Spring Vol. 76 No. 1 (2025)

NORTHERN IRELAND

LEGAL QUARTERLY

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

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NORTHERN IRELAND
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Spring Vol. 76 No. 1 (2025)

Special issue:
On-going challenges, responsibility and influences in healthcare law and policy – essays in honour of Chris Newdick

Guest editor: Thérèse Callus

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Articles DOI: 10.53386/nilq.v76i1.1175

Editorial: On-going challenges, responsibility and influences in healthcare law and policy – essays in honour of Chris Newdick

Thérèse Callus
University of Reading
Correspondence email: m.c.callus@reading.ac.uk.

ABSTRACT

This special issue critiques the challenges, responsibilities and influences facing different stakeholders in the development of healthcare law and policy in the United Kingdom. It brings together leading scholars to offer insightful analysis on the many questions posed on how decisions on whom to treat are taken at macro and micro levels. The inspiration for this special issue stems from the work of Professor Christopher Newdick, who has been instrumental in forging a new way of resolving conflict between competing interests in the provision and regulation of healthcare. A symposium was held at the University of Reading in April 2022 to celebrate Newdick's work and some of the papers presented there make up this special issue.

Keywords: healthcare law and policy; NHS; regulation; patients' rights; funding.

The provision of public health – whom we should treat,[1] how it should be paid for, and how it ought to be regulated – poses on-going challenges and unresolved tensions across the United Kingdom (UK)[2] and elsewhere. The increasing prevalence of so-called lifestyle diseases,[3] the inadequacy of state funding to deal with them and the central tenets of individual autonomy and subjective rights[4] create a melting pot of conflicting interests and responsibilities. Added to that are the important commercial and socio-economic influences which

1 C Newdick, *Who Should We Treat? Rights, Rationing and Resources in the NHS* 2nd edn (Oxford University Press 2005).

2 Tensions which pre-dated the introduction of the NHS in England: H Lasswell, *Politics: Who Gets What, When, How* (Whittlesey House 1936).

3 See, for example, K Veitch, 'Obligation and the changing nature of publicly funded healthcare' (2019) 27 (2) Medical Law Review 267–294; J Coggon and B Kamunge-Kpodo, 'The legal determinants of health (in)justice' (2022) 30(4) Medical Law Review 705–723.

4 C Newdick, 'The positive side of healthcare rights' in S McLean (ed), *First Do No Harm: Law, Ethics and Healthcare* (Ashgate 2006) 573–586; R Dworkin, *Taking Rights Seriously* (Harvard University Press 1977).

mean that, just as Newdick has previously asked, we are still left asking the question of '[W]hat is the proper responsibility of individuals, governments and corporate interests working within a global trading environment' to ensure health equality and social justice?[5]

The issues raised are not unique to the UK. Whilst the articles in this special issue focus on the national picture, the questions of equitable access to healthcare and how it is funded are relevant around the world. Irrespective of how a health service is funded, decisions need to be made as to how finite resources will be allocated and how individual rights will be exercised. Inevitably, these decisions will have a political element.[6] The global trading environment adds further pressures to cash-strapped public health services, and worldwide there is an increasing recognition of the role of commercial enterprises in determining health inequalities and outcomes.[7] The risk of embedding market fundamentalism within the healthcare sector is acute. There is thus an emerging awareness at an international level that more work needs to be done in addressing commercial determinants of health.[8] Indeed, as some of the articles in this issue candidly expose, the disruptive influence of commercial interests could be said to pose the greatest challenge to existing healthcare systems around the world.

To contribute to these debates, this special issue critiques the challenges, responsibilities and influences facing different stakeholders in the development of healthcare law and policy in the UK.[9] It brings together leading scholars to offer insightful analysis on the many questions posed on how decisions on whom to treat are taken at macro and micro levels. The inspiration for this special issue stems from the work of Professor Christopher Newdick, who has been instrumental in forging a new way of resolving conflict between competing interests in the provision and regulation of healthcare. His work has questioned the application, and interpretation, of traditional concepts such as autonomy, community and justice. Long-standing challenges – exacerbated notably by the Covid-19 pandemic – concerning resource allocation, community imperatives and individual interests are all in

5 C Newdick, 'Health equality, social justice and the poverty of autonomy' (2017) Health Economics, Policy and Law 1–23.

6 C Di Constanzo, 'Healthcare resource and priority-setting – a European Challenge' (2020) 27 European Journal of Health Law 93–114.

7 A B Gilmore et al, 'Defining and conceptualising the commercial determinants of health' (2023) 401 The Lancet 1194–1213.

8 See, for example, the World Health Organisation's preparation for a Global Report on the commercial determinants of health.

9 Whilst the Health and Social Care service in Northern Ireland is not technically part of the NHS due to its combined mandate of health and social care, it subscribes to the same founding principles: *Re Eileen Wilson and May Kitchen* [2023] NIKB 2, para 1.

need of a novel approach. At a one-day symposium held at the University of Reading, the contributors came together to celebrate Newdick's extensive contribution and to offer forward-looking critiques to some of the questions that Newdick has identified over the years. Responses to some of these issues range from judicial activism in reviewing the processes in resource allocation decisions, to public enquiries, or the introduction of criminal sanctions. The articles in this issue thus draw inspiration from the ground-breaking work of Newdick and reveal the richness of ideas which continue to flourish at both academic and policy levels. The original articles written by contemporaries of Newdick offer critical analysis on the on-going challenges that face both individuals and the National Health Service (NHS) and the reactive responses of government to help to address some of them. Indeed, as both Newdick[10] and Coggon identified some years ago, the questions raised by public health are inimically political.[11]

Through the articles, an argument emerges to support a new way of thinking about the regulation and provision of healthcare, and it becomes clear both that the focus on individual autonomy has to give way to a more communitarian approach and that traditional notions of society and solidarity must necessarily be revised within the context of economic, indeed market, forces.[12] One of the most complex issues is to identify how the inherent tensions between a universal healthcare system, on the one hand, and individual entitlement to access that system, on the other, can be resolved. At the heart of Aneurin Bevan's NHS was the notion of a healthcare system available to all and free at the point of need.[13] Newdick affirms this in his work, and the inevitable impossibility of agreeing on any hierarchy between these principles means that we need to turn to the *process* of the allocation of finite resources to help to find a solution – that is, who decides and how?[14] James Hart, Sapfo Lignou and Mark Sheehan engage with

10 C Newdick, 'Healthcare rights and NHS rationing: turning theory into practice' (2014) 32 Revista Portuguesa de Saúde Pública 151–157.

11 J Coggon, *What Makes Health Public? A Critical Evaluation of Moral, Legal and Political Claims in Public Health* (Cambridge University Press 2012).

12 Notwithstanding the fact that Bevan's vision has been characterised as 'a zone of non-commodified human relations': J Harrington, 'Visions of utopia: markets, medicine and the National Health Service' (2009) 29 Legal Studies 376–399.

13 See, for example, *The New NHS: Modern, Dependable* (Department of Health/HMSO Cm 3807 1997). Notwithstanding the challenges facing the NHS identified in the Darzi Report, the principle of a publicly funded system of healthcare, free at the point of use and based on need, is held to be absolute: Lord Darzi of Denham, *Independent Investigation of the National Health Service in England* (September 2024) (the Darzi Report) 131.

14 N Daniels and J Sabin, *Setting Limits Fairly: Can We Learn to Share Medical Resources?* (Oxford University Press 2022).

the Ethical Framework,[15] proposed originally by Newdick, to show how consistency and predictability in the decision-making process of allocating treatment offers the best chance of all patients having a 'fair opportunity at the best health that can be provided'.[16] These authors drill down into this process and offer a next steps approach to the Ethical Framework when considering how individual funding requests might be more fairly dealt with. Instead of requiring the patient to be an exception to other patients, they suggest that the patient is exceptional compared to the justification for the policy in the first place. Consequently, both the communitarian aspect of healthcare and the individual entitlement to healthcare are both better respected, compatible with the notion of 'social citizenship'.[17]

Building upon the limits associated with a focus on clinical exceptionality, and underscoring the fluidity[18] of this category, Rachel Horton explores the question of exceptionality from a complementary perspective – that of the potential discriminatory application of rationing policies in the light of protected personal characteristics.[19] She suggests that decisions must inevitably go beyond the simply clinical imperatives and that we need a transparent process for this to happen. If a robust process is to be at the heart of the provision of a fair healthcare system, Keith Syrett's insightful analysis into the 'priority-setting matrix', suggested previously by Newdick,[20] shows how challenging resource allocation requires an enhanced judicial review approach. Syrett has previously identified how courts in the different jurisdictions of the UK diverge in their willingness to adopt what Newdick has termed a 'hard look'[21] procedural scrutiny, and he argues that courts play an important role both for patients to seek redress and, arguably, to shine a light on the process to aid public understanding of the immensely difficult balancing act required in allocating finite healthcare funds.[22] In this issue, Syrett justifies

15 Thames Valley Priorities Committee, Ethical Framework.

16 J Hart, S Lignou and M Sheehan, 'Exceptionality in the context of individual funding requests' (this issue).

17 C Newdick, 'The European Court of Justice, transnational health care, and social citizenship – accidental death of a concept?' (2009) 26 Wisconsin International Law Journal 845–868.

18 D Hughes and S Doheny, 'Constructing "exceptionality": a neglected aspect of NHS rationing' (2019) 41(8) Sociology of Health and Illness 1600–1617.

19 R Horton, 'Equality, discrimination and exceptionality in access to healthcare' (this issue).

20 C Newdick, 'Can judges ration with compassion? A priority-setting rights matrix' (2018) 20 Health and Human Rights Journal 107–120.

21 Newdick (n 1 above) 100–107.

22 K Syrett, 'Why are we waiting? Judicial scrutiny of delays in access to healthcare in Northern Ireland' (2024) 75 (2) Northern Ireland Legal Quarterly 420–432.

singling out healthcare as worthy of special consideration in part due to the competing tensions (also identified in a number of other articles) between the communitarian aspirations of a national health service and the individual subjective rights which are engaged.[23]

The question of individual responsibility is one which is clearly becoming more visible in discourse on the provision of, and access to, healthcare. We might suggest that the inevitable corollary to recognising individual rights (as recognised by Hart et al, as well as by Horton) must be the acceptance of responsibility by individuals for their choices which have detrimental (and costly) effects on their own health. Patients have obligations too.[24] To what extent does justice require that a financially strapped health service should not have to fund an individual's irresponsible lifestyle choice? Newdick has identified what he termed the 'poverty of autonomy',[25] but Coggon further suggests that traditional concepts such as patient autonomy are misplaced in the context of macro-level healthcare implications.[26] Consequently, taking the patient's perspective as the starting point fails to get to the heart of the problem. In the same vein, as Coggon identifies, while individual responsibility may have a place at the table, it is necessary to look at the broader social context, as well as considering the significant commercial interests and pressures at play.

Commercial interests of a different kind are also at stake when we consider the phenomenon of the outsourcing of publicly funded healthcare to the private sector. Veitch articulates competing demands and further recognises how traditional notions of community and solidarity are brought into question by the necessary market nature of relationships created through schemes such as the private finance initiative.[27] Once again, the Covid-19 pandemic brought into sharp relief the tensions inherent in a constrained publicly funded national health service, forced to purchase equipment from private providers.[28] The final article in this issue brings together the questions of responsibility and commercial interests in the context of the use of artificial intelligence (AI) in healthcare. Just as recognition of

23 K Syrett, 'Into the matrix and beyond: seeking an understanding of problem priority-setting cases in the English courts' (this issue).

24 M Brazier, 'Do no harm – do patients have obligations too?' (2006) 65(2) Cambridge Law Journal 397–422.

25 C Newdick, 'Health equality, social justice and the poverty of autonomy' (2017) Health Economics, Policy and Law 1–23.

26 J Coggon, 'The boundaries and goals of legal scholarship within health of the public research' (this issue).

27 K Veitch, 'Contract, social relations and the outsourcing of publicly funded healthcare' (this issue).

28 'PPE procurement in the early pandemic' (Department of Health and Social Care 2021).

individual responsibility in healthcare is growing (as explored by both Newdick and Coggon), so too is the recognition that AI has a place in the provision of healthcare. Yet who may be identified as responsible for the consequences of AI remains an open question which James Devenney and Geraint Howells explore.[29] It is apt that this final article invokes the early work of Newdick on product liability regimes as it clearly shows the solution-based approach that has pervaded all of Newdick's work over the years. Just as Newdick faced the difficulty of reconciling Bevan's vision of health solidarity with increasing individual claims,[30] Devenney and Howells grapple with balancing the potentially disruptive forces of AI with the needs of citizens to access the latest, most effective healthcare as safely as possible. Ultimately, as other presentations during the symposium also identified, a culture of transparency and readily identifiable responsibility and liability are prerequisites for a well-functioning healthcare system that can meet the opportunities and the challenges of the twenty-first century.

