15 Ibid para 114.
16 Ibid para 116.
17 Ibid para 125.
18 Ibid para 89.
19 Ibid para 129.
20 Ibid paras 90–9.
21 Ibid para 127.
22 Ibid para 130.

Simons responded that he did not find these matters 'persuasive'.[23] The court therefore declined jurisdiction on the grounds that there was no arguable case of a duty of care owed by RDS to the claimants.

3 Case Analysis

3.1 Clarification of *Lungowe v Vedanta*

The decision provides clarification of the precedent in *Lungowe v Vedanta*.[24] That case was significant for declining to stay proceedings on the basis of *forum non conveniens*, a common law doctrine which entails that courts can refuse to take jurisdiction over matters where there is a more appropriate forum available to the parties. The court in *Lungowe* read Article 4 of the Parliament and Council Regulation (EU) No 1215/2012[25] as precluding English courts from declining what was a mandatory jurisdiction where the defendant was a company domiciled in England and Wales.[26] Sufficient proximity was established between the parent company, Vedanta, and the claimants, local residents in Nchanga, Zambia, whose waterways had been contaminated by harmful effluent discharged during the mining operations carried out by Vedanta's subsidiary company, Konkola Copper Mines. A decisive factor contributing to a finding of proximity was Vedanta's governance framework setting out mandatory health, safety and environmental policies and standards.[27] The Court of Appeal in *Okpabi* claims to confirm the *Chandler v Cape* test. However, it departs from that test by denying that issuing inadequate standards can give rise to parent company liability, instead requiring active control over the subsidiary's actions.[28] The judgment demonstrates that the level of control required to secure jurisdiction over the parent company is a high threshold and cannot depend merely on health and safety guidelines directed at the overall group of subsidiaries.

3.2 Shortcomings of tort law as a regulatory framework

Okpabi provides evidence of the inability of tort law to ensure English domiciled parent companies take measures to prevent against harm to the health, safety and environment of communities affected by the extraterritorial operations of their subsidiaries. The case demonstrates that parent corporations are more likely to be liable in tort the more they attempt to alleviate environmental harm, thus encouraging corporations to desist from exercising due diligence in relation to the operation of their subsidiaries. This is contrary to the due diligence requirement of corporations to take measures to avoid infringements of human rights enshrined in the non-binding, but authoritative, UN Guiding Principles on Business and Human Rights and Organisation for Economic Co-operation and Development (OCED) and Guidelines for Multinational Enterprises.[29] Further, a tort law framework means that the larger the scale of atrocity committed by the subsidiary, the less likely the claimants will have access to English courts. In order for a duty of care to arise

23 Ibid para 131.

24 Lungowe (n 2).

25 Article 4, Parliament and Council Regulation (EU) No 1215/2012, 12 December 2012: 'Subject to the Regulation, persons domiciled in a Member State shall, whatever their nationality, be sued in the courts of that Member State.'

26 *Lungowe* (n 2), citing *Owusu v Jackson* [2005] 2 WLR 942, [2005] ECR I-1383.

27 *Lungowe* (n 2) para. 84.

28 Amnesty International, 'Rule 15 submission to Supreme Court of the United Kingdom by Amnesty International: *Okpabi and others vs Royal Dutch Shell plc and another* UKSC 2018/0068' (26 April 2018) 3.

29 See, for example, UN Guiding Principles on Business and Human Rights 17–24; OECD Guidelines for Multinational Enterprises, 23–4.

in tort, the defendant's actions must result in losses to claimants 'of a kind in respect of which damages are recoverable'.[30] Lord Justice Simon found that the claimants who owned land in the vicinity of the pipeline which was damaged from the oil spill was not a sufficiently defined group of people affected for the purposes of establishing a duty of care. He stated it was important to distinguish between a 'duty owed to a particular person or class of persons' from 'abstract concepts of moral responsibility', including to reduce global warming and protect the environment.[31] Further, a parent company is more likely to be held liable in tort if only one of its subsidiaries causes particular concern, rather than all of its subsidiaries or a significant number of them, as a result of the 'fair, just, and reasonable' requirement that the damage be recoverable. The more widespread and systemic the harm to peoples' health and environment, the less likely the court will have jurisdiction to hear a case.

Denial of jurisdiction in the home state of the parent company in practice means that access to justice is denied to victims of the subsidiary's harmful activities. Structural problems including 'a weak rule of law, corruption, lack of independence of the courts and corporate capture' mean that victims cannot access justice in the state hosting the subsidiary corporation and where the harmful activity takes place.[32] The duty of care test applied in *Okpabi* effectively gives rise to corporate immunity as a result.

3.3 An alternative regulatory framework: human rights law?

Whether an emphasis on the international human rights law framework could improve regulation and accountability of extraterritorial corporate environmental harm is contested. Unlike non-state actors – such as corporations, insurgents and international organisations – states have legally binding international human rights obligations: they are duty bearers of human rights when they become signatories to international human rights treaties and incur binding international legal obligations towards the right bearers. While the UN Guiding Principles and OECD Guidelines use the language of human rights to denote the harm committed by corporations, under international law 'non-state actors . . . do not violate the relevant human right—it was never their obligation to secure or ensure it'.[33] The UK is a signatory to the European Convention on Human Rights (ECHR), which is incorporated in domestic law through the Human Rights Act (HRA) 1998. The UK Parliament requires courts to 'take into account' the jurisprudence of the European Court of Human Rights (ECtHR) when determining whether the state has committed a violation of its obligations under the HRA 1998.[34]

While the ECtHR recognises that states have negative obligations to not interfere with the rights of inhabitants on their territory, it also imposes certain positive obligations on the state to ensure that third-party, non-state actors are prevented from committing harms against individuals. This includes an obligation to ensure that domestic law, regulating the relationship between private actors, prevents private actors from committing certain harms against individuals. In *Wilson v UK*,[35] the applicants alleged violations of their right to freedom of expression and assembly[36] when their employer corporation offered them financial incentives to renounce their right to engage in

30 *Okpabi* (n 1) para 134.

31 Ibid para 88.

32 Amnesty International (n 28) 2.

33 Jane Wright, *Tort Law and Human Rights* (Hart 2017) 23.

34 HRA 1998, s 2.

35 *Wilson v UK* [2002] ECHR 552, paras 41, 48.

36 Articles 10 and 11 ECHR.

collective bargaining with their trade union. This was not illegal under the UK Act of Parliament, the Trade Union and Labour Relations (Consolidation) Act 1992, which regulated work relations between employees and employers. However, the ECtHR ruled that the UK had a responsibility 'to secure to the applicants *under domestic law* the rights set forth in article 11 of the Convention'.[37] A violation arose as a result of the lack of prohibition in domestic law for corporations to take measures to incentivise employees to forfeit trade union participation. The UK has positive obligations under the HRA 1998 to ensure that its domestic legal frameworks prevent corporations from committing harm contrary to human rights standards expected in a member state of the ECHR.