The two book reviews in this issue complement the themes raised in the symposium, namely individual rights, justice, private commercial interests, technological advances and the common good. Shirin Boroomand in her review of *Justice in Global Health*[31] commends the book as offering a new perspective on practical challenges for global health justice. Just as Newdick explored through his work, Boroomand highlights how the book engages with the disparities between states, the pressures that commercial entities may bear and the inequalities in technological advances which require considerations of the different perspectives involved. Başak Bak's review of *Protecting Genetic Privacy in Biobanking through Data Protection Law*[32] also reveals how contemporary scholarship in this field engages with what Newdick essentially put on the map: how can we best achieve the necessary balancing between individual rights and legitimate communitarian goals? Bak's review also recognises that health knows no borders and that more can be done on an international level.

Taken as a whole, this collection of essays and book reviews pays tribute to the intellectual contributions of Newdick over many decades. During the one-day symposium at the University of Reading

29 J Devenney and G Howells and, 'Developing product liability networks for AI systems in the medical context' (this issue).

30 C Newdick, 'Citizenship, 'Free movement and health care: cementing individual rights by corroding social solidarity' (2006) 43 Common Market Law Review 1645–1668.

31 Shirin Boroomand, book review (this issue) of Himani Bhakuni and Lucas Miotto (eds), *Justice in Global Health: New Perspectives and Current Issues*.

32 Başak Bak, book review (this issue) of D Hallinan, *Protecting Genetic Privacy in Biobanking through Data Protection Law*.

to mark Chris Newdick's retirement, many colleagues, including the contributors here, bore testimony to the positive impact that he had had on them, both professional and personal. This special issue is offered as a reflection of Chris's dedication to informing, educating and inspiring others to consider healthcare law and policy in a way that promotes individual and societal flourishing: we hope that the articles collected here will further contribute to this end, in the UK and further afield.

Northern Ireland
Legal Quarterly
Vol. 76 No. 1 (2025) 8–25
Articles DOI: 10.53386/nilq.v76i1.1135

Exceptionality in the context of individual funding requests

James Hart
Sapfo Lignou
Mark Sheehan
Ethox Centre, University of Oxford
Correspondence email: james.hart@ethox.ox.ac.uk.

ABSTRACT

The National Health Service operates under significant resource constraints, both financially and in terms of staffing, leading to challenges in providing comprehensive healthcare for all. This poses a problem for commissioners: how do we prioritise treatment allocation? Chris Newdick's influential work in ethics and law has shaped discourse in this area for over three decades. However, we critique a specific aspect of Newdick's work concerning individual funding requests (IFRs) within the healthcare resource allocation system.

The allocation problem involves balancing population-wide healthcare needs with the ethical imperative to treat individuals. Decision-making frameworks like the 'Accountability for Reasonableness' (A4R) framework aim to address this by fostering fair processes. In the United Kingdom, local priority forums, guided by ethical frameworks, play a crucial role in resource allocation decisions. While these processes strive to be fair, they are not flawless. These processes cannot consider every potential patient perspective, circumstance or reason for needing treatment. To address this, A4R frameworks include mechanisms for revision and appeals. IFRs form an important part of this picture by providing a recourse for patients whose cases may not have been adequately considered because they are in some sense unusual or 'exceptional'.

However, current processes often rely on a problematic interpretation of 'exceptionality' which fails to align with A4R principles. This interpretation sometimes excludes those who ought to be included, and includes those who ought to be excluded. We argue for a revised understanding of exceptionality to ensure fairness and effectiveness in resource allocation processes informed by Newdick's work.

Keywords: individual funding requests; IFR; exceptionality; significant clinical benefit; resource allocation; accountability for reasonableness.

INTRODUCTION – THE PROBLEM OF ALLOCATION

The NHS has persistently been operating in circumstances of limited resources, both financially and with regards to staffing. Unfortunately, this means the National Health Service (NHS) cannot treat everyone for every condition. This poses a big problem for commissioners: who should receive treatment and for which conditions? Chris Newdick's work both in academic and in policy contexts over the past 30 years has had a profound effect on how the NHS, policymakers and academics have thought about and dealt with this question. His book, *Who Should We Treat?*, tackled this question head on and has set the standard for academic work in ethics and law in this area since it was first published in 1995.[1] In what follows below, we take issue with one small part of the Newdick corpus of work, which deals with individual funding requests (IFRs) within the healthcare resource allocation system.

The problem of allocation is a nasty one. The NHS does not just face the challenge of providing comprehensive healthcare for the whole population within budgetary constraints, but it must also take seriously the particular needs of individual patients. Ethics and justice require that the NHS must be open to treating individuals, and it should sometimes actually treat them, even when this means a less effective distribution of resources at the population level.[2]

Of course, the NHS needs to weigh these various obligations to solve how it will allocate healthcare resources in any given timeframe. But inevitably it is impossible to find agreement on any solution to how we ought to allocate these resources and which obligations the NHS ought to meet. More fundamentally, we cannot even find agreement on the strength of various obligations and needs, nor on which principles govern how we ought to weigh such obligations. This disagreement occurs even among those who recognise that there is reasonable disagreement and are disposed to find a just and fair solution. How then do we solve problems where there is reasonable disagreement but where decisions need to be made?

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1 Chris Newdick, *Who Should We Treat?* (Clarendon Press 1995).

2 See Chris Newdick, 'Judicial review: low-priority treatment and exceptional case review' (2007) Medical Law Review 236–244, and Chris Newdick, 'Rebalancing the rationing debate: tackling the tensions between individual and community rights' in Eckhard Nagel and Michael Lauerer (eds), P*rioritization in Medicine: An International Discussion* (Springer 2016) 123–140.

In the context of reasonable disagreement, United Kingdom health law follows an 'Accountability for Reasonableness' (A4R) framework.[3] As Newdick has carefully articulated, the central insight of this approach is that, where we cannot agree on any solution or particular distribution of resources, the only way to make progress is to construct a process that treats the disagreement respectfully so that all those affected by the outcome can sign up to the decisions that the process generates.[4] That is, we should adopt a decision-making process that treats reasonable claims fairly and gives all patients a fair opportunity for the best healthcare that can be provided.

In the NHS, local and regional priorities forums/committees are an instantiation of this process. They make recommendations to commissioners about allocations and the recommendations typically become policy for that region. These forums have 'ethical frameworks' which include sets of relevant considerations that guide (but, importantly, do not determine) the decision-making process. Forums receive evidence appraisals, expert advice and, crucially, patient perspectives and consider the information provided in accordance with the ethical framework.[5] In the South Central region, the *Ethical Framework* was initially drafted by Newdick in 2004 and represents the gold standard, adopted and adapted across the NHS.

This process thus treats all those with claims to healthcare with respect. It listens to the concerns of patients, their carers and clinicians. It allows reasonable disagreement to be aired, promotes discussion of the various ethical considerations and gives space for different values to be expressed and accounted for. The ensuing policy, whilst not to the satisfaction of everybody, ought to be acceptable to all as the conclusion of a fair procedure.

Nonetheless, these processes are not flawless. Relevant considerations which ought to have been taken into account can be missed, and reasonable perspectives accidentally ignored. In such cases, the persons whose circumstances or perspectives have been left out of the process have not been treated fairly and have grounds for not assenting to the policy decision that affects them.

For this reason, A4R frameworks include versions of the following Revision and Appeals Condition:

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3 See Norman Daniels and James E Sabin, *Setting Limits Fairly: Can We Learn to Share Medical Resources?* (Oxford University Press 2002) and Norman Daniels, Mary B Saltonstall and James E Sabin, 'Accountability for reasonableness: an update' (2008) British Medical Journal 337.

4 Chris Newdick, 'Can judges ration with compassion? A priority-setting rights matrix' (2018) Health and Human Rights Journal 107–120.

5 Thames Valley Priorities Committee, *Terms of Reference* (2021).

> **Revision and Appeals Condition:** There must be mechanisms for challenge and dispute resolution regarding limit-setting decisions, and, more broadly, opportunities for revision and improvement of policies in the light of new evidence or arguments.[6]

This condition achieves two goals. First, it allows decision processes to improve and to correct prior errors in light of new evidence. Secondly, it gives voice to those whose circumstances or perspectives were excluded from the initial decision process and who thus have not been treated fairly by the otherwise fair process.

In practice, this condition is partly captured in the local priorities committee's ethical framework via exceptionality conditions. For instance, the Thames Valley Priorities Committee (TVPC) used to include the following:

> There will be no blanket bans on treatments since there may be cases in which a patient has special circumstances which present an exceptional need for treatment. Individual cases are considered by each respective CCG [clinical commissioning group]. Each case will be considered on its own merits in light of the clinical evidence. CCGs have procedures in place to consider such exceptional cases through their Individual Funding Request Process.[7]

Individuals thus have access to recourse against the CCG (and the priorities committee) if they have not been given the proper consideration that they are owed. To do so patients, alongside their clinicians, submit an IFR, outlining why their case is exceptional.[8] This IFR is then screened to ensure it meets the relevant initial exceptionality criteria and has a reasonable chance of success. If it passes the screening, it will then be sent to an IFR panel to decide whether the funding request is successful. The IFR process thus provides fair consideration for the individuals who were originally excluded from the decision-making process.

For instance, the NHS does not routinely fund breast reduction surgery.[9] Such surgery is considered cosmetic and thus is not routinely commissioned: it is one of a whole set of procedures that are understood, broadly, to be not medically necessary (or 'medically indicated') and so are low priority. However, there are clearly cases where patients might claim exceptionality. For example, when a patient develops severe and chronic back pain as a result of excessive breast size. Such patients can currently apply via the IFR process for surgery on this basis.

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6 Daniels and Sabin (2002) 45 (n 3 above)

7 Thames Valley Priorities Committee, *Ethical Framework* (2017) 5.

8 NHS England, *Commissioning Policy: Individual Funding Requests* (2023).

9 Thames Valley Priorities Committee, *Commissioning Policy Statement No TVPC 16: Aesthetic Treatments for Adults and Children* (2015).

The IFR process is only intended to decide in a particular individual's case and does not change the policy itself. However, during the screening process (or at the request of the IFR panel), if the individual's circumstances indicate that there is a wider group of patients for whom these considerations of exceptionality apply, then changes to the policy might be necessary and these would need to be considered either via reconsideration by the priorities forum or through the alternative Service Development process.[10] The Service Development process develops new (or makes amendments to) routine commissioning policies by looking at the clinical evidence for new services or clinical pathways, their financial and organisational impact, and their value for money.

Importantly, the IFR and Service Development processes together capture the Revision and Appeals Condition of A4R. Both processes allow individuals with reasonable claims to appeal decisions, and they ensure that those who might have been excluded from the fair process have a means to be included. The Service Development process also means that, where necessary, policies can be revised and improved.

Of course, the entire process turns on how we understand exceptionality and, specifically, how we determine when an individual's case is exceptional. In our view, this issue has not been given sufficient attention and has led to, what we take to be, a weakness in local priorities forums' ethical frameworks and the current IFR processes they oversee.[11]

On the face of it, we can separate out two different interpretations of exceptionality in this context:

1. *Particular patients themselves are taken to be exceptional cases.* On this interpretation, patients are compared with other patients in order to determine their status: the key reference point is the population of patients (with this condition/requiring this

10 NHS England (n 8 above) 10.

11 There has been some consideration of these issues in the academic literature: see Amy Ford, 'The concept of exceptionality: a legal farce?' (2012) Medical Law Review 1–33 and 'Accountability for reasonableness: the relevance, or not, of exceptionality in resource allocation' (2015) Medicine, Healthcare and Philosophy 217–227. Ford's criticisms largely focus on the lack of conceptual, ethical and legal clarity around the concept of exceptionality, and she, largely, argues against funding on the basis of exceptionality. Whilst we agree with many of her criticisms, we believe exceptionality still plays an important role in just allocation. In our opinion, many of her criticisms are predicated on the first of the two interpretations of exceptionality that we outline and argue against in this article. We hope our article also provides some more needed conceptual and ethical clarity on how the concept should be used, though there will be legal and practical issues that will still need addressing.

treatment). The patient will be taken to be exceptional if, on some measure, they stand out markedly from all other patients. The most obvious scale of comparison here will be the benefit that they stand to gain from the treatment.

2. *Particular patients represent, or present as, exceptions to the rule or policy*. On this second interpretation, the key reference point is the rule or policy. What matters here are the considerations that lie behind the policy. The patient's circumstances are compared to the circumstances considered when setting the policy. In particular, this may involve considering the kind of benefit to the patient or the patient's reasons for needing or valuing the benefit.

In the following we consider both of these interpretations. We will argue in favour of the second interpretation and against the first. We will show that the first interpretation is problematic because it includes in the process those who ought to be excluded and excludes some of those who ought to be included. It also does not match the A4R reasoning and justification that Newdick has helped develop and implement.

Importantly, Newdick has been instrumental in developing the current IFR process. In particular, he was central in the writing of both the Welsh individual patient funding request (IPFR) policy and the TVPC *Ethical Framework*.[12] Unfortunately, both of these policies are based on the first interpretation of exceptionality. As such, we suggest that current, Newdick-informed processes are not fair and not fit for purpose. In the final section, we will outline how the ethical frameworks and IFR processes could be amended to capture exceptionality in line with the second interpretation.

EXCEPTIONAL PATIENTS AND SIGNIFICANT CLINICAL BENEFIT

Let us start then with the first interpretation. On this interpretation patients are exceptional if they can sufficiently distinguish themselves from the reference population, namely others with the same or similar conditions. In practice, this has been further limited only to differences in clinical benefit, where a patient is deemed exceptional only if they can gain significantly more clinical benefit from a given treatment than others in similar positions. For instance, a patient whose breast size is causing chronic pain issues that have not been resolved with other treatments, can demonstrate that she will gain significantly more clinical benefit than other patients requesting breast reduction surgery.

12 NHS Wales, *NHS Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR)* (2017); Thames Valley Priorities Committee, *Ethical Framework* (2021).

She would thus count as exceptional. We can see this approach in IFR policy. The Welsh IPFR's exceptionality condition reads as:

> It is important to note that the NHS in Wales does not operate a blanket ban for any element of NHS healthcare. We will consider each IPFR on its individual merits and in accordance with the arrangements set out in this policy. We will determine if the patient should receive funding based on the *significant clinical benefit* expected from the treatment and whether the cost of the treatment is in balance with the expected clinical benefits.[13]

Clinicians thus need to submit an IPFR application describing:

> i. why the patient is likely to gain a significant clinical benefit from the proposed intervention; and
>
> ii. demonstrating that the value for money of the intervention for that particular patient is likely to be reasonable[14]

Similarly, the TVPC has the following exceptionality condition:

> There will be no blanket bans on treatments since there may be cases in which the clinician providing the care can demonstrate why an individual patient is likely to obtain *significant clinical benefit* at reasonable cost from an intervention which is not normally funded.[15]

Plus these two clauses for determining if an intervention meets the exceptionality condition:

> (a) the clinician can demonstrate persuasive evidence why the patient's clinical circumstances are significantly different to those of the population of patients for whom the recommendation has been made not to use the intervention, **and**
>
> (b) the clinician can demonstrate why the patient is likely to gain significantly more clinical benefit from the intervention than would normally be expected from patients for whom the recommendation is not to fund it[16]

In practice this means that those who can demonstrate that they have more capacity to benefit from the treatment are eligible for funding whilst those who do not have such capacity (or cannot show that they have such capacity) are ineligible.

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13 Ibid 5 (our italics).
14 Ibid.
15 TVPC (n 12 above) 5 (our italics).
16 Ibid.

Criticism 1 – the scope is too wide

Firstly, this approach includes patients in the process who ought not to be included. Allowing individual cases to be evaluated via the IFR process will sometimes allow the re-litigation of issues that have already been considered in the development of the policy. Of course, re-litigating issues is an inefficient use of an IFR panel's time, but more importantly, it is unfair.

If the policy has been developed with the knowledge that some patients might receive significantly more clinical benefit relative to others (or stand out markedly from all other patients for some other reason), and it has nevertheless been decided that the treatment will not be funded for those patients, then they have already been included in the process. This means that these individuals have already had their circumstances considered, and their perspectives listened to, in the policy-setting decision. Whilst there might still be reasonable disagreement about whether the decision was the right one, the individuals' circumstances have been included in the process and thus not treated unfairly.

For instance, consider again our breast reduction surgery case. Suppose that the initial policy-setting process considered breast reduction surgery not just for aesthetic reasons, but also for chronic pain-related reasons. Suppose it, nevertheless, came to the same conclusion that surgery should not be routinely funded, and made no exception for pain-related reasons. In this case, on the significant clinical benefit account, the small number of patients with chronic pain would still be eligible for consideration by IFR. This is because they stand out significantly from the majority of the population for whom the recommendation is not to fund, and they are capable of gaining significantly more benefit than that population. But given that the initial policy discussion included their circumstances, this would simply be re-litigating these cases.

To re-litigate these individual cases then, is to give the individuals a second opportunity to settle the reasonable disagreement in their favour. But this is clearly unfair. The whole point of an A4R framework is that a fair procedure is agreed at the outset such that all claims are considered, and the resulting decision can be agreed to in advance and assented to by all involved. To use a crude analogy, it is like permitting a rematch for a team already knocked out of a competition, or moving from best of three to best of five after someone has already lost. If we allow certain individuals a second opportunity, whilst denying that opportunity to others, we undermine the credibility of the entire process. Those who do not get a second opportunity are treated unfairly. Of course, we are not suggesting that those who unfairly benefit from these processes are purposefully cheating the system, or

are acting unfairly themselves. They are individuals, often in desperate circumstances, trying to navigate a complex healthcare system, and deserve compassion. But such compassion does not justify unfair treatment, when there are others just as deserving of compassion who will miss out.

As is so often the case, this unfairness does also look likely to intersect with, and be magnified by, socio-economic disparities: those from disadvantaged groups are much less likely to receive a second opportunity to advance their case. There is some, admittedly anecdotal suggestion, that access to the IFR process is not distributed equally across regions and demographic contexts: those patients and clinicians who are better educated and better placed to access more specialised healthcare are similarly better placed and more likely to access the IFR process. Whilst disparities are neither unique to IFR nor to this particular definition of exceptionality, this definition of exceptionality does have the potential to worsen their effects. Disparities affecting people's ability to access and navigate a fair process will apply to all approaches (though they should, of course, be mitigated where possible), but this approach to exceptionality also introduces disparities where some can disproportionately benefit from an *unfair* second opportunity to have their case considered.

Criticism 2 – the scope is too narrow

Perhaps more problematically, this approach also excludes many whom it ought to include. Firstly, the current conditions require clinicians to demonstrate the potential for significant clinical benefit. This seems reasonable, until we recognise that this includes only those who can provide evidence of the potential to benefit. Naturally, this means many for whom gathering evidence is difficult, or for whom there is a lack of evidence, are excluded from the process.

Of course, those who are most exceptional are likely to be those who are least able to provide evidence in support of their claims. For instance, patients with rare diseases, unusual presentations or complex comorbidities present some of the most exceptional cases and are least likely to have been considered in the policy-setting process. However, the nature of these cases means there is less research and evidence available on the effects of any particular intervention on those individuals. If evidence was relatively available, then it ought to be (and is likely to have been) accounted for in the initial policy decision. Perversely then, on the 'significant benefit' criteria, those who are most exceptional are those most likely to be excluded by the exceptionality condition! Moreover, this is likely to adversely affect those from minority and disadvantaged groups disproportionately more than

those from majority groups because they are under-represented in medical research.[17]

Furthermore, in the way this has been developed in practice, it also puts the burden of proof on the wrong people. It should not be up to the clinician, or the patient, to demonstrate that there is potential for significant benefit. This role ought to be performed by the experts assigned to collect and review the evidence (in the TVPC's case this is a specialised Commissioning Support Unit) that is then presented to the IFR panel. Clinicians are not well placed to gather and assess this evidence, and we might think it is an inefficient use of their time. It also introduces too much arbitrary luck into the process. Certain clinicians will be much better at demonstrating a patient's need or ability to benefit than others, and this will lead to disparities in access.

Secondly, this approach limits the kinds of considerations that can make an individual's circumstances exceptional to the clinical realm. Doing so excludes many potentially relevant considerations from the process before deliberation even occurs. It is important to remember that the scope of reasonable disagreement that the priorities forums intend to address is supposed to allow space for disagreement about fundamental values, to give voice to patient perspectives and consider a wide variety of ethical considerations. By limiting the initial scope to clinical benefit, we ignore these vital elements of the process.

For instance, a drug may not normally be funded because there is a cheaper and more effective alternative. However, suppose the alternative uses compounds derived from blood. A Jehovah's Witness could not demonstrate significantly greater clinical benefit than others with her same condition, and so she would be excluded from the IFR process. However, it seems as if she has a good claim to being an exceptional case. The process has ignored her important core beliefs and fundamental values, and so she has a strong claim to having been treated unfairly and not having had a chance to express her disagreement. By defining exceptionality as significant clinical benefit, we have missed the inherent value laden-ness of these decisions.

Furthermore, there are cases where a patient may gain significant benefit from treatment by allowing them to perform 'activities of daily living', though these might not register as clinical benefits.[18] In one case a grandmother of a particular ethnicity who lived in a close-knit ethnic community was unable to leave her house due to

17 Andrew Smart and Eric Harrison, 'The under-representation of minority ethnic groups in UK medical research' (2017) Ethnicity and Health 65-82.

18 Thames Valley Priorities Committee, *Commissioning Policy Statement Policy No TVPC 101: Application of the Use of 'Activities of Daily Living' to Individual Funding Requests* (2020).

the stigma caused by her hirsutism. This also prevented her from looking after her grandchildren, picking them up from school and such, and performing other basic activities. Whilst depilatories are not particularly expensive, the TVPC (and its constituent CCGs) did not routinely fund cosmetic surgery. Thus, her case might also have been excluded from consideration as the way in which she would benefit is not clinical.

These cases are good examples of how the narrow scope can get things wrong. But it is important to note here that these are not just unfair consequences caused by an ineffective process. The process itself is unfair if it excludes these considerations. When the initial policy decision was made, it would have been made in light of these wider relevant features, not just the clinical benefits.[19] Patient perspectives, a variety of values and the wider ways patients could benefit would all have been considered in the development of the policy. Thus, there was scope for reasonable disagreement on these features. If those whose cases were initially excluded from that deliberation do not have their cases judged on the same range of features, then they have not been treated equally to those who were.

More broadly, this entire approach of treating certain individuals as exceptional seems to go against the fundamental A4R justification. It treats some people as exceptional, as if the rules do not apply to them. If we have a fair process that we use to settle disagreement, but then we allow some people to have their cases determined outside of that process, this undermines the whole justification and process for settling the reasonable disagreement. How are patients supposed to sign up to the conclusion of such a process in such circumstances? They would have good claims to withholding their assent.

Understanding exceptionality in this way then is clearly flawed. No patient should themselves be considered exceptional. The rules and policies ought to apply to everyone equally, and no one should be considered above or outside those rules. This is the only way that we can treat everyone equally and ensure all reasonable individuals can sign up to the ultimate decision that commissioners have to make.

However, if this is the case, how ought we to understand exceptionality, and how can the Revision and Appeals condition of A4R be met?

19 Of course, if these features were not taken into consideration, then the policy-making process was itself deficient.

EXCEPTIONAL CIRCUMSTANCES

We need to develop an understanding of exceptionality then that does not violate the fair procedure with which we make decisions. Such a definition ought to exclude those who ought to be excluded and include those who ought to be included. We suggest that exceptionality should thus be understood not relative to other patients, but relative to the considerations that determined the rule. Recall the second interpretation of exceptionality:

2. *Particular patients represent, or present as, exceptions to the rule or policy*. On this second interpretation, the key reference point is the rule or policy. What matters here are the considerations that lie behind the policy. The patient's circumstances are compared to the circumstances considered when setting the policy. In particular, this may involve considering the kind of benefit to the patient or the patient's reasons for needing or valuing the benefit.

For instance, in the breast reduction surgery case, a patient who has very severe pain issues would count as having exceptional circumstances if the policy was only developed with aesthetic considerations in mind. The kind of benefit she would receive, and her reasons for needing the surgery, differ from the circumstances that were considered when determining the policy. The policy was determined in light of aesthetic considerations, but this patient's reasons for needing care are pain-related. Her circumstance thus represents an exception to the rule.[20]

Fundamentally, this approach better matches the A4R framework and allows us to settle reasonable disagreement in a way that is procedurally fair to all participants. The conclusion of the process can thus receive broad assent. Instead of treating some people as deserving to be treated outside of the process, we treat all people as deserving to be included in the process. In this way it does not undercut the ethical legitimacy of the initial commissioning decisions but reinforces it.

We thus suggest amending (in italics and underlined) the Welsh IPFR policy to something like the following, to better capture this second approach to understanding exceptionality:

> It is important to note that the NHS in Wales does not operate a blanket ban for any element of NHS healthcare. We will consider each IPFR on its individual merits and in accordance with the arrangements set out in this policy. We will determine if the patient should receive funding based on *(a) whether the patient has special circumstances which were not considered when the policy not to fund treatment was decided, (b) the patient's reason for needing treatment, and (c)* whether the cost of the treatment is in balance with the expected clinical benefits.

20 If there is a sufficiently large cohort of individuals whom this affects, as there is for breast-reduction surgery, then there should also be an update in the policy.

And simplifying the evidence clinicians need to submit as part of an IPFR application to:

i. *why a patient's reasons for needing the intervention differ significantly from the reasons considered when setting the policy*; and

ii. demonstrating that the value for money of the intervention for that particular patient *has the potential to be* reasonable.

In the TVPC context, we suggest reverting to the older definition of exceptionality with a few tweaks and updates:

> There will be no blanket bans on treatments since there may be cases in which a patient has special circumstances which *were not considered when the policy not to fund treatment was decided*. Individual cases are considered by each respective ICB [integrated care board]. Each case will be considered on its own merits in light of *the patient's reason for treatment and* the clinical evidence. ICBs have procedures in place to consider such ~~exceptional cases~~ through their Individual Funding Request Process.