States are required to take reasonable measures to prevent corporations committing environmental harm in their own territories.[38] For example, in *Tatar v Romania*,[39] a violation of the ECHR arose as a result of a cyanide spill in a goldmine owned and operated by a private corporation: 100,000 cubic metres of contaminated water were released into rivers crossing Romania, Hungary, Serbia and Bulgaria. The applicants claimed that the operation of the mine entailed serious risks to human life and health, infringing upon their right to respect for private and family life.[40] The state was found to have failed in its positive duties to carry out effective regulation of the activities of the mining corporation and in its rejection of several administrative and criminal complaints made by the claimants. The state failed to provide proper avenues for compensation and criminal complaints.[41] This demonstrates that there is the potential to hold member states accountable for failing to prevent corporate environmental harm.

The ECtHR is yet to impose positive obligations to prevent extraterritorial corporate environmental harm. In order for the ECHR to be applicable extraterritorially, the state must exercise either 'effective control over the territory' or 'state agent authority and control'.[42] Therefore, the ECtHR's approach to the extraterritorial application of human rights is of 'limited value to the business and human rights domain because it is premised on the physical presence of State agents outside the State's territory'.[43]

However, there is an increasing international trend towards imposing positive obligations on the state to prevent extraterritorial corporate environmental harm.[44] This is relevant to the ECtHR because it uses international law standards to ensure evolutive treaty interpretation that keeps up to date with contemporary attitudes about what should be the scope of human rights protection.[45] On 7 February 2018, the Inter-American Court of Human Rights (IACtHR) issued an advisory opinion on whether states had obligations under the American Convention on Human Rights (ACHR) in relation to extraterritorial environmental damage in the Wider Caribbean Region, carried out by

37 *Wilson* (n 35) para 41 (emphasis added).

38 See further *Oneryildez v Turkey* (2005) 41 EHRR 20; *Lopez v Spain* (1995) 20 EHRR 277.

39 *Tatar v Romania* App No 67021/01, ECtHR, 27 January 2009.

40 Article 8 ECHR.

41 This case is available in French, Italian, Romanian and Russian. For a useful summary of the case see: James Harrison, 'International Law: Significant Environmental Cases 2008–09' (2009) 21(3) Journal of Environmental Law 501.

42 *Al Skeini v UK* (2011) 53 EHRR 18, paras 133, 138.

43 Daniel Augenstein and Lukasz Dziedzic, *State Obligations to Regulate and Adjudicate Corporate Activities under the European Convention on Human Rights* (European University Institute Working Paper Law 2017/15 2017) <http://cadmus.eui.eu/bitstream/handle/1814/48326/LAW_2017_15.pdf?sequence=1&isAllowed=y>.

44 See, for example, James Harrison, 'Significant International Environmental Law Cases 2017–18' (2018) 30(3) Journal of Environmental Law 527.

45 See e.g. Julian Arato, 'Constitutional Transformation in the ECtHR: Strasbourg's Expansive Recourse to External Rules of International Law' (2012) 37(2) Brooklyn Journal of International Law 627, 627.

corporations situated in their territories.[46] This was a case concerning transboundary environmental harm, meaning that a corporation situated within the territory of the member state was committing environmental harm against individuals situated in a different territory. However, the principles on the extraterritorial application of the ACHR were quite expansive. It stated that:

> The activities undertaken in the jurisdiction of one State party shall not deprive other States of their capacity to ensure that persons under their jurisdiction enjoy their rights under the Convention . . . it is understood that the person whose rights have been breached fall within the jurisdiction of the State of origin if there is a causal link between the facts occurring in its territory and the violation of the human rights of person outside its territory.
>
> It is the State in whose territory or in whose jurisdiction these activities are undertaken, who has effective control over them and is in a position to prevent the causation of transboundary damage that may affect the enjoyment of human rights of individuals outside its territory. The potential victims of the negative consequences of these activities should be deemed to be within the jurisdiction of state of origin for the purposes of any potential state responsibilities for failure to prevent transboundary damage.[47]

This advisory opinion is progressive insofar as it requires a 'causal link between the facts occurring' in the respondent state and the violation of the human right in a different territory rather than requiring the state's presence in the extraterritorial territory. The 'facts occurring' is quite a broad criterion and could include, arguably, a domestic regulatory framework that fails to hold home state corporations accountable for the activities of their subsidiaries, but this is not stated explicitly and the case concerns transboundary activity. The test limits itself to only protecting individuals in extraterritorial territories that are also member states of the ACHR, rather than territories outside of the Inter-American system. If this test was adopted by the ECtHR, the UK could not be held accountable for human rights abuses happening in the Niger Delta.

Conclusion

Enforceable human rights obligations appear to have the potential to hold states accountable for extraterritorial corporate environmental harm, including for failing to provide an adequate regulatory framework that disincentivises corporations to be negligent in relation to their extraterritorial activities. On assessment of the *Okpabi* case, human rights could impose an obligation on the state to produce a legislative framework regulating private actor behaviour that is in conformity with human rights standards. While international human rights law has not quite reached the point of imposing enforceable international obligations on states, one could speculate, considering the direction of international human rights litigation, that it may become a reality in the foreseeable future.

46 IACtHR, Environment And Human Rights Advisory Opinion Oc-23/17, 15 November 2017.

47 Ibid paras 101–02. The original judgment is only available in Spanish. This translation is taken from: Giovanny Vega-Barbosa and Lorraine Aboagye, 'Human Rights and the Protection of the Environment: The Advisory Opinion of the Inter-American Court of Human Rights' (*EJIL: Talk!*, 26 February 2018) <www.ejiltalk.org/human-rights-and-the-protection-of-the-environment-the-advisory-opinion-of-the-inter-american-court-of-human-rights>.

NILQ 70(1): 163–169

Legislation

Acknowledging or erasing intersex experiences? Gender 'diversity' in German law

PETER DUNNE*

Lecturer in Law, Centre for Health, Law, and Society, University of Bristol Law School

Introduction

In November 2018, the German Parliament enacted legislation to affirm the 'diverse' legal gender of persons who experience intersex variance.[1] For those who fall within the terms of the new law, it is possible to gain formal acknowledgment as neither 'male' nor 'female'.[2] The German reform is part of a growing global movement – legal, political and advocacy-based – to validate identities and experiences of gender beyond the traditional gender binary.[3] At present, numerous jurisdictions, including Malta, Canada and New Zealand, provide access to gender registration beyond 'man' and 'woman' categories – although entry requirements across the different regimes vary measurably.[4] In 2018, the English High Court was asked to decide whether individuals have an entitlement to an 'X' passport, which would include gender markers that are neither male nor female, in this jurisdiction.[5] In 2018, the government specifically included non-binary recognition as part of its UK-wide consultation on the Gender Recognition Act 2004.[6] This note explores Germany's attempt to legislate for the 'diverse' identities of persons who experience intersex. While the note

* Pd17563@bristol.ac.uk.

1 Gesetz zur Änderung der in das Geburtenregister einzutragenden Angaben (GeRegÄndG; Bundesgesetzblatt (BGBl.) 2018 I, 2635. See also, Melissa Eddy, 'Not Male or Female, Germans can now Choose "Diverse"' *New York Times* (New York, 14 December 2018) <www.nytimes.com/2018/12/14/world/europe/transgender-germany-diverse.html>.

2 'Germany Introduces Third Gender – Fails Trans People' (*Transgender Europe*, 18 December 2018) <https://tgeu.org/germany-introduces-third-gender-fails-trans-people>.