And that the clauses for determining whether a patient's circumstances count as exceptional should be updated in the following way:

(a) the clinician can demonstrate ~~persuasive evidence~~ why the patient's clinical circumstances are significantly different to the general population of patients for whom the recommendation is not to use the intervention, **and**

(b) the clinician can demonstrate why the *patient's reasons for needing the intervention differ significantly from the reasons for needing the intervention given by* patients for whom the recommendation is not to fund it[21]

Of course, these amendments to both the Welsh and TVPC policies are only sufficient for determining whether a case is eligible for review. The panel will have to adjudicate on whether the individual's case is strong enough, and the cost reasonable enough, to be worth funding. Nevertheless, these eligibility criteria may reduce the burden on clinicians (in doing so they may also reduce disparities in applications) and mean the IFR experts are the ones who will gather evidence on effectiveness. Most importantly, these changes would mean that the process is more consistent with A4R and so fairer: those who were excluded from the process can now have their claims included with fewer barriers to entry.

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21 It might be necessary to include guidance about what kinds of circumstances, considerations and reasons might count as exceptional. This may look like a list of potential sources of reasons and could include example cases to help guide clinicians and relevant support staff.

Correct scope

This approach to exceptionality gets the scope right in all the cases that the prior definition got wrong. First, it excludes all those who ought to be excluded: those whose circumstances have already been considered in setting the policy do not have a second opportunity to have their circumstances considered.

Now, it is important to say here that this does not mean there is no process for appealing the decision not to fund treatment. The appeals and revision condition in A4R requires that all policy decisions can be appealed and updated if necessary. There need to be options for holding decision-makers to account for their decisions, and there needs to be a mechanism for adjusting policy in light of new evidence, or changes in finance, opportunity cost, and even social values, as well as to correct for errors made in prior decisions.

What is importantly different, however, is that exceptionality and the IFR process would not be the way that individuals can challenge or appeal such decisions (if their circumstances were considered in the original policy-setting decision). Such individuals would only have access to the same appeals process as others who might benefit from a treatment that is not funded, but who could not demonstrate significantly greater clinical benefit than average. Any successful appeal would then change the routine commissioning policies. In this way, there is no two-tier system of appeals, and, if an appeal is successful because the policy is lacking in some way, then the update will apply to everyone, not just that individual.[22]

Our interpretation of exceptionality also includes everyone who ought to be included and was excluded by the significant clinical benefit approach. Firstly, it includes individuals whose cases are perhaps so unusual that there is a lack of accessible evidence to demonstrate their exact potential to benefit. Of course, this is not to say that decisions ought to be made without regard to clinical evidence or without good reason to think that the patient might benefit. Only that such factors should not initially exclude such cases from consideration. Relevant experts via the IFR screening process ought to be responsible for

22 There are, of course, further questions that fall outside of the scope of this article about what these appeals processes look like, and how they should relate to IFR. Both successful and unsuccessful IFR appeals may tell us about how policies should be improved, and more attention should also be paid to service development processes and reviewing current policies. It will be particularly important that there is a level of consistency between these different processes and that individuals do not fall through the gaps between different processes or are left in policy development limbo. See Warwick Heale and Keith Syrett, 'Challenging NHS England's individual funding request policy' (2018) British Journal of Healthcare Management 218–221.

identifying evidence and deciding whether the case has a reasonable chance of success, rather than leaving it to clinicians to provide such evidence. Such cases would thus still be included in the process, even if they were ultimately unsuccessful.

Secondly, it includes all those whose circumstances (or reasons for needing treating) were not considered in the initial policy-setting process. This includes those whose clinical circumstances are different, but importantly also those whose fundamental values and beliefs were not included in the initial process (ie the Jehovah's Witness case) and those whose social circumstances mean they stand to benefit by allowing them to perform more basic activities of daily living (ie the hirsutism case). Again, even if there are good reasons not to fund the treatment in these cases, simply including them in the process respects the individuals by giving them a fair chance.

Nevertheless, we might still worry that our approach sometimes excludes some people from consideration when they ought to be included. There may be cases where an individual has the potential for significant clinical benefit, and their case is so unusual that it would be inappropriate for the Service Development process. In which case it seems appropriate for this individual to go through the IFR process. We might think that by stepping away from the significant clinical benefit approach, this person's case would not be eligible for review.

However, whilst we have presented our approach as an alternative to significant clinical benefit, that is not to say significant clinical benefit could not count (in some limited circumstances and in conjunction with other features) as exceptional circumstances. A patient's potential for significant clinical benefit can count as exceptional when that larger amount of clinical benefit was not (or indeed could not have been) considered in the original policy-setting decision. In that case, the individual was initially excluded from the process. They thus need to have their case included. But note here that the justifying reason to include their case is because they were initially excluded, not because they could gain significant clinical benefit. The significant clinical benefit is simply the contingent property which generates that justifying reason.

For instance, suppose there is a drug that helps tackle anxiety and depression. The drug is expensive, and its effects are only very minor, so the drug is not funded. Now suppose that there is strong evidence that the effects on one individual will be very strong. It is not known why the effects on this individual are so much stronger than for others, and

there seem to be no other exceptional circumstances to explain it.[23] In this case, whilst we cannot identify any other exceptional reasons, the individual's greater capacity to benefit will itself count as exceptional circumstances. The policy decision did not consider individuals who would gain such large benefits and so such individuals were excluded from the process and are eligible for IFR review.

In this way, the significantly greater scale of benefit to the patient becomes a difference in the kind of benefit to the patient. It is now a kind of benefit that was not previously considered in the decision-making. Of course, in most such cases there will also be some other reason as to why the individual would gain significantly more clinical benefit than others, and that reason is also likely to be exceptional to the cases the commissioning team will have considered. Either way, individuals in such cases would not be excluded from consideration, and thus the exceptional circumstances approach correctly includes everyone it ought to.

Exceptional circumstances in practice

Where exceptionality is determined as an exception to the rule, it becomes necessary for clinicians and others involved in the IFR process to understand the reasoning behind the rule. If they do not, then they will not be able to assess correctly whether an individual is an example of an exception to the rule. This does seem to pose a practical problem and might require much more understanding of the commissioning decisions than clinicians currently have.

There are a few ways to tackle this practical wrinkle. Firstly, it should be noted that, whilst this approach asks more of clinicians in understanding the reasons behind the commissioning decision, it asks less of them overall as they do not need to find persuasive evidence of significant clinical benefit. Secondly, steps can be taken when commissioning decisions are made to clearly express the types of cases considered and the reasons for denying funding. Not only will this simplify the process for clinicians, but it will also provide greater transparency in decision-making.

Third, broad guidance should be released to help clinicians identify the types of cases and considerations which typically fall outside the scope of the policy. Of course, there will still be a large scope of

23 Of course, without having a reason to explain why the effects would be particularly strong, it is unlikely that there would be evidence of the significant clinical benefit. But for the purpose of argument, we can set such considerations aside. Let us suppose that the individual has previously been on the drug (perhaps abroad or on a drug trial or for some other condition that it is approved for) such that there is evidence of its effect on the individual without identifiable reasons for why they receive much greater clinical benefit.

discretion for the committee to make decisions about whether a particular consideration or reason is sufficiently different from prior considerations or reasons to require evaluation. Just as there may be reasonable disagreement about whether a particular treatment ought to be funded, there is likely to be reasonable disagreement about whether someone's circumstances represent an exception to the rule.

This consequence, however, should not be seen as a downside. The significant clinical benefit approach does not allow this reasonable disagreement to be settled as part of the process, but instead predetermines under what conditions someone counts as exceptional: once again excluding certain features from fair consideration. Conversely, acknowledging and accommodating reasonable disagreement about what counts as exceptional allows our approach to be more responsive to the relevant features and perspectives that will come up when dealing with exceptional and unusual cases and to be fairer in doing so.

Lastly, there has been some concern that the language of exceptionality is confusing, for patients as well as providers.[24] Our own discussion further highlights that ambiguity. Patients whose applications are unsuccessful may wonder why they are not considered 'exceptional', and not unreasonably understand the judgement to mean that they are not as deserving of the intervention as others. It is partly for this reason that Newdick attempted to clarify the exceptionality concept as significant clinical benefit in the first place. In order not to return to such confusion, in practice it may be best to replace talk of exceptionality with talk of omission. A patient's circumstances are eligible for IFR review if those circumstances were omitted from the initial policy-setting procedure. This language captures the exceptional circumstances approach, whilst more clearly focusing on the rule, and the considerations behind the rule, such that it avoids the distress and confusion of exceptionality.

SUMMARY

To conclude, IFRs play a vital role in justifying allocations of healthcare resources. Not only do they allow the NHS to be sensitive to individual needs, but they also ensure all patients – no matter their circumstance, perspectives and values – are included in the resource allocation process. Such inclusion is crucial if the allocation process is to be fair and the outcome of the process to be acceptable to all.

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24 Andrew Blakeman et al, 'Independent Review of the Individual Patient Funding Request (IPFR) Process in Wales' (2017) Welsh Government 14–15.

However, whilst the purpose of IFRs is to play a role in a fair process, they are currently undermined by their focus on clinical outcomes rather than fair process. In some respects, they have become a second-chance saloon and a way to pass the buck on the difficult decisions made in policy-setting discussions. As we have shown, not only does this undermine the IFR process, but it undermines the justifiability of the initial policy-setting decision too.

Thus, the NHS ought to abandon IFRs understood in terms of significant clinical benefit and clinical outcomes. Instead, it ought to adopt an understanding of individual exceptions to the rule and/or omissions from fair process: exceptionality should not give us resources for treating people outside the normal process but should equip us to include those exceptions who have not been included in the process.

Northern Ireland
Legal Quarterly
Vol. 76 No. 1 (2025) 26–50
Articles DOI: 10.53386/nilq.v76i1.1146

Equality, discrimination and exceptionality in access to healthcare

Rachel Horton
University of Reading
Correspondence email: r.e.horton@reading.ac.uk.

ABSTRACT

Where healthcare commissioners decide, as an overall policy, that they will not generally fund a particular medical treatment or intervention (or will restrict its availability to those meeting certain criteria), individual patients denied under the policy can ask for an exception to be made. This is usually done by means of an individual funding request (IFR) whereby the patient, typically with the support of their medical team, can make a case for individual funding on the basis that there are significant and relevant differences between their circumstances and those of other patients who might need or want the treatment in question. The approach of healthcare commissioners to deciding on IFRs is normally to take into account clinical factors only – policies tend to make clear that they will not take into account 'social factors', including personal characteristics such as race, sex, age, religion, disability and sexual orientation, in deciding whether or not to make an exception – because of a desire to avoid discrimination and to treat patients fairly. This article explores the way equality law might bear on decisions to make exceptions to funding policies. It identifies, as far as is possible, the circumstances under which equality law will permit or will require the personal characteristics of patients to be taken into account in order to avoid discrimination and to treat patients fairly. It also highlights a number of challenges the equality law framework presents for commissioners in making decisions about how to allocate scarce resources.

Keywords: equality discrimination; health; healthcare; human rights.

INTRODUCTION

> [I]t is an unhappy but unavoidable feature of state funded healthcare that ... health authorities have to establish certain priorities in funding different treatments from their finite resources.[1]

So noted Auld LJ in *R v North West Lancashire*, a case concerning a decision by a health authority to not fund gender reassignment surgery. Following the most recent reorganisation of the National Health Service (NHS), this difficult task currently falls largely to integrated care boards (ICBs) alongside NHS England and a number of other authorities, often acting with reference to the guidance of the National Institute for Health and Care Excellence (NICE).[2] These commissioning bodies will make the policy decisions that determine, for example, whether or not to fund (and for whom) *in vitro* fertilisation (IVF), cosmetic surgery and new drugs for cancer or for dementia, for the relevant populations. In doing so, they are under a statutory obligation to break even in each financial year.[3]

Where healthcare commissioners decide, as a general policy, that they will not generally fund a particular medical treatment or intervention (or will restrict its availability to those meeting certain criteria), individual patients denied under the policy can ask for an exception to be made. This is usually done by means of an individual funding request (IFR) whereby the patient, typically with the support of their medical team, can make a case for individual funding on the basis that there are significant and relevant differences between their circumstances and those of other patients who might need or want the treatment in question. The openness of public decision-makers to making exceptions to a general policy is a central requirement of public law – decision-makers must not fetter their own discretion by applying policies rigidly and must be willing to consider whether to depart from the policy in an individual case.[4]

The approach of healthcare commissioners to deciding on IFRs is normally to take into account clinical factors only. The key question is whether the individual patient – clinically speaking – is likely to

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1 *R v North West Lancashire Health Authority ex parte A* [2000] 1WLR 977, para 991.

2 On 13 March 2025 the Government announced its intention to abolish NHS England and to bring its functions within the Department of Health and Social Care. In previous reorganisations of the NHS primary responsibility for commissioning lay with Primary Care Trusts (PCTs) or Clinical Commissioning Groups (CCGs). Much of the case law discussed in this article makes reference to these organisations.