3 Jens Thielen, 'Beyond the Binary: Rethinking the Right to Legal Gender Recognition' (2018) 3 European Human Rights Law Review 249, 249, 254; Michael Bochenek and Kyle Knight, 'Establishing a Third Gender Category in Nepal: Process and Prognosis' (2012) 26(1) Emory International Law Review 11, 29–30; Jack Harrison, Jaime Grant and Jody L Herman, 'A Gender not Listed Here: Genderqueers, Gender Rebels, and OtherWise in the National Transgender Discrimination Survey' (2012) 2 LGBTQ Policy Journal at the Harvard Kennedy School 13; Anna James Neuman Wipfler, 'Identity Crisis: The Limitations of Expanding Government Recognition of Gender Identity and the Possibility of Genderless Identity Documents' (2016) 39(2) Harvard Journal of Law and Gender 491.

4 See generally, Zhan Chiam, Sandra Duffy and Matilda González Gil, *Trans Legal Mapping Report* (ILGA 2017).

5 Mary Welstead, 'To Bi or not to Bi – Gender and Passport X' (2018) 48(Sep) Family Law 1237. The relevant case is: *Re Elan-Cane* [2018] EWHC 1530 (Admin).

6 'Reform of the Gender Recognition Act 2004' (*UK Government Website*, 3 July 2018) <www.gov.uk/government/consultations/reform-of-the-gender-recognition-act-2004>.

acknowledges the symbolism of extending legal boundaries beyond 'male' and 'female', it highlights two key weaknesses – non-inclusion and misdirected focus – which limit the potential impact of reform – for intersex communities and for those trans-identified[7] persons whose identities stretch beyond the binary.

Law reform: a 'diverse' gender option

Under the new law, individuals – who (through a process of medical certification) experience intersex variance and who do not have a male or female identity – can apply for a 'diverse' gender status rather than having to bring themselves within the existing 'man' and 'woman' categories.

The Commissioner for Human Rights of the Council of Europe defines intersex individuals as 'people who cannot be classified according to the medical norms of so-called male and female bodies with regard to their chromosomal, gonadal or anatomical sex'.[8] There are no definitive statistics for intersex in Europe – with estimates ranging from between one in every 2000 births, up to 1.7 per cent of the population.[9] Intersex is distinct from issues relating to transgender communities and the question of 'gender identity'.[10] While 'intersex' concerns experiences of body, 'gender identity' relates to internal understandings of gender. 'Transgender' is an increasingly used umbrella term which embraces all persons who identify with a gender (binary or non-binary) which deviates from the status assigned to them at birth. While a person who experiences intersex might also have a transgender identity, this frequently is not the case.

In October 2017, the German Constitutional Court – which, since 1978, has issued numerous landmark opinions on gender and sexual diversity[11] – ruled that existing domestic rules for birth registration violated the country's constitutional law.[12] The legal challenge was initiated by a female-assigned individual, who experienced intersex variance and who self-identified as non-binary. In finding that the current system was constitutionally impermissible, the Constitutional Court held that enforced binary gender (for persons in the position of the litigant) violated both the right to personal

7 'Trans' or 'transgender' refers to individuals who do not self-identify with the gender to which they are assigned at birth.

8 Commissioner for Human Rights of the Council of Europe, *Human Rights and Intersex People: Issue Paper* (Council of Europe 2015) 13.

9 Leonard Sax, 'How Common is Intersex? A Response to Anne Fausto-Sterling' (2002) (39(3) Journal of Sex Research 174; Melanie Blackless et al, 'How Sexually Dimorphic are We? Review and Synthesis' (2000) 12(2) American Journal of Human Biology 151, 161.

10 The 'Introduction' to the Yogyakarta Principles describes 'gender identity' as 'each person's deeply felt internal and individual experience of gender, which may or may not correspond with the sex assigned at birth, including the personal sense of the body . . . and other expressions of gender, including dress, speech and mannerisms.' Yogyakarta Principles, 'Introduction' (*Yogyakarta Principles Website*, no date) <www.yogyakartaprinciples.org/introduction>.

11 Anatol Dutta, 'The Legal Status of Transgender and Transsexual Persons in Germany' in Jens M Scherpe (ed), *The Legal Status of Transgender and Transsexual Persons* (Intersentia 2015) 207–22. Among these various judgments, the German Constitutional Court has struck down the requirement that individuals divorce before obtaining legal gender recognition (Federal Constitutional Court of Germany, 1 BvL 10/05 (23 July 2008)). This is a more progressive approach than that adopted by the European Court of Human Rights (*Hamalainen v Finland* [2015] 1 FCR 379). The German Constitutional Court also struck down sterilisation requirements prior to the European Court of Human Rights (*AP, Garcon and Nicot v France* App Nos 79885/12, 52471/13 and 52596/13 (ECtHR, 6 April 2017) .

12 Federal Constitutional Court of Germany, 1 BvR 2019/16 (10 October 2017).

development and guarantees of equality based on sex.[13] The German government was offered two remedial options: (a) to introduce a 'third' gender option; or (b) to remove the requirement to register legal gender altogether.[14]

As one of the first judicial statements in favour of non-binary gender options, the Constitutional Court judgment stands as an important judicial affirmation of gender diversity. Grounded in substantive constitutional protections, rather than mere advocacy – the decision establishes a coherent rights-based framework for gender recognition outside male and female categorisation.

However, a complicating factor in the opinion is the extent to which the Constitutional Court focused on intersex. Following the judgment, questions arose as to what obligation the decision placed upon the German government.[15] On the one hand, the judges spoke in general terms about respect for identities beyond male and female. This suggested a possibly broad scope of application – extending to all non-binary persons, irrespective of their experience of body. However, on the other hand, the facts of the constitutional challenge were limited to a specific litigant, who did exhibit non-standard sex characteristics. Furthermore, the Constitutional Court made frequent reference to those characteristics when explaining its conclusions. There was, thus, an apprehension that the German government would interpret the opinion in a conservative manner – tying third gender rights to experiences of body.

In August 2018, when the German government announced its official response to the judgment, these fears were realised.[16] The government rejected the possibility of abolishing gender registration, favouring an alternative identity status. Such additional gender classification, however, would be restricted only to those persons who experience intersex variance. These proposals have now been enshrined through the new legislation, as affirmed by Germany's Parliament.[17] The new law creates an option (not a requirement) for individuals with non-typical sex characteristics to apply for a 'diverse' gender marker. Such marker becomes an official gender designation, and it can be reproduced on all official documentation (e.g. passport, driving licence etc.). In order to obtain 'diverse' gender recognition, an individual must forward an application, along with medical certification relating to intersex variance. Without such certification, applicants are excluded from the alternative gender option.

13 For a substantive analysis of the German Constitutional Court's judgment, see Peter Dunne and Jule Mulder, 'Beyond the Binary: Towards a Third-Sex Category in Germany' (2018) 19(3) German Law Journal 627.

14 Ibid 629–31.

15 Ibid 631.

16 The Draft Bill and Report of the Expert Meeting (both in German) can be found at: <www.bundestag.de/presse/hib/-/580562> and <http://dip21.bundestag.de/dip21/btd/19/046/1904669.pdf>; Grietje Baars offers commentary on the Draft Bill: see Grietje Baars, 'New German Intersex Law: Third Gender but not as We Want It' (*Critical Legal Thinking*, 24 August 2018) <criticallegalthinking.com/2018/08/24/new-german-intersex-law-third-gender-but-not-as-we-want-it>. See also: 'German Cabinet Approves Third Gender Identity' (*DW*, 15 August 2018) <www.dw.com/en/german-cabinet-approves-third-gender-identity/a-45090243>.

17 Gesetz zur Änderung der in das Geburtenregister einzutragenden Angaben (GeRegÄndG; Bundesgesetzblatt (BGBl.) 2018 I, 2635.

Critiquing 'diverse' gender: exclusion and misdirection

In the comparably short time since its enactment, Germany's 'diverse' gender option has attracted considerable international attention.[18] Building upon previous attempts by the German legislature to affirm non-binary gender,[19] the reforms are an important step towards acknowledging diverse, non-standard experiences of identity. Despite the limitations of the law, explored in greater detail below, there is symbolism in acknowledging the possibility of lives which deviate from expected male–female norms. As social science research – across Europe and beyond – reveals, a growing number of individuals self-identify outside the binary,[20] and these people struggle where domestic legal frameworks marginalise or ignore their experiences.[21] To the extent that the new law (however imperfectly) embraces a broader vision of gender, this is something which can be (and is) rightly celebrated.[22] Furthermore, for intersex individuals (including the appellant), whose bodies and lives have been hidden through legal and medical regulation, there may be significance in laws which expressly acknowledge their existence and rights.[23] Although, as noted below, there is a risk that the reforms mischaracterise and misdirect intersex preferences, there is some positivity in the German legislature taking a stance to acknowledge the concerns of intersex voices.

Despite these positive symbolic elements, however, the new law gives rise to numerous concerns. While some of the critiques (unsurprisingly) come from opponents of lesbian, gay, bisexual and transgender (LGBT) rights in Germany's Parliament,[24] stronger dissent is evident among domestic and international advocates.[25] In broad terms, their dissatisfaction with the 'diverse' gender law arises from two claims, that: (a) the reforms misunderstand non-binary identities, excluding a majority of individuals who are neither male nor female; and (b) Parliament's response misdirects intersex concerns, ignoring legitimate complaints regarding bodily integrity. In the remaining sections, this note explores each of these critiques in turn – identifying some key deficiencies which limit the impact of the new law.

18 Colin Drury, 'Germany Approves Third Gender "Intersex" Option for Official Documents' *The Independent* (London, 15 December 2018) <www.independent.co.uk/news/world/europe/germany-third-gender-identiy-official-records-diverse-binary-intersex-a8684646.html>; Melissa Eddy, 'Not Male or Female, Germans Can now Choose "Diverse"' *New York Times* (New York, 14 December 2018) <www.nytimes.com/2018/12/14/world/europe/transgender-germany-diverse.html>.

19 Robert Hupf, 'Allyship to the Intersex Community on Cosmetic, Non-Consensual Genital Normalizing Surgery' (2015) 22(1) William and Mary Journal of Women and the Law 73, 96; Adam Herpolsheimer, 'A Third Option: Identity Documents, Gender Non-Conformity, and the Law' (2017) 39(1) Women's Rights Law Reporter 46, 64.

20 See e.g. Christina Richards et al, 'Non-binary or Genderqueer Genders' (2016) 28(1) International Review of Psychiatry 95.

21 See generally, Genny Beemyn and Susan Rankin, *The Lives of Transgender People* (Columbia University Press 2011) 26. For information on non-binary experiences in the UK, see Vic Valentine, *Non-Binary People's Experiences in the UK* (Scottish Trans Alliance 2016).

22 Vade offers an interesting perspective on the merits of increasing *legal* gender diversity: Dylan Vade, 'Expanding Gender and Expanding the Law: Toward a Social and Legal Conceptualization of Gender that is more Inclusive of Transgender People' (2005) 11(2) Michigan Journal of Gender and Law 253.

23 See, generally, Alison Reddick, 'What Happened at Hopkins: The Creation of the Intersex Management Protocols' (2005) 12(1) Cardozo Journal of Law and Gender 289; Fundamental Rights Agency of the European Union, *The Fundamental Rights Situation of Intersex People* (FRA EU 2015) <file:///C:/Users/peter/Downloads/fra-2015-focus-04-intersex.pdf>.

24 'Gender Adds "Diverse" as a Gender to Birth Register" (*DW*, 14 December 2018) <www.dw.com/en/germany-adds-diverse-as-a-gender-to-birth-register/a-46737328>.

25 'Germany Introduces Third Gender – Fails Trans People' (*Transgender Europe*, 18 December 2018) <https://tgeu.org/germany-introduces-third-gender-fails-trans-people>.

Excluding non-binary identities

An important shortcoming in the 'diverse' gender option is the extent to which it excludes large numbers of individuals who self-identity outside 'man' and 'woman' classifications. In responding to the Constitutional Court judgment, the German government has limited the new rules to persons who experience intersex variance. This means that – although people who have both ambiguous sex characteristics and an ambiguous gender identity may apply for a 'diverse' gender status – all other individuals are excluded. In particular, transgender populations who, although they do not experience a male or female gender, have expected body characteristics, cannot seek relief under the new reforms.[26]

In legal terms, restricting the 'diverse' gender category to intersex communities contradicts (if not the letter) at least the spirt of the 2017 judgment. While, in that case, the Constitutional Court was immediately faced with an intersex litigant, the broader arguments about respect for personal gender and the tangible harms of gender invisibility were equally relevant to non-binary persons.[27] To the extent that involuntary categorisation as male or female creates impermissible harm for non-binary persons who experience intersex, the same is true for non-binary persons with expected sex characteristics.[28] Leaving this latter group out of the reform potentially reproduces unconstitutionality and will likely encourage additional litigation.[29]

In practical terms, limiting the new gender status to intersex populations reduces any actual impact that the diverse gender option may have. If a majority of persons who self-identify outside the binary have typical sex characteristics, those individuals will not be accessing a regime which requires evidence of intersex variance.[30] Thus, the new law expressly excludes the main constituency to whom its protections should apply.

At the same time, the law does apply to a population, most of whose members have no desire for the 'protections' which the reform offers.[31] A significant proportion of intersex individuals self-identify within the binary and many persons are sceptical of laws which tie (even implicitly) experiences of intersex to an alternative, 'third' gender classification.[32] Both the Third and Fourth International Intersex Fora have made explicit recommendations to raise intersex youth within the gender binary (while maintaining a flexibility to transition if required).[33] Thus, the German law achieves a unique distinction of embracing a group of people who view its introduction with suspicion, while simultaneously excluding those who experience their omission as a deep social injury.

Misdirecting intersex concerns

The new reform is also criticised for concentrating on questions of legal identity despite the fact that – for many intersex persons – their primary concern is the involuntary medicalisation of young intersex bodies.