3 National Health Service Act 2006, s 223GC.

4 *R (A) v Secretary of State for the Home Office* [2021] UKSC 37.

benefit significantly more from the treatment in question, or to suffer considerably more if denied, than other patients in their cohort.[5] This is often no easy task for a patient to demonstrate. According to NHS England:

> Very few patients have clinical circumstances which are genuinely exceptional. To justify funding for treatment for a patient which is not available to other patients, and is not part of the established care pathway, the IFR Panel needs to be satisfied that the clinician has demonstrated that this patient's individual clinical circumstances are clearly different to those of other patients, and that because of this difference, the general policies should not be applied. Simply put, the consideration is whether it is fair to fund this patient's treatment when the treatment is not available to others.[6]

IFR policies tend to make clear that they will not take into account 'social factors' in deciding whether or not to make an exception. Social factors include the role of the patient as an employee or parent or carer; whether or not the patient has a criminal conviction; and the responsibility of the patient for behaviours which have contributed to their need for treatment. They may also include personal characteristics such as sex, age, religion and others protected by the Equality Act 2010 (Equality Act), or by article 14 of the European Convention on Human Rights (ECHR), in part through concern that to do otherwise would amount to unfair and potentially unlawful discrimination.

This article explores the way equality law might bear on decisions to make exceptions to funding policies. It will aim to identify, as far as possible, the circumstances under which equality law will permit or require the personal characteristics of patients be taken into account in determining whether an exception should be made. It will also highlight a number of challenges the equality law framework presents for commissioners in making decisions about how to allocate resources. It is divided into two sections. The first section outlines the approaches taken to making exceptions in the context of IFRs, the reasons behind these and the approach the courts have taken to decisions to exclude social factors from consideration. The second section then briefly outlines the equality law framework – both the Equality Act and article 14 of the ECHR – before looking in more detail at three sets of circumstances in which commissioners may be permitted, or required, to take personal characteristics into account when deciding on an approach to exceptions: positive action, reasonable adjustments and indirect discrimination.

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5 For a more detailed discussion of this process, see Hart et al in this issue.

6 NHS England, *Commissioning Policy: Individual Funding Requests* version 3 (NHS England February 2023) 8.

INDIVIDUAL FUNDING REQUESTS

Individual funding request policies

Generally, policies on IFRs make clear that when making decisions about whether to make an exception for an individual patient, it is only their clinical circumstances which will be taken into account. Non-clinical or social factors will not be considered. Where social factors are defined in policies, they tend to embrace two different categories. First are value judgements about the usefulness of factors related to the role of the individual in society – whether the patient is an employee or parent or carer – and value judgements about the deservingness of the patient – for example the lifestyle of the patient and the extent to which they may bear some responsibility for bringing about their need for medical treatment. The second category – and that of interest in this article – includes the personal characteristics of the patient: sex, age, disability and so on. For example, one current IFR policy states that '[n]on-clinical social factors (for example, but not limited to, age, gender, ethnicity, employment status, parental status, marital status, carer status, religious/cultural factors) will not be taken into account in determining whether exceptionality has been established';[7] another that 'IFRs should not be made on the basis of non-clinical social factors, personal or protected characteristics'.[8]

The position is complicated by the fact that some personal characteristics, including age, sex and disability, may sometimes be highly relevant to the clinical benefit an intervention is likely to produce. Accordingly, some IFR policies may make clear that where personal characteristics are relevant to the clinical effectiveness of a treatment then they may be taken into account as part of this assessment.[9] The scope of this is not clear, however, and, in relation to co-morbidities (concurrent health conditions, some of which may amount to disabilities and therefore be protected characteristics under the Equality Act), NHS England suggests that:

> If the usual treatment cannot be given because of a pre-existing comorbidity which is unrelated to the condition for which the treatment is being sought under the IFR or is not unusual in the relevant patient group or generally, the fact that the co-morbidity is present in this

7 NHS Staffordshire and Stoke-on-Trent Integrated Care Board, *Individual Funding Request Policy* (8 July 2022) para 4.2.5.

8 NHS Cornwall and Isles of Scilly, *Individual Funding Requests Policy and Procedures* (December 2022) 5.

9 Nottingham and Nottinghamshire Integrated Care Board, *Individual Funding Requests (IFR) Commissioning Policy* (June 2024–June 2027) para 7.5.

> patient and its impact on treatment options for this patient is unlikely to make the patient clinically exceptional.[10]

Finally, some IFR policies make express reference to the need to improve health inequalities and the need to sometimes give priority to health services which target population groups who tend to have poorer than average health outcomes or who are disadvantaged in some way in relation to access to healthcare.[11] It is not obvious how this is envisaged working in the context of considering IFRs (rather than, say, in the context of an overall strategic approach to priority-setting where resources may be targeted to disadvantaged groups from the outset). It is not clear, for example, whether patients from groups with poorer health outcomes generally are more likely to be given individual funding, and, if so, whether this would be the case for those with poorer outcomes related to the specific conditions for which treatment is sought or for those with poorer outcomes more generally.

At best, therefore, there is lack of clarity as to the way personal characteristics will, if ever, be relevant to determining when to make an exception to a funding policy and the criteria for determining whether and when it will. The focus on clinical reasons for exceptionality, and the broad rejection of the relevance of social factors, including personal characteristics, appears to stem from a number of related concerns. First, it is clear that there is some worry that treating social factors as relevant to decisions about individual funding risks discrimination. The decision to treat social utility, personal responsibility or personal characteristics as irrelevant stems, at least in part, from concern to ensure that the health of one individual is not valued any more or less highly than that of another. Thus, for example, one ICB states that '[t]he ICB considers all lives of all patients to be of equal value and in making decisions about funding treatments will seek not to discriminate on the grounds of age, sex, sexuality, race, religion' and so on;[12] and NHS England notes that '[as] a central principle, the NHS does not make judgements about the worth of different individuals and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce this concept of "worth" into clinical decision making.'[13] There is also a more practical problem. Commissioners will usually lack the data and expertise to evaluate non-clinical evidence and to compare this across individuals and populations.[14] While initial cost-effectiveness reviews of the relevant treatment or drug, based on

10 NHS England (n 6 above).

11 For an example, see NHS Kent and Medway Integrated Care Board, *Principles and Guidance for Dealing with Individual Funding Requests* (August 2022) 22.

12 Nottingham and Nottinghamshire Integrated Care Board (n 9 above) para 6.5.

13 NHS England (n 6 above) 11.

14 NHS Staffordshire and Stoke-on-Trent Integrated Care Board (n 7 above) 22.

published trial data, for example, will have given a good idea of the average and typical range of clinical responses, allowing exceptions to be identified with more confidence, the same is not true of social factors.

Underlying these concerns is a desire to treat patients fairly. This includes both fairness as between those who are denied under an IFR and those who are successful; and fairness to those patients from whose treatment the money spent on making an exception in a particular case might be divested. While those deciding on IFR requests (and indeed the courts adjudicating claims made by individual patients refused under an IFR) are able to know the circumstances of the individual asking for an exception to be made, they will not be similarly aware of the needs and circumstances of those whose heath care may be compromised by the consequent reduction in budget. The difficulty with this – often apparently blanket – approach to the (ir)relevance of personal characteristics, however, is that it ignores the disadvantage that can be caused to (or reinforced in) members of protected groups by adopting 'characteristic blind' decision-making criteria. Sole focus on clinical response, while apparently fair, may ignore both underlying differences in ability to access treatment and underlying disadvantage, which may itself result from other forms of discrimination and will be compounded by lack of access to treatment. The following sections now turn to consider the circumstances under which the legal framework may in fact require, or permit, departure from an equal treatment or characteristic blind model so that personal characteristics are taken into account in commissioning decisions in order to avoid or reduce substantive inequalities.

Individual funding requests in public law

In common with all public bodies, healthcare commissioners are under a public law duty to not fetter their own discretion. In deciding which medical interventions to fund, and the access criteria for these, they must therefore remain open to the possibility of making exceptions to a general policy in response to individual patient circumstances. This duty was explained in *R v North West Lancashire*, a case concerning the refusal of gender reassignment surgery, where Auld LJ held that 'it is proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in "exceptional circumstances" and to leave those circumstances undefined'.[15]

Case law subsequent to *Lancashire* has addressed questions about the scope of this duty but has failed to produce clear guidance.

15 *R v North West Lancashire Health Authority* (n 1 above) para 991.

Commissioners must make decisions about whether individual patients are 'exceptional' in accordance with the general principles of public law – and, in particular, in this context, in accordance with the principle of rationality – but what rationality requires has proved difficult to pin down. As a result, the criteria for determining the circumstances under which an exception should be made – and the factors relevant to making these decisions – remain fraught with uncertainty. In particular, it remains unclear how 'unusual' a patient has to be, and in what respects. Indeed, the lack of clear guidance from the courts or elsewhere on this issue has resulted in what has been described as a 'legal farce', creating uncertainty for patients, clinicians and commissioners.[16]

One aspect of exceptionality on which the courts have sent a much clearer message, however, is in relation to the exclusion of social factors from decision-making on IFRs. The courts have sanctioned the approach to exceptionality which treats non-clinical factors as irrelevant. The leading case is *Condliff*, a case which did not itself involve any claims of discrimination.[17] Mr Condliff was morbidly obese and wanted laparoscopic gastric by-pass surgery. The policy of North Staffordshire Primary Care Trust (PCT) was then to fund this surgery only for those patients whose body mass index (BMI) exceeded 50, and Mr Condliff was not eligible because his BMI was below this threshold. He therefore made an IFR, supported by his general practitioner and by a number of other specialists, which noted the serious impact of his condition on his mental and physical well-being, and on his lifestyle, but his request was turned down by the PCT, whose IFR policy stated that social factors (including personal characteristics such as age, gender and ethnicity as well as employment, parental and marital status and religious or cultural factors) would not be taken into account in deciding whether or not a patient was exceptional.

Mr Condliff challenged the social factors exclusion arguing, among other things, that it was in breach of article 8 of the ECHR because it failed to take into account all factors relevant to his article 8 right to a private life.

Neither the High Court nor the Court of Appeal found any breach of article 8. In the first place, it was doubted that article 8 founded any positive right to treatment in the circumstances; even it if did, it was held that the approach of the PCT would amount to a justified interference with Mr Condliff's article 8 rights because it had struck a fair balance between the rights of individual patients and the needs of the community. The Court of Appeal noted that:

16 A Ford, 'The concept of exceptionality: a legal farce?' (2012) Medical Law Review 20(3): 304–336.

17 *R (on the application of Condliff) v North Staffordshire Primary Care Trust* [2011] EWHC 872 (Admin); [2011] EWCA Civ 910.

> The policy of allocating scarce medical resources on a basis of the comparative assessment of clinical needs is intentionally non-discriminatory. The statutory function of the PCT is to use the limited resources provided to it for the purposes of the provision of healthcare … To perform that function by allocating those resources strictly according to the PCT's assessment of medical need … is to do no more than to apply the resources for the purpose for which they are provided without giving preferential treatment to one patient over another on non-medical grounds.[18]

A similar approach was taken in *Longstaff*: a case concerning a patient who wanted access to artificial blood products which were not routinely funded.[19] His reason for rejecting human blood was a phobia developed as a result of his brother's death from contaminated blood products. The court suggested that there is a difference in kind between a refusal of treatment for clinical reasons and a refusal based on other factors including phobia or religious belief.[20] While neither of these cases involved claims of discrimination, the remainder of this article now turns to consider what equality law might require of commissioners in determining their approach to these kind of decisions where personal characteristics are involved. Under what circumstances may, or must, personal characteristics be taken into account when deciding whether or not to make an exception from a general rule or policy to not fund a particular medical intervention?

EQUALITY LAW

Introduction

Public bodies exercising public functions and providing services – as will be the case for commissioning bodies in the UK including ICBs, NHS England and NICE – have obligations under both the Equality Act and the Human Rights Act 1998 (HRA).

The Equality Act prohibits discrimination in a number of different contexts – including service provision and exercise of public functions – where this involves one or more of the characteristics protected by

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18 Ibid para 36. At first instance, Waksman LJ suggested that some social factors were directly relevant to clinical outcomes – but that these would then constitute clinical factors themselves and so not be caught by the policy. On the facts, Mr Condliff's circumstances did not fall into this category: ibid para 23.