26 Ibid.

27 Dunne and Mulder (n 13) 633–4.

28 Theodore Bennett, '"No Man's Land": Non-Binary Sex Identification in Australian Law and Policy (2014) 37(3) University of New South Wales Law Journal 847, 850–1.

29 'Germany Introduces Third Gender' (n 25).

30 Ibid.

31 Fae Garland and Mitchell Travis, 'Legislating Intersex Equality: Building the Resilience of Intersex People through Law' (2018) 38 Legal Studies 587–606, 596–7.

32 Commissioner for Human Rights of the Council of Europe (n 8)

33 See e.g. 'Third International Intersex Forum' (*ILGA-Europe*, December 2013) <www.ilga-europe.org/what-we-do/our-advocacy-work/trans-and-intersex/intersex/events/3rd-international-intersex-forum>.

In Germany, as in many jurisdictions across Europe, there remains concern that medical professionals continue to perform non-therapeutic 'normalising' surgeries on intersex infants.[34] These procedures are intended to 'correct' sex characteristics which deviate from aesthetic expectations for male or female bodies.[35] In 2011, the UN Committee against Torture specifically recommended that Germany halt physical interventions, which have no health benefit for young persons who experience intersex.[36] Indeed, in many respects, German civil society discussions regarding intersex have, for at least a decade, focused on questions of body rather than alternative legal identities. Intersex normalising surgeries raise significant concerns for physical integrity rights, and they have historically been performed in circumstances of secrecy, prioritising medical or parental biases over informed consent.[37] Given the long-term impact of such treatments, including requirements for multiple interventions and possible loss of sexual sensation,[38] there are increasing calls within Germany to limit non-therapeutic procedures on intersex bodies.

The new reforms – although acknowledging the existence of intersex lives outside the binary – do nothing to proscribe the involuntary medicalisation of intersex youth. A person who experiences non-standard sex characteristics can apply for a 'diverse' gender option. There is no guarantee, however, that such individual will be protected from external decisions to physically amend their healthy body as an infant. For many intersex individuals, such protections are significantly more important than affirming alternative gender categories.

A similar critique was offered against an earlier German law in 2013. That original law, which was challenged as part of the 2017 litigation, created a non-specified gender category in which intersex children could be placed if, at the point of birth, it was not possible to assign a definitive legal sex classification.[39] The rationale for the 2013 reform was that, by removing a requirement to immediately gender intersex infants, parents and doctors would be encouraged to refrain from undertaking unnecessary surgical interventions. However, there is suggestion that, rather than reducing 'normalising' procedures, the 2013 law has increased such treatments – with parents anxious to avoid

34 Amnesty International, *First, Do No Harm: Ensuring the Rights of Children with Variations of Sex Characteristics in Denmark and Germany* (Amnesty International 2017); OII-Europe, 'New Draft Bill in Germany Fails to Protect Intersex People' (*OII-Europe*, 20 August 2018) https://oiieurope.org/new-draft-bill-in-germany-fails-to-protect-intersex-people>. See also Jens Scherpe, Tobias Helms and Anatol Dutta, *The Legal Status of Intersex Persons* (Cambridge University Press 2018) where there are contributions on numerous European jurisdictions, such as France, Netherlands and Sweden. For a broader, pan-European perspective, see: Commissioner for Human Rights of the Council of Europe (n 8)

35 For a general overview of medico-legal controversies surrounding genital normalising surgeries, see Melanie Newbould, 'When Parents Choose Gender: Intersex, Children and the Law' (2017) 24(4) Medical Law Review 474. This article deals with many of the issues which have direct relevance within the current German debate.

36 UN Committee against Torture, 'Concluding Observations on the Fifth Periodic Report of Germany' (12 December 2011) UN Doc No CAT/C/DEU/CO/5, [20].

37 Alison Davidson, 'Surgery for Intersex Children' (2011) 26 Wisconsin Journal on Law, Gender and Society 1, 15–16; Anne Tamar-Mattis, 'Exceptions to the Rule: Curing the Law's Failure to Protect Intersex Infants' (2006) 21 Berkeley Journal of Gender, Law and Justice 59, 59. Newbould notes how, while we may assume that parents will act for the welfare of their child, this might not always be objectively the case where parents are confronted with sexual diversity: Newbould (n 35) 478.

38 Kishka-Kamari Ford, 'First, Do No Harm – The Fiction of Legal Parental Consent to Genital-normalizing Surgery of Intersexed Infants' (2001) 19(2) Yale Law and Policy Review 469, 485; Erin Lloyd, 'Intersex Education, Advocacy and the Law: The Struggle for Recognition and Protection' (2005) 11(2) Cardozo Women's Law Journal 283, 284.

39 Law on Civil Status (*Personenstandsgesetz*), s 22(3).

the stigma of the non-specified gender category.[40] As in 2013, critics of the new law argue that, if policy-makers aim to reduce the rate of non-therapeutic surgeries, legal prohibition is the most coherent, effective method.

Conclusion

The new 'diverse' gender option in Germany represents a symbolic milestone in European gender politics. Acknowledging the possibility of lives outside 'man' and 'woman', the reform is a significant affirmation for non-binary experiences. Yet, by tying gender diversity to intersex, the German Parliament has limited both the practical and symbolic impact of the new legislation. The 'diverse' gender category excludes trans-identified non-binary communities and obscures broader intersex advocacy demands – most notably the eradication of involuntary normalising surgeries. Germany's intervention is an important step forward – but it must be reinforced (in Germany and beyond) by laws which respond to the actual lived-experience of gender (inside and outside the binary) across Europe.

40 Garland and Travis (n 31) 600–01 speak to emerging and anecdotal evidence in this regard. Of course, given the invisibility of intersex lives – particularly within the medical sphere – it is difficult to identify definitive evidence that the 2013 law has precipitated a rise in surgical procedures on young intersex bodies.

NILQ 70(1): 171–174

Book review

Depression: Law and Ethics, edited by Charles Foster and Jonathan Herring*

Dr Paul Skowron

Wellcome Research Fellow, York Law School, University of York

Depression: Law and Ethics is not Charles Foster and Jonathan Herring's first collaboration. The two Oxford-based academics have written two Springer Briefs in Law together;[1] and, with Israel Doron, they edited *The Law and Ethics of Dementia*.[2] Readers of the latter book will find aspects of *Depression* familiar. Both books are separated into parts written from first-person, clinical, ethical and legal perspectives. *Depression* is not, however, completely modelled on *Dementia*. It does not, for instance, have any analogue of the older book's 'Social Aspects of Dementia' section.[3] One reason for this may simply be space. *Dementia* sprawled across 539 pages, but *Depression* is less intimidating at 303. This obvious difference in size is accompanied by a subtler shift in emphasis. *Depression* is not an attempt to capture the entire 'state-of-the-art' across several disciplines. As the editors explain, their goal is more modest. They aim to facilitate a conversation between different groups that have theorised depression in different ways: 'sufferers, clinicians, philosophers, and lawyers'.[4]

The order that the parts of the book appear in may also reflect a shift in editorial philosophy. *Dementia* started with 'Medical Fundamentals', but *Depression* starts instead with 'Sufferers': three pieces written from a first-person perspective. These are extremely short, the longest is just four pages, and they are written with a lyricism that few will expect from a book subtitled 'Law and Ethics'. They provide an intimate introduction to experiences that, as Iain McGilchrist says in the first, are not 'like anything on Earth':[5] depression should not be confused with 'being sad, even the saddest you have ever been'.[6] His point is reinforced by Jay Griffiths, who, appropriately in this surprisingly poetic section, draws attention to some metaphors for depression: black holes, cliff edges and drowning. She notes that such metaphors, when spoken by someone with depression, are

* Published by Oxford University Press (2017), 336pp, £60hb ISBN: 978 0198801900.

1 Charles Foster and Jonathan Herring, *Altruism, Welfare and the Law* (Springer 2015); Charles Foster and Jonathan Herring, *Identity, Personhood and the Law* (Springer 2017).

2 Charles Foster, Jonathan Herring and Israel Doron, *The Law and Ethics of Dementia* (Hart 2014).

3 Ibid Part IV.

4 Charles Foster and Jonathan Herring (eds), *Depression: Law and Ethics* (Oxford University Press 2017) vii.

5 Ibid 2.

6 Ibid.

not literary 'decoration' but a 'desperate attempt to send out an SOS';[7] she then draws attention to the differences between them. Feeling as though you are surrounded by precipitous drops is not, for instance, the same as feeling as though you are drowning. Different metaphors capture different experiences that depression can bring. Her point is especially apt in the context of this book. In the abstract worlds of law and ethics, these metaphors are seldom visible on the page; but they are nevertheless likely to shape underlying ideas of what it is like to be depressed. In these circumstances, there is a real danger of an unexamined metaphor for one experience being mistaken for a complete phenomenology of a more complicated whole.

Although the 'Sufferers' section is short, the book's attention to first-person experiences of depression is not tokenistic. It is also visible in the first essay of each subsequent section. This is most obvious in Richard Ashcroft's introduction to the 'Ethics' section, which combines personal narrative with a clear distinction between standard approaches to ethics and depression, which are largely concerned with the correct response to a depressed person, and the need for an 'ethics of depression', which includes the depressed person as an actor within the ethical field.[8] Less obviously, however, a concern with first-person perspectives also underwrites Mary Donnelly's introduction to the 'Law' section. She draws on Matthew Ratcliffe's phenomenological account of experiences of depression, which – like Griffiths' chapter – pays close attention to the metaphors used to express depression,[9] to illustrate how 'severe depression itself limits assessors' ability to determine capacity'.[10] Similarly, Phillip Cowen, in the first chapter of the 'Clinical' part of the book, does not give an abstracted 'symptomatology, diagnosis, and classification' of depression but one constantly enriched with descriptions of what it is like to be depressed and what it is like to be around a person who is depressed.[11]

Perhaps ironically, given the 'Law and Ethics' subtitle, the 'Clinical' section is in some ways the book's most complete. In addition to Cowen's chapter, there are introductions to the aetiology, epidemiology and cultural history of depression, and two chapters outlining the treatment options.[12] Although there is some repetition of material between chapters, particularly some of the historical information, the standard is high. Any lawyer or ethicist wishing to escape the unfortunate tendency of both disciplines to treat 'mental disorder' as a homogeneous category could start by using this section to learn more about depression in particular. A tension, also apparent in other chapters,[13] does, however, cut across this part: balancing the need to include people with depression as part of the shared human community and the need to acknowledge how completely isolating the experience of depression can be.[14] Although the book does not directly engage with this tension at any length, the 'Clinical' section contains some of its best indirect resolutions. Anthony James's chapter on depression in childhood and adolescence and Julian C Hughes's chapter on depression in the ill and dying both emphasise depression's diversity.[15] Doing so shows how it can be both entirely unique, unlike 'anything on

7 Ibid 6.

8 Ibid 132.

9 Matthew Ratcliffe, *Experiences of Depression: A Study in Phenomenology* (Oxford University Press 2015) ch 2.

10 Foster and Herring (n 4) 207.

11 Ibid 21.

12 Ibid chs 5–7, 10–11.

13 For example, ch 3.

14 Ratcliffe (n 9) 64–71.

15 Foster and Herring (n 4) chs 8–9.

Earth',[16] yet still embedded in the world and shaped by individual differences, circumstances and age. In this respect, the case studies that illustrate some of the different ways that physical ill-health and depression can interact are especially valuable.[17]

By putting a 'Clinical' section in the same volume as parts on 'Ethics' and 'Law', this book makes plain the extent to which the latter two disciplines have failed to properly engage with depression as a theoretical entity in its own right, distinct to the vaguer notion of a 'mental disorder'.[18] To point this out is not to criticise the contributors to the latter parts of the book. They, to borrow the editors' metaphor, are in the room, beginning a conversation. The contrast between these parts and the 'Clinical' section's attention to the diversity and phenomenological richness of depressive experiences is, however, glaring. For the most part, contributors to the 'Ethics' section are left evaluating the fit between extremely abstract ideas – authenticity, values-based practice, the metaphor of a physical disease, and mental capacity – and depression, a unique experience that none of these concepts was developed in direct response to.[19] If depression really is 'not like anything on Earth',[20] then how helpful can such generic principles alone be? The evidence here suggests that they barely get ethical thought away from the starting line. Whether examining capacity,[21] the Mental Health Act 1983,[22] or the degree to which physicians should 'exhort and cajole' their patients to undertake psychotherapy,[23] this part of the book is almost entirely concerned with exactly when the, implicitly superior, knowledge of experts justifies exerting social pressure on people with depression. This is an important ethical question; but, as Ashcroft points out in his excellent introduction to the section, it is far from the only one.[24] Furthermore, depression leaves many grappling with the 'one truly serious philosophical problem . . . judging whether life is or is not worth living'.[25] Grappling with that problem, as opposed to treating it as an intellectual plaything, is terrible and ugly. It is still an *ethical* grappling nonetheless. Ashcroft is right to call for an ethics of depression that fully includes depressed people as moral agents;[26] but the editors' envisaged conversation between sufferers and ethicists may also require an ethics *in* depression, which treats depressive thought as, among other things, a species of moral thought.

'Ethics' also includes a chapter by Harry Minas on 'Depression in the Developing World'.[27] Although obviously an important subject, this is a strange fit for the section. The chapter gives an overview of prevalence, impact and treatment options in the developing world, but it does not directly engage with the ethical implications of the state

16 Ibid 3.

17 Ibid 94–102.

18 At least 'ethics' in its current academic form. As authors in the book point out, Mill and Montaigne, to name but two, had psychological crises, with at least some of the features of depression, which deeply influenced their work. Ibid 130, 200.

19 Ibid chs 13–16.

20 Ibid 3.

21 Ibid chs 13, 16.

22 Ibid ch 14.

23 Ibid ch 15.

24 Ibid 132.

25 Albert Camus, *The Myth of Sisyphus,* Justin O'Brien (trans) (Penguin 2005 [1955]) 1. Similarly, see Ludwig Wittgenstein, *Notebooks 1914–1916*, G H von Wright and G E M Anscombe (eds), G E M Anscombe (trans) (Blackwell 1961) entry for 10.1.17.