19 *R (on the application of Longstaff) v Newcastle NHS Primary Care Trust* [2003] EWHC 3252 (Admin)

20 Ibid para 56.

the Act.[21] There are several forms of prohibited discrimination. Direct discrimination – 'less favourable treatment because of a protected characteristic' – captures the principle that likes should be treated alike. Where there are no other relevant differences between two individuals, it is not lawful to treat one less favourably than the other because of a protected characteristic, and it is not (with some exceptions) generally possible to legally justify treatment that amounts to direct discrimination.[22] This seems to be the type of discrimination which underlies concerns, in IFR policies, about treating personal factors as relevant to the decision to make an exception. In many ways direct discrimination is also something that will often fall foul of 'rationality' already required by judicial review, which will require decision-makers to treat likes alike and to not take irrelevant considerations into account.[23]

The prohibition on direct discrimination is only part of the story, however. Anti-discrimination has long reflected a recognition of the limits of equal treatment as a means to achieve substantive equality. The Equality Act therefore also includes a number of prohibitions and obligations which reflect the fact that disadvantage can also be created or become entrenched where the differences between groups sharing particular characteristics are not recognised and accommodated. Among these are three sets of obligations which will be explored in more detail below. These are positive action, as a form of exception to the prohibition on direct discrimination; the duty to make reasonable adjustments in the case of disability; and indirect discrimination which arises where an apparently neutral policy or practice serves to disadvantage those sharing a protected characteristic and cannot be justified.

It is important to note here that the Equality Act also imposes an obligation on commissioners, in common with all public sector bodies, in the form of the public sector equality duty (PSED). This requires public bodies to have 'due regard' to the need to eliminate discrimination and to advance equality of opportunity when formulating policy. In order to satisfy these obligations, public bodies need to consider, proactively, at policy stage, what disparate impacts, relevant to characteristics

21 In relation to services and public functions these are age, disability, gender reassignment, race, religion or belief, sex and sexual orientation – Equality Act 2010, ss 4 and 28.

22 The exception is less favourable treatment because of age (Equality Act 2010, s 13). There are also a number of exceptions in the Act; and, in relation to disability, pregnancy and gender reassignment, only those with the characteristic are protected under the Act – there is no prohibition on treating someone less favourably because they do *not* have one of these characteristics.

23 See, for example, *Matadeen v Pointu* [1999] 1 AC 98, 109.

protected under the Act, the policy may have and whether or not the policy should be amended as a result. The courts have made clear that the duty imposes an obligation on authorities to engage meaningfully with the duty as something 'of very great substantial, and not merely technical importance'[24] and as of fundamental importance in meeting the aims of anti-discrimination and making equality issues an essential part of public decision-making.[25] The relevance of the duty to the question of exceptionality is considered further below.

The HRA imposes obligations on public authorities to act in a way that is compatible with the ECHR.[26] Article 14 of the ECHR provides that:

> the enjoyment of the rights and freedoms set forth in [the] Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status

Article 14 is not a freestanding right – claimants are required to demonstrate that the facts in issue fall within the 'ambit' of one of the other Convention rights (although they are not required to demonstrate a breach of one of the other rights). In relation to access to healthcare, the article most likely to be relevant in the current context is article 8 (although articles 2, 3 and 9 may also be relevant) Both the European Court of Human Rights (ECtHR) and the domestic courts have been reluctant to find that article 8 grounds a positive right to healthcare, the ECtHR noting that member states are to be afforded a wide margin of appreciation in this respect.[27] However, this does not mean that article 14 will not be relevant, particularly in circumstances where healthcare is provided but in a way that is discriminatory. Indeed, in *R (AC) v Berkshire*, a case considered in more detail below, the Court of Appeal did not dismiss the relevance of article 14 to a claim of discrimination resulting from a policy not to treat trans and non-trans women differently in access to breast enlargement surgery.[28]

What follows will now focus on three contexts in which commissioners may be permitted, or required, to treat individuals or groups of patients differently because of their protected characteristics: positive action, the duty to make reasonable adjustments and avoiding indirect discrimination.

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24 *R (C) v Secretary of State for Justice* [2008] EWCA Civ 882.

25 *Bracking v Secretary of State for Work and Pensions* [2013] EWCA Civ 1345.

26 HRA 1998, s 6.

27 *Sentges v Netherlands* [2004] 7 CCL Rep 400; *Pentiacova v Moldova* [2005] 40 EHRR SE23.

28 *R (AC) v Berkshire West Primary Care Trust* [2010] EWHC 1162 (Admin); *R (AC) v Berkshire West Primary Care Trust* [2011] EWCA Civ 247.

Positive action

Positive action under the Equality Act

The Equality Act provides that positive action is permitted in certain circumstances. Positive action involves the use of steps to help those facing particular disadvantages connected to a protected characteristic to overcome them.[29] It is normally distinguished from positive or 'reverse' discrimination, which is generally unlawful in the UK, and is normally characterised as preferential treatment of an individual because of a protected characteristic – although the division between these two concepts is not always clear. Positive action in any form is controversial because it can involve the perception that it creates unfair advantage for some groups at the expense of others; the boundary between redressing disadvantage and creating unfair advantage is sometimes hard to draw. On the other hand, it is widely acknowledged that some form of positive action is often necessary to achieve substantive equality and to ensure that society is sufficiently responsive to the different needs and experiences of different groups.[30]

Section 158 of the Equality Act provides that positive action will be lawful where service providers, or those carrying out public functions, reasonably think that individuals who share a particular protected characteristic are at a disadvantage connected to the characteristic, or have needs that are different from those who do not have the characteristic; when this is the case, it is then lawful for service providers to take *proportionate* steps to help them to overcome the disadvantage or to meet those needs.

There are, as yet, no cases considering the application of section 158 in relation to healthcare resources, but a first judgment on the scope of these provisions by the Supreme Court in 2020 in *R(Z) v Hackney*, in the context of social housing, gives a useful example of how the provision may operate in the context of public services.[31] A portion of the social housing stock in Hackney was owned by the Agudas Israel Housing Association (AIHA), whose policy was to prioritise its housing stock for members of the Orthodox Jewish Community. The claimant, who had young children, including two with autism, was considered by Hackney Council to be among the group with the highest need for housing but was not nominated by the council for a series of suitable properties owned by AIHA because of its priority policy. She claimed

29 For a helpful categorisation of different forms of positive action, see C McCrudden, 'Rethinking positive action' (1986) 15(4) Industrial Law Journal 219–243.

30 For a useful summary of the debate on positive action, see S Fredman, *Discrimination Law* 3rd edn (Oxford University Press 2022) ch 7.

31 *R (Z) v Hackney London Borough Council and another* [2020] UKSC 40.

that she had suffered direct discrimination on grounds of religion and race under the Equality Act as she had been treated less favourably because she was not Jewish. The Supreme Court found that there had been no discrimination because (among other things) the council and the AIHA were able to rely on the positive action provisions in section 158. There was undisputed evidence that the Orthodox Jewish Community faced 'real and substantial disadvantage' connected with their religion in relation to housing, as well as having different needs to those who were not members of the community. The court held that the correct approach to determining the proportionality of a positive measure was to weigh the disadvantage to the group in question – here the Orthodox Jewish Community – against the disadvantage other groups would face in consequence of the disputed measure.[32] On the facts, although the individual claimant in this case was significantly disadvantaged by the measure because of her particular circumstances, the evidence suggested that the wider group of those in need of social housing were not because the housing stock of the AIHA formed such a small proportion of the overall housing stock available to the council. The measure was therefore proportionate.

In the context of commissioning healthcare, the positive action provisions should therefore allow an approach to considering IFRs which takes into account the protected characteristics of patients in some circumstances. Where it is recognised that a decision not to fund a particular treatment is likely to disadvantage members of a particular group, commissioners are unlikely to be acting unlawfully if they allow for exceptions to be made for those within that group, provided that this is proportionate. Arguably, this could be achieved *either* by carving out an exception as part of the funding policy itself – for example by generally funding a drug or intervention *only* for members of the relevant group – *or*, alternatively, by having an IFR policy which makes clear that protected characteristics may be relevant to individual decisions where the positive action provisions of the Act apply. There are good reasons to take the first approach wherever possible, not least because, as argued by Hart et al in this journal, identifying exceptional groups at the policy stage is likely to prove fairer, more effective and more transparent. The exercise of the PSED should equip commissioners to consider needs and disadvantage at an early stage of policy-making. On the other hand, there may be situations where it is

32 Ibid para 79. This accords with the guidance in the EHRC, *Equality Act 2010 Statutory Code of Practice: Services, Public Functions and Associations* (EHRC January 2011) which notes at para 10.22 that '[t]he seriousness of the relevant disadvantage, the degree to which the need is different … need to be balanced against the impact of the action on other protected groups, and the relative disadvantage, [or] need … of these groups'.

more challenging to identify in advance the groups whose needs may be different to others affected by the policy or who may be particularly disadvantaged in relation to it for reasons connected to a protected characteristic. In these circumstances, allowing the disadvantage to be overcome or needs met through the mechanism of the IFR process may be another way of utilising the positive action provisions for commissioners wishing to do so.

Therefore, while positive action is possible, commissioners may nonetheless have understandable reservations about taking such action when they are not required to. This has certainly proved true in other contexts. In relation to employment, for example, research suggests that 'organizations prefer to steer clear of this opportunity to address disadvantage suffered by protected groups'[33] and that a lack of clarity as to the boundaries of permissible public action, and resulting lack of confidence, may be to blame.[34] It would be unsurprising if this was also true of policy-makers in the NHS.

Clarity and confidence aside, a second challenge for policy-makers is to determine an approach for voluntary positive action that accords with their broader ethical framework (as well as the legal one) and is compatible with the principles that underscore their approach to resource allocation. In line with the legal framework, this exercise will involve at least two elements. The first is identifying the respects in which a group should be disadvantaged (or have different needs) in order to trigger the use of permissible positive action in the first place. The Equality Act appears to allow a broad definition of relevant disadvantage in this context which could potentially include both disadvantage related to a particular policy or funding decision and disadvantage in relation to access to healthcare or healthcare outcomes more generally, although the boundaries remain unclear. The answer to this question will be highly significant to deciding whether and when positive action in access to healthcare may be used as a mechanism to address health inequalities more broadly. A second step comes in relation to deciding whether making a group exception to a particular funding decision is a proportionate response. Following the Supreme Court's guidance in *Re Z*, it is clear that this will involve a weighing of the disadvantage to the protected group which has triggered the need for positive action in the first place (here, Orthodox Jews in need of housing) against any disadvantage caused *by* the positive action to those not in the protected group. In *Re Z*, the group disadvantaged by the

33 C M Davies and M Robison, 'Bridging the gap: an exploration of the use and impact of positive action in the United Kingdom' (2016) 16(2–3) International Journal of Discrimination and the Law 83–101.

34 C Davies, *Exploring Positive Action as a Tool to Address Under-representation in Apprenticeships* (EHRC Research Report 123 2019).

positive action were those, like the claimant, also seeking housing in the borough and were therefore relatively easy to identify. When it comes to healthcare commissioning, this weighing exercise is potentially much more challenging. Money spent on funding exceptions may need to be divested from healthcare provision which may be entirely separate from the treatment and cohort being considered, and as a result it is likely to be much more difficult for commissioners to identify who is likely to be impacted. If I need access to more expensive drug B because my religion prevents me from using the cheaper and generally available drug A, the money spent on eliminating my disadvantage (and that of others in my position) in relation to that treatment may be taken from others who are disadvantaged, in different ways (and indeed in relation to other protected characteristics) in relation to health outcomes and access to healthcare. Arguably at least, this will therefore require a different and potentially more complicated weighing exercise than required of Hackney Council in *R(Z),* and a clear and transparent process will be needed.

Positive action under the HRA

Under the HRA, positive action is not only permitted but may sometimes be required. The ECtHR made clear in *Thlimmenos v Greece* that it is possible for a breach of article 14 to arise because of a failure to treat individuals differently, without justification, where there are relevant differences between them.[35] Mr Thlimmenos had been refused appointment as a chartered accountant because of a criminal conviction for refusing to wear a military uniform because of his religious beliefs. In finding that this failure to make an exception for individuals in the position of Mr Thlimmenos was a violation of article 14, in conjunction with article 9, the court held that:

> [t]he right not to be discriminated against in the enjoyment of the rights guaranteed under the Convention is also violated when States without an objective and reasonable justification fail to treat differently persons whose situations are significantly different.[36]

In common with all claims under article 14, when determining whether a failure to treat people differently in this way amounts to unjustified discrimination, the domestic courts engage in varying intensity of review which will determine the approach taken to proportionality and the extent to which the assertions of policy-makers will be accepted by the courts without the need for close scrutiny. The approach to be taken in any particular case depends on a complex matrix of factors including the ground of discrimination (with some grounds calling for

35 *Thlimmenos v Greece* App no 34369/97 (ECtHR, 6 April 2000).