26 Foster and Herring (n 4) 132.

27 Ibid ch 17.

of affairs it reports. In this respect, the book's 'law and ethics' framing, with separate parts for separate disciplines, can obscure more than it reveals. Similar issues are found in the 'Law' section. Although John Coggon and Jonathan Herring are both professors of law, their respective chapters, for taking a public health approach to depression and for treating childhood depression as a child protection issue respectively,[28] are closer to political philosophy than to fine-grained legal analysis. There is nothing wrong with that. Indeed, these are two of the best chapters in the book. Nevertheless, their placement does make one of the biggest gaps left by the 'law and ethics' framing more obvious: politics. The political aspects of depression are mentioned in the preface,[29] and Coggon makes it completely clear that he is engaged in political philosophy;[30] but political explanation and argumentation has its own character, not reducible to either ethics on one side or legal analysis on the other.[31] To the extent that a 'law and ethics' framing obscures the particular character of political thought, it seems likely to inhibit, rather than enable, the conversations that the editors wish to see.[32]

These concerns should not distract from the virtues of the 'Law' section. Many of the chapters, in particular those pertaining to treatment, criminal liability, civil liability and employment serve as excellent introductions to relevant areas of law and its implications for people with depression.[33] Other chapters are narrower or more speculative. For instance, Richard Huxtable examines international trends towards more permissive policies on medically assisted dying.[34] In one sense, however, the scope of this part of the book is narrow. A lot of detail is given about England and Wales; but other jurisdictions, even within the UK, are seldom mentioned. Space restrictions almost certainly presented the editors with a choice between the detailed consideration of one jurisdiction and a superficial overview of many; and by taking the former option they have maximised the book's usefulness in England and Wales, especially to those from disciplines other than law. Their choice does, however, come at some cost in terms of a wider market, although this point should not be overstated. Many legal systems are similar enough to England and Wales for aspects of even the legal chapters to have broader appeal; and this issue barely affects the other parts of the book at all. Indeed, this book deserves a wide readership. It is always well written, often enlightening, and sometimes provocative. As is the nature of edited collections from a university press, its primary audience is likely to be other academics; but it will be just as valuable to students from a wide range of disciplines, especially those engaged in postgraduate study or otherwise writing a thesis on depression.

28 Ibid chs 19, 24.

29 Ibid vii.

30 Ibid 217–19.

31 This is far from a new distinction, see Aristotle, *Politics*, Ernest Baker (trans) (Oxford University Press 1995) bk III, ch 11.

32 For an extended argument on this general point, see John Harrington, *Towards a Rhetoric of Medical Law* (Taylor and Francis 2017).

33 Foster and Herring (n 1) chs 20–3.

34 Ibid ch 25.

NILQ 70(1): 175–179

Book review

Human Rights in Global Health: Rights-Based Governance for a Globalizing World, edited by Benjamin Mason Meier and Lawrence O Gostin*

Louise Hatherall

PhD Candidate, Centre for Health, Law, and Society, University of Bristol Law School

The 'Introduction', written by the editors of *Human Rights in Global Health*, opens as follows: 'Institutions matter for the advancement of human rights in global health', thus putting the key theme of this volume up front and centre.[1] Aiming to address the gap in human rights scholarship left by a focus on national governments, this edited collection instead focuses on global institutions. It brings together an ambitious range of contributions from academia, non-governmental organisations and scholars from within the UN system to examine the complex and evolving relationship between human rights, public health and global governance. This expansive and carefully researched collection is the first systematic review of the institutions of global governance, both filling a gap in the existing literature and calling for a new research field on human rights in global health governance. Each chapter offers a consistent structure, beginning with an historical context, before moving to discuss current practices, and concluding with an analysis of future opportunities or challenges. This consistent structure means that it is light work for the reader to draw out common themes and tensions across the collection, something which, given the breadth of material presented, deserves admiration. Some chapters assume an underlying understanding of definitions and characteristics of the global health system, but the book is clearly written and is eminently readable in all sections. Although no detailed previous knowledge is required to draw worthwhile lessons from this collection, the volume will be instructive for scholars and practitioners alike. Some chapters are yearning for more space to expand their analysis and conclusions, but the strict subject boundaries and structure ensure that the empirical comparison between institutions is methodologically rigorous.

The collection spans 24 chapters split into five sections. The breadth of material covered makes detailed examination of each chapter beyond the scope of this review, but notable chapters of interest to the reviewer will be focused on here.

Section One, entitled 'Global Health and Human Rights', provides the contextual, theoretical and historical basis for the collection and highlights the relevance of human rights for global health, with a particular focus on the rights-based approach to health. The first chapter, written by the editors, is a concise and wonderfully written introduction

* Published by Oxford University Press (2018), 585pp, £79hb ISBN: 976 0190672676.

1 Benjamin Mason Meier and Lawrence O Gostin, *Human Rights in Global Health: Rights Based Governance for a Globalizing World* (Oxford University Press 2018) 1.

to the origins of human rights in global health. This chapter – tracing international frameworks of human rights through the introduction of the UN, the International Covenant on Economic, Social and Cultural Rights, the World Health Organization (WHO) and the Universal Declaration of Human Rights – charts the pivotal shifts which allowed public health to be understood as shaped by social determinants, as well as understanding human rights as rights enforceable against states. Chapter 2 traces the evolution of applying human rights to health and begins with a refreshing caveat concerning the subjectivities of this history, and a call for a critical eye from the reader to assess such disagreements and subjectivities. The chapter deftly and concisely weaves through the evolution of applying human rights to health. The next chapter examines the shift from state obligations under international health law to institutional responsibilities under global health law and frames human rights law through global health governance. Chapter 4 neatly moves from the context of global health governance set in the previous chapter to considering the future of 'Global Governance for Health'. Split into two parts, this chapter explores the shortcomings of the current global health agenda resulting from the failure of governance to put people and their rights at its core and considers seven interrelated and mutually reinforcing reform proposals to transform the agenda with a rights-based paradigm at its heart. These transformations are broad and wide ranging, from ensuring accurate and detailed disaggregate data to enable effective scrutinisation of government performance, to addressing the negative human rights implications of corporate tax avoidance.

The second section explores the evolving role of the WHO in the development and implementation of human rights, before looking to the future of the organisation in an expanding global health landscape. The first chapter in this section begins with a description of the development of human rights through the WHO and its attempts – and failures – to achieve a rights-based approach for implementing human rights for global health. This chapter notes that the WHO Secretariat originally neglected a human rights discourse, instead projecting the WHO as a purely technical organisation, which resulted in a squandering of potential opportunities to implement rights-based approaches to health. This raises important questions about the framing of global institutions, as 'objective' and purely technical, and the tension this can create when attempting to hold governments accountable for global health policies and practices. Although the authors highlight that the WHO eventually gained traction in mainstreaming the health and human rights discourse by developing its normative framework, later chapters – such as Chapter 16 on the World Bank – demonstrate that endeavouring to maintain a purely technical veneer are problematic when attempting to bring in broader socio-economic bases for challenging state failures to promote health and human rights. The remaining chapters in this section review how the WHO has sought to revitalise the rights-based approach to health and human rights through its gender, equity and human rights mainstreaming efforts across the WHO; as well as looking to the future to discuss what role the efforts of the WHO to enable legal environments, increase accountability and focus on reaching marginalized communities will have in the future of global governance. Chapter 7 also questions the likelihood of the success of human rights mainstreaming without a strong leader championing commitment, funding and staffing.