36 Ibid para 44.

a more intense review than others), the seriousness of the disadvantage created by the contested policy or treatment and whether or not the relevant policy involves questions of socio-economic policy and the allocation of resources.[37] In cases involving difficult decisions about the allocation of resources – as will normally be the case in relation to healthcare commissioning – the courts tend to take a deferential approach, although this is not automatic and stricter scrutiny may still be called for in some circumstances.[38]

Deference was very much in evidence in a rare case involving claims of '*Thlimmenos*' discrimination in the context of healthcare commissioning. In *R (AC) v Berkshire*, the claimant, a male to female transexual, sought judicial review of a decision by Berkshire West PCT to refuse her breast augmentation surgery.[39] It was the policy of the PCT to treat breast augmentation surgery as low priority, and it was only funded for those who could demonstrate exceptional clinical need or benefit. The claimant had made a number of requests for funding which had been rejected. Her claim included an argument that by failing to make an exception for her, by agreeing to her IFR, the PCT was in breach of article 14, together with article 8 of the ECHR.[40] The claimant argued that there were relevant differences between her need for surgery and those of a natal woman because, as the Equality and Human Rights Commission (EHRC) (intervening) put it in its submission 'only a transgender woman needs breasts to address the very condition from which she suffers, and only transsexuals suffer, of living in a body which is not the gender which they feel themselves to be'.[41] In rejecting her claim, however, the Court of Appeal effectively delegated the decision on the question of which differences between individuals are relevant to the PCT.[42] As the PCT had decided it was not relevant that 'one of the women seeking treatment was born a

37 *R (SC) v Secretary of State for Work and Pensions* [2021] UKSC 26.

38 Ibid.

39 *R (AC) v Berkshire West Primary Care Trust* (2010) (n 28 above); *R (AC) v Berkshire West Primary Care Trust* (2011) (n 28 above).

40 At the time the claim arose, there was no legal protection from indirect discrimination on grounds of gender reassignment under the Equality Act – a claim which may be now advanced on the same facts.

41 *R (AC) v Berkshire West Primary Care Trust* (2011) (n 28 above) 41.

42 While a deferential approach is not surprising here, given the context of resource allocation, it is arguable that the appropriate sphere of deference should have arisen in relation to the question of whether a decision to not treat the claimant differently was justified here, rather than the question of whether or not there was potential discrimination requiring justification in the first place. See, for example, *Burnip v Birmingham City Council* [2012] EWCA Civ 629.

woman whereas the other has become a woman or seeks to become a woman', that was the end of the matter.[43]

Using article 14 to argue successfully that exceptions should be made may therefore prove a difficult task for patients. More recently, however, a less deferential approach to the scope of *Thlimmenos* discrimination was taken by the court in *R (Adath Yisroel Burial Society) v HM Senior Coroner for North London*,[44] which involved religious belief and therefore concerned article 9 (freedom of religion) as well as article 14. The case offers some useful insights as to how obligations to make exceptions might arise. It concerned a policy of the Senior Coroner not to prioritise deaths because of the religious belief of the deceased or their families – where, for example, their religion required that burial take place as soon as possible after death. Instead, deaths would be dealt with in the order in which they were referred – described by the defendant as the 'cab rank rule'. The only basis on which prioritisation was permitted was for homicide and organ donation. Prioritisation for religious – or any other reason – had been described by the defendant as 'queue jumping', and she had expressed concern about the impact of prioritising one group on the families of others who were therefore pushed further back in the queue.[45] It was also suggested in argument that, among other things, one of the reasons for the coroner's refusal to prioritise deaths on religious grounds was a fear of discriminating under the Equality Act,[46] concerns which echo those seen in IFR policies.

The claimants successfully challenged the policy on a number of grounds, including that it was a breach of the claimant's article 9 and article 14 rights. In relation to article 9, the court held the policy constituted a *prima facie* interference with the right to freedom of religion which could not be justified. In particular, it noted that it was relevant to justification that prioritisation on grounds of religious belief is not unlawful under the Equality Act because it is consistent with the positive action provisions of section 158, discussed above. The coroner's concerns about giving priority to one person over another on religious grounds were therefore 'misguided'.[47] In relation to article 14, the court, having established that this was a *prima facie* case of *Thlimmenos* discrimination – because there were significant relevant differences between those requiring expedited burial for religious reasons and others using the services of the coroner – considered whether there

43 *R (AC) v Berkshire West Primary Care Trust* (2011) (n 28 above) 54.
44 *R (Adath Yisroel Burial Society) v HM Senior Coroner for North London* [2018] EWHC 969.
45 Ibid para 50.
46 Ibid para 108.
47 Ibid para 112.

could be any 'objective and reasonable' justification for the coroner's policy of not allowing exceptions to be made on religious grounds. On the facts, there was not. The coroner had advanced two justifications – the first that a 'bright line rule' was easier to understand and to administer; the second that the resources of the coroner's office were limited. The court dismissed both. The fact that the coroner allowed for exceptions in other circumstances undermined the argument about administrative workability.[48] In relation to concerns about managing finite resources – perhaps of particular resonance in the context of thinking about the approach to commissioning healthcare – the court noted that:

> Limits on resources may explain why it is not possible to help a particular family to achieve expedition (whatever the reason for their request for expedition, whether or not it is based on a religious belief) but they cannot justify discrimination of this kind, which means that certain reasons for a request for expedition (religious ones) are excluded from consideration altogether.[49]

Given a diversity in judicial approach in considering article 14, the scope of the obligation on public bodies therefore remains unclear. It is certainly plausible, however, that commissioners might be required *at least* to be open to the possibility of making exceptions for patients whose religious beliefs or other characteristics underlie their need to access generally unfunded treatment options. While concerns about the impact on funding for others may justify a particular decision not to make a policy exception for those from a particular group – or refuse an exception for a particular individual – these wider impacts would be factors to be weighed in the balance when considering the question of justification. IFRs which rule out the relevance of personal characteristics may fall foul of article 14.

The duty to make reasonable adjustments

Sometimes a patient may be unable to access available treatment for their condition because of an unrelated health condition or 'comorbidity' – because, for example, that treatment may exacerbate their comorbidity or interact badly with medication taken for it or because the available treatment is in some other way inaccessible. If alternative treatments, which would be accessible, are not normally funded, then the patient may need to make an IFR to ask that the unfunded treatment be made available to them instead. Commissioners may agree to IFR where, because of comorbidity, you can demonstrate you are able to derive significantly more clinical benefit from the unfunded treatment and

48 Ibid para 123.
49 Ibid para 124.

are therefore clinically exceptional. However, NHS England policy suggests that it will not usually be enough simply to demonstrate that you are unable to access a treatment because of a comorbidity, particularly where the condition is a common one because 'a patient cannot be exceptional by virtue of also having a comorbidity which is common in the general population'.[50]

The court considered what common law rationality requires of decisions in this type of situation in *R (SB) v NHS England*.[51] Here, the claimant was a severely autistic child who also had a rare condition called phenylketonuria (PKU) which inhibits the ability to ingest protein and can cause serious disabilities if not treated. The usual treatment for PKU is dietary management – involving a very restrictive diet. Because of his severe autism, the claimant was unable to cope with the required dietary restrictions and so – supported by his doctors – had requested to be treated with the drug Kuvan. This request had been rejected by NHS England (the relevant commissioning body). The court held that its rejection was irrational for a number of reasons. In particular, the court noted that, given the rarity of the combination of conditions, their severity and the evidence that Kuvan would prove a clinically effective option:

> it is difficult to see how the Panel could reach any other rational conclusion than that he was likely to gain significantly more clinical benefit from taking Kuvan than other children with PKU whose condition could be managed by the conventional treatment alone …[52]

The combination of severe autism and PKU in this case was very rare indeed – only one or two individuals in the whole of the UK, including the claimant, were both affected by the two conditions and responsive to Kuvan.[53] It remains unclear how rare a case – and how significant the clinical benefit – would have to be before a refusal to treat as exceptional is irrational.

However, where – as will sometimes be the case – the comorbidity in question amounts to a disability within the meaning of the Equality Act,[54] additional legal obligations will arise which do not depend on how common or rare that condition is in the population. Separate from the positive action provisions, the Equality Act includes an obligation on service providers and those charged with public functions to treat

50 NHS England (n 6 above) 9.

51 *R (on the application of SB) (by his father and litigation friend PB) v NHS England* [2017] EWHC 2000 (Admin).

52 Ibid para 49.

53 Ibid para 43

54 An individual is disabled under the Equality Act if they have a physical or mental impairment which has a substantial and long-term adverse effect on their ability to carry out normal day-to-day activities (s 6(1)).

individuals with disabilities differently in some circumstances by making reasonable adjustments. Section 20 of the Act provides that, where there is a policy, criterion or practice which puts disabled persons at a substantial disadvantage in comparison with persons who are not disabled, service providers are obliged to take such steps as are reasonable to avoid the disadvantage. Failure to do so amounts to unlawful discrimination.[55] The purpose of reasonable adjustments is to eliminate, as far as possible, the disadvantage attaching to that disability in order to improve equality of access and opportunity, and the duty is generally seen as a transformative legal tool which has significant potential to improve inclusion across the areas in which it applies.[56] There have been instances – mainly in an employment context where most of the case law still is – where courts have taken a very expansive approach to interpretation of the duty.[57] Importantly, unlike with rationality at common law, the existence of the obligation to make reasonable adjustments to policy will apply irrespective of how rare or common the relevant disability is.

An adjustment will only be required if it is reasonable. Reasonableness is left undefined by statute. The EHRC Code of Practice provides some guidance, suggesting that of particular relevance will be the extent to which a proposed adjustment would overcome the disadvantage and the practicability and cost of the adjustment.[58] Of especial concern in this particular context will, of course, be the extent to which budgetary considerations are relevant to the question of reasonableness: will it be reasonable to make an exception irrespective of the implications of diverting resources away from other patients? The *Code of Practice* notes that '[t]he resources available to the service provider as a whole are likely to be taken into account as well as other demands on those resources'.[59]

There is little case law to assist in assessing reasonableness in the context of public services. In an employment context it is clear that, while cost alone is unlikely to disqualify a potential adjustment from being reasonable, the relative cost of the adjustment might be. Laws LJ, in *Sanders v Newham Sixth Form College*[60] (another employment case), made clear that it was not possible to assess the reasonableness of an adjustment separately from the question of how significant the disadvantage caused by the policy is. The more significant the

55 Equality Act 2010, s 29(7).

56 For a comprehensive account of the duty, see A Lawson, *Disability and Equality Law in Britain: The Role of Reasonable Adjustment* (Hart 2008.)

57 See, for example, *Archibald v Fife Council* [2004] IRLR 651.

58 EHRC (n 32 above) paras 7.29–7.30.

59 Ibid para 7.32.

60 *Sanders v Newham Sixth Form College* [2014] EWCA Civ 734.

disadvantage, the greater the resources that are required to be spent before the cost prevents the adjustment from being a reasonable one. In *Cordell v Foreign and Commonwealth Office* (FCO) (Employment Appeal Tribunal (EAT), the (very high) cost of the adjustment in question – the provision of a lip-reading service in Kazakhstan – was considered relative to the overall budget available for reasonable adjustments. The FCO had a budget set aside for reasonable adjustments, and the impact on that budget was to be taken into account according to its own policy. The EAT decided that, while the size of this budget could not be decisive (as the size of the budget was itself a decision of the employer and an employer cannot be permitted to avoid its legal obligations simply by selecting a smaller budget for adjustments), it was nonetheless a relevant factor. It was also held that the general resources of the employer were relevant to the question of reasonableness as 'no-one's resources, not even the government's, are infinite'.[61]

In relation to commissioning healthcare, the cost of making an adjustment and the impact of doing so on the overall commissioning budget will therefore be factors likely to be relevant to the question of reasonableness – but only when considered in relation to the nature of the disadvantage faced of the individual patient whose disability means they cannot access a funded course of treatment in the same way as can other patients. For this reason, where a disability is – in the words of NHS England – 'common in the general population', this *may* have a bearing on whether or not commissioners are obliged to make adjustments or exceptions for this group. But the prevalence of that disability will have no bearing on whether or not the duty to make reasonable adjustments arises in the first place.

In contrast to employment, the duty is an anticipatory one.[62] Commissioners (and other service providers) cannot wait for individuals with disabilities to present themselves but must consider in advance what adjustments to policies and practices might be reasonable in relation to disabled services users generally. While it may be easiest to do so by identifying in advance a set of alternative arrangements for the relevant group at the stage of determining funding policy, it is arguable that this duty could also be met by ensuring that there is a route to access alternatives by means of an IFR. In any case, in addition to the anticipatory duty, it is likely that the duty to make reasonable adjustments will also apply in a reactive way – as it does in other contexts such as employment and education – in response to specific difficulties faced by specific individuals which become known

61 *Cordell v Foreign and Commonwealth Office* [2012] ICR 280 (2011), paras 32 and 33.

62 Equality Act 2010, sch 2, 2(2), stipulates that the duty arises in respect of 'disabled persons generally'.

to commissioners.[63] In these circumstances, making an exception to the original funding policy may well amount to a reasonable adjustment and IFR policies should reflect this.[64]

Indirect discrimination

In determining the approach to take to dealing with requests for individual funding, commissioners should also be mindful that their approach to dealing with IFRs may also be relevant to whether or not the *original* funding policy from which an exception is sought – such as a decision not to fund a particular drug – is itself discriminatory. Most funding policies do not directly discriminate although some do – the use of age limits for access to IVF would be an example of potential direct age discrimination, for example, although it will be remembered that, unlike for other characteristics, direct age discrimination can be justified under the Equality Act. Funding policies are more likely to be susceptible to charges of indirect discrimination – prohibited both under section 19 of the Equality Act and article 14 of the ECHR. A policy will be *potentially* indirectly discriminatory where it is apparently neutral, and applies equally to those with and without the relevant protected characteristic, but in fact serves to disadvantage those sharing a characteristic more than it does those without it. For example, a policy which determines that artificial blood products will not generally be funded applies equally to all but may disadvantage those who are unable to be treated with human blood because of their religious beliefs; and a policy which determines that only one hearing aid, rather than two, will generally be funded will disadvantage older age groups because they are more likely to benefit from having access to two hearing aids. Importantly, the impact, or disadvantage which is relevant to identifying indirect discrimination will be broader than one relating solely to clinical considerations. Nor will the size of the group affected be relevant here. There is no need to show that the impact on the individual is unusual or exceptional. Indeed, part of the point of indirect discrimination is to understand the disadvantage faced by an individual in the context of the disadvantage faced by a much wider group with a shared protected characteristic.

Where policies have disparate impact, they can be justified where the policy-makers can show that the policy is a proportionate means of achieving a legitimate aim. Behind many or most decisions to restrict access to health interventions is, of course, the need to ration limited resources and to target those limited resources towards interventions which commissioners believe will be most cost-effective

63 Recently confirmed, in the context of higher education, in *The University of Bristol v Dr Robert Abrahart* [2024] EWHC 299 (KB).

64 EHRC (n 32 above) paras 7.7 and 7.8.

or otherwise beneficial. It is important to note in this particular context that, while discrimination cannot be justified simply because it is cheaper, courts have recognised that the imperative of meeting wider budgetary constraints is likely to amount to a legitimate aim.[65] However, commissioners will still be obliged to demonstrate that the policy choices made to achieve that aim are proportionate because while 'saving cost is a legitimate objective of public policy … if a benefit is to be limited to save costs it must be limited in a non-discriminatory way'.[66]

It is in relation to proportionality that the role of exceptions is likely to be relevant. The case law on proportionality is complex and often inconsistent and, for reasons of space, there is not scope to consider the test in detail here. However, most approaches to proportionality require *either* an assessment of whether *or* not the measure is necessary to achieve the aim (or whether a less discriminatory alternative route is available) or a balancing between the aim of a measure and its impact on those disadvantaged by it. Often both are required because 'there are some situations in which the ends, however meritorious, cannot justify the only means which is capable of achieving them'.[67]

To what extent is a willingness to make exceptions capable of 'saving' the original policy from being indirectly discriminatory? Given that the possibility of making exceptions to a general rule means that the harmful impacts of the rule may be reduced and, further, that a willingness to make exceptions will sometimes amount to a less discriminatory way of achieving the overall aim, it seems plausible that it should be a relevant factor. Identifying and considering disparate impact on protected groups is of course required of commissioners to ensure they comply with the PSED to have 'due regard' to the need to avoid discrimination and promote equality. Indeed, Fredman has argued that, where disparate impact has been identified as part of the exercise of the PSED, pre-emptive action may be required in order to correct any practices identified as potentially discriminatory, amounting to a form of mandatory positive action.[68] In relation to reasonable adjustments, the EHRC *Code of Practice* makes clear that it will be difficult to establish proportionality, and therefore justification, where there has been a failure to make reasonable adjustments to the policy or practice in question.[69]

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65 *R (Coll) v Secretary of State for Justice* [2017] UKSC 40.

66 Ibid para 40.

67 *Akerman-Livingstone v Aster Communities Ltd* [2015] UKSC 15, at 28.

68 S Fredman, 'Addressing disparate impact: indirect discrimination and the public sector equality duty' (2014) 43(3) Industrial Law Journal 349–363, 354; and see discussion in Davies and Robison (n 33 above).

69 EHRC (n 32 above) para 5.34.

There is case law to suggest that a willingness to make exceptions will be relevant to whether or not a policy is indirectly discriminatory. In *Watkins-Singh*, a uniform policy at the school which prohibited the wearing of jewellery was indirectly discriminatory on grounds of race and religion *because* the school had refused to make an exception to the policy in the case of a Sikh pupil who needed to wear jewellery for religious reasons.[70] Similar considerations were also evident, in the context of article 14 of the ECHR. In *AL (Serbia)*, for example, it was one of the features that led the court to conclude that the government policy of using family status to determine eligibility for indefinite leave to remain was justified. The measure was proportionate because, among other things, 'it permitted compelling claims by those falling outside the policy to be recognised and accommodated'.[71]

On the other hand, it is unlikely that a mere willingness to make exceptions in principle will always be enough to prevent a funding policy amounting to indirect discrimination. In *Eisai v NICE*, there was a challenge to NICE guidance which had recommended that Aricept, a drug manufactured by Eisai to alleviate symptoms in those with mild to moderate Alzheimer's disease, should only be funded for patients whose scores fell within a certain range on a cognitive test. Eisai argued, among other things, that the guidance was indirectly discriminatory on grounds of race and disability because the test disadvantaged those with learning difficulties and those for whom English was not a first language. NICE accepted this but argued that there was unlikely to be discriminatory impact in practice because the guidance made clear it was not to be followed slavishly – clinicians were able to identify these anomalies and funding policies and decisions could reflect this accordingly. NICE argued that this flexibility should be enough to defeat any charge of discrimination. Dobbs J in the High Court disagreed. He found that the issue of atypical groups had been dealt with in an unsatisfactory way in the guidance because:

> instead of looking at how NICE as a public body could itself promote equal opportunity, having accepted that the Guidance could have a discriminatory effect if applied slavishly, the approach taken was to leave it to others to sort out in the hope and expectation that they would.[72]

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70 *R (on the application of Watkins-Singh) v Governing Body of Abderdare Girls' High School* [2008] EWHC 1865.

71 *AL (Serbia) v Secretary of State for the Home Department* [2008] UKHL 42 at 3.

72 *Eisai Limited v The National Institute for Health and Clinical Excellence (NICE)* [2007] EWHC 1941 (Admin) at 83.

This failure to deal adequately with disadvantaged groups in the guidance meant that the guidance did amount to indirect discrimination.

Making exceptions for a group – or being open to making exceptions for individuals – on the basis of personal characteristics may also undermine the aim of the original funding policy decision in some circumstances. This is most obviously the case where the original policy relates to a treatment which would be wholly or mainly likely to benefit a protected group if it were available, but where a decision has been made that the resources to fund that treatment would be better spent elsewhere. In these circumstances, the onus will be on commissioners to justify the original policy as proportionate in the context of wider funding priorities. Even where this is not the case, the likely size of the group for which exceptions are potentially appropriate should – arguably at least – have a bearing on whether or not they need to be made in order to justify the original funding policy. The likely cost of making exceptions will have a direct bearing on the reduction in resources available for other patients and should therefore be relevant to any proportionality assessment which involves the weighing of disadvantage to those who will be impacted by the measure.

CONCLUSION

Equality law has long recognised that the requirement to treat likes alike can only go so far in eliminating unfair discrimination and promoting equality. Being blind to personal characteristics will often create or entrench disadvantage where those characteristics inhibit access to available services or are otherwise relevant to the impact a policy will have on those to whom it applies. In the ways described above, therefore, the law sometimes permits, and sometimes requires, service providers and others subject to equality law to make exceptions to general rules so as to eliminate disadvantage experienced by particular groups in access to healthcare. Using, or complying, with these provisions presents a number of challenges for policy-makers, however.

It will have become apparent in the discussion above that there is still some uncertainty over the boundaries of permissible positive action and the question of what will amount to a reasonable adjustment. One thing does seem clear, however: an IFR policy, or an approach to identifying exceptions to a funding policy which excludes altogether the relevance of protected characteristics from considerations of exceptionality is likely to be legally problematic. As well as identifying the likely disparate impact of funding policies on protected groups as part of the exercise of the PSED, commissioners should consider whether

exceptions can or should be made for protected groups. Exceptionality policies should make clear that exceptions will be made for individuals disadvantaged by protected characteristics where required by law. Consideration should also be given to the circumstances under which use will be made of the optional positive action provisions to redress disadvantage or meet needs.

As Chris Newdick has long argued, there is a need to balance the compelling cases of individuals against the healthcare needs and outcomes of the wider population, and as a result the legal framework needs to permit commissioners to find an appropriate compromise between realising individual rights and addressing communitarian concerns. This was recognised by the High Court in *Condliff* where it was held that:

> it is impossible to see how the Social Factors Exclusion, as part of the PCT policy of medical resource allocation, does not amount to a fair balance between the individuals seeking treatment under the IFRs and the medical requirements of the community as a whole.[73]

One of the challenges posed by the equality law framework, and in particular the provisions discussed above, however, is that it requires commissioners to also consider a third dimension in arriving at this balance: that of groups whose shared characteristics disadvantage them, or give rise to particular needs, in relation to individual treatments or interventions or more generally in relation to access to healthcare or health outcomes. This is not to suggest that groups disadvantaged by protected characteristics need be prioritised or treated more favourably than those disadvantaged in other ways. As was seen above, there is scope to consider the impact of making exceptions for protected groups and individuals on other patients in the context of determining proportionality (for positive action and indirect discrimination) or reasonableness (for reasonable adjustments), but consideration of the needs of these groups must be part of the balancing act.

73 Waksman LJ in *R (on the application of Condliff)* (n 17 above) 67.

Northern Ireland
Legal Quarterly
Vol. 76 No. 1 (2025) 51–74
Articles DOI: 10.53386/nilq.v76i1.1143

Into the matrix and beyond: seeking an understanding of problem priority-setting cases in the English courts

Keith Syrett
University of Bristol
Correspondence email: keith.syrett@bristol.ac.uk.

ABSTRACT

Drawing upon and developing Chris Newdick's work on legal regulation of resource allocation in healthcare, this article analyses a series of problematic judicial review cases in the English courts in which judges appear to move away from scrutiny of procedure towards a form of review that is much more substantive in nature. The 'priority-setting rights matrix', which Newdick developed in later work, enables us to distinguish these cases from others, calling into question the claim that the jurisprudence in this field has evolved in a linear fashion. However, while the matrix has considerable value as a classificatory tool, it requires supplementation if we are to understand why judges respond differently in distinct scenarios. To this end, the article explores potential reasons for judicial preference for individual interests over collective priority-setting goals, which may explain the shift away from procedural review which characterises these cases.

Keywords: judicial review; priority-setting; procedural and substantive review; identifiability; rights.

INTRODUCTION

Chris Newdick's work on the legal regulation of healthcare resource allocation was truly pioneering. In *Who Should We Treat?*, first published in 1995,[1] he set out to explore an issue which had previously attracted virtually no attention from scholars working in the then still nascent field of medical law,[2] namely how the legal relationship between physician and patient was shaped and constrained by the organisational context in which healthcare was delivered, and particularly by the seemingly inevitable fact of scarcity of resources. The timing of the monograph was propitious, as this issue was just beginning to attract broader public attention.

1 C Newdick, *Who Should We Treat? Law, Patients and Resources in the NHS* (Clarendon Press 1995).

2 The work of Diane Longley affords a partial exception: see eg D Longley, *Public Law and Health Service Accountability* (Open University Press 1993).

This was so for two reasons. First, the creation of the so-called 'internal market' in the National Health Service (NHS) as an element of neoliberal policy during the early 1990s had visibly exposed limitations to the purportedly comprehensive coverage of the NHS, as purchasing health authorities sought, for reasons of cost, to restrict the 'menu' of services and treatments available to the population for whose health they were statutorily responsible.[3] This gave rise, in turn, to concerns as to geographical inequities in access ('postcode prescribing') which, later in the decade and under a different colour of government, prompted the establishment of the body which was originally styled the National Institute for Clinical Excellence (NICE). Secondly, the decision in *R v Cambridge Health Authority, ex parte B* – remarkable in itself for the fact that the first instance and appeal court had ruled on the same day[4] – demonstrated that courts were highly likely to become drawn into questions of allocation of scarce healthcare resources.[5] This was particularly the case as scientific advances raised the prospect of successful treatment in previously hopeless situations, but at significant cost to the public purse, necessitating some mechanism for resolution of competing individual and collective claims to limited resources.

In the almost three decades which have elapsed since then, the judicial review of allocative decisions has become a familiar, albeit still not commonplace, feature of regulation of the NHS. In turn, this has engendered a minor cottage industry of academic analysis, with scholars offering various readings of the evolving role for the courts in this field. This article contributes further to this debate by making use of a model developed in Newdick's later work, the 'priority-setting rights matrix',[6] to seek to explain certain more problematic English judicial review cases in which the courts have seemingly strained at the very limits of judicial competence. It will be argued that the matrix can be of considerable assistance in building understanding of *how* these cases can be differentiated from other decisions in this particular

3 See L Locock, 'The changing nature of rationing in the UK national health service' (2000) 78 Public Administration 91–109.

4 *R v Cambridge Health Authority, ex parte B* [1995] I FLR 1055 (QBD); [1995] EWCA Civ 49.

5 This was not the first such judicial consideration of resource allocation in the NHS; that had occurred in 1980 in *R v Secretary of State for Social Services, ex