Human Rights in Global Health then shifts toward a comparative analysis of institutions which have either an explicit or implicit health and human rights mandate. Section Three focuses on inter-governmental organisations (IGOs), dedicating a chapter each to the UN International Child Emergency Fund (UNICEF), the International Labour Organisation

(ILO), the UN Educational, Scientific and Cultural Organisation (UNESCO), the UN Population Fund (UNFPA), the Food and Agricultural Organisation of the UN (FAO) and the Joint United Nations Programme on HIV/AID (UNAIDS) to explore global governance beyond the WHO. Each chapter in this section begins by outlining the origins of the institution and the evolution of global health and human rights within it, before describing current efforts to mainstream human rights through institutional policies and practices. This historical framing is followed by consideration of the factors which facilitate or inhibit human rights mainstreaming in global governance for health. Each chapter concludes by looking forward at future efforts of these institutions to mainstream human rights in global health governance. Overall, this section explores how such IGOs have played a pivotal role in implementing human rights through health-related mandates and demonstrates a chasm between actions and words which calls out for further research. Despite having specific human rights mandates, some IGOs, such as the FAO and UNFPA, have struggled to implement human rights mainstreaming whereas others, such as the ILO and UNESCO, have achieved significant advances in mainstreaming human rights without constitutional or institutional mandates to do so. Understanding why this is so requires more research. Some of the difficulties in implementation are clear: a lack of technical knowledge and expertise, lack of leadership and limited resources. However, a more detailed comparative analysis exploring the reasons for varying outcomes across the UN IGOs would provide some answers as to why there is intermittent success of implementing constitutional frameworks for achieving human rights aims. As succinctly noted in Chapter 9: 'In the end, the labels are less important than the practice.'[2] The editors, however, do remark at this point that there are rich seams in this collection that require more attention, noting that this volume is the 'start of a larger research agenda on human rights in global health governance'.[3] The section concludes with a chapter dedicated to the future of IGO partnerships for health and human rights, noting a deficit in human rights-based approaches and suggesting potential remedies for this deficit.

Section Four moves on to interrogate institutions which have sought to address the link between economics and global health and critically assesses their attempts to integrate human rights into their recommendations and practices. Chapter 15 explores the integration of human rights-based approaches and the right to development into global governance for health. The section then moves on in Chapter 17 to examine the World Trade Organization (WTO) and the public health implications of its intellectual property rules in two prominent health-related issues where health and trade clash: access to medicines and tobacco control. These examples are well chosen by the authors and demonstrate how the ability of states to take action concerning public health is constrained by the rules governing global trade. The difficulties and political sensitivities of interfering in the market to protect health-related human rights and the resultant precarity of the position of health within the WTO are also discussed. More attention is paid here to the challenges in securing access to medicine rather than tobacco control. This is appropriate as access to medicines issues have had a longer history of conflict at the WTO than the relatively recent emergence of concerns surrounding tobacco control. What is aptly drawn out is the reactionary nature of the shifts in understanding intellectual property rights as linked with health and human rights rather than purely trade issues. For example, attempts by developing countries to clarify that nothing in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) would

2 Ibid 217.

3 Ibid 570.

prevent the adoption of measures aimed at protecting public health were blocked by the USA until the threat of an anthrax attack was amplified by limited access to the only effective treatment, the drug ciprofloxacin, as a result of patents. This led to the USA relaxing its hard-line position. The reactionary nature of health and human rights developments is subsequently highlighted in Chapter 19, which critically explores the role of the public/private partnership of the Global Fund to Fight AIDS, TB and Malaria. The birth of the Global Fund grew out of a reluctance of traditional funders to finance anti-retroviral therapy which slows down the development of HIV. The strategies and initiatives undertaken to support human rights-centred programmes are described, as well as the Global Fund's history in becoming the principle funder for TB, malaria and HIV programmes. A striking comparison between Chapters 17 and 19 is the nature of relationships between global economic institutions and international non-governmental bodies. The Global Fund has formalized collaborations with international non-governmental bodies, such as Stop TB, to reduce human rights barriers. However, the WTO relationship with similar bodies, such as Médecins Sans Frontières, is more combative than collaborative. Chapter 17 outlines the heterogeneous ways in which civil society groups have responded to access to medicines negotiations, including through protest, petitions and media advocacy. These relationships, and the effectiveness of collaboration or conflict, are some of the rich seams which require more attention, and the comparative nature of the book expertly draws such themes to the fore.

The last section in the book focuses on the UN human rights systems and examines their roles in advancing human rights to global health, critically analysing the role of the Office of the UN High Commissioner for Human Rights, the UN Special Procedures and human rights treaties bodies in Chapters 21, 22 and 23 respectively. A common theme in the chapters of this final section is the need for further collaboration, not only with civil society groups, but also cross-institutional and cross-disciplinary collaboration, highlighting the complexities involved in mainstreaming human rights in global governance. The section concludes with an analysis of whether the Universal Periodic Review (UPR) will provide an opportunity to strengthen human rights accountability for global health. The UPR, under the auspices of the Human Rights Council, provides a periodic review of the human rights records of all UN member states and presents an opportunity for states to highlight what actions they have taken in respect of fulfilling their human rights obligations. The concluding chapter outlines that the UPR's recommendations, contained in an outcome report following assessment of a member state, have achieved uneven success to date. Nevertheless, it is still optimistic about the future of the UPR.

The collection concludes by drawing out four general themes from the preceding chapters and highlighting them as specific structures which shape human rights implementation. Governance mechanisms, specifically constitutional mandates and secretariat leadership, are vital for translating standards into mandates. Staff, through bureaucracy, need to see human rights as a normative basis for their human rights efforts. Staff particularly require commitment, understanding and application by technical professionals to sustain the incremental changes necessary for culture change. Collaborations with NGOs and inter-organisational partnerships are required to galvanise disparate sets of actors to a shared vision of human rights. Finally, internal and external accountability need to be strengthened, a point reiterated in many of the contributions to the collection. The conclusion yearns for more space to discuss such overarching issues, but it is bracing to look forward to further volumes dedicated to tackling such mechanisms and their relationship with human rights.

The editors have included an afterword to reflect on the rise of nationalist movements and the increasing isolationism of nations. One only needs to look at the withdrawal from UNESCO of the USA and Israel in 2017, and the similar proposed withdrawal of the UK announced in 2018, to see the impact that such threats may have on the institutions studied in this collection. The editors consider the effect such movements could have on global governance and human rights and conclude that, despite such challenges, the preceding chapters demonstrate a strength and resilience in the global institutions to resist such retrenchment from human rights. They remain optimistic about efforts to materialise the highest standards of health.

In conclusion, this volume is a timely and comprehensive analysis of the organisational approaches to human rights mainstreaming. The collection is the first systematic and comparative review of global institutions in operationalising human rights for global health and succeeds in providing contextual background and critical analysis of a broad range of institutions, as well as in providing an insightful, timely and necessary current commentary on the intersection of global governance, public health and human rights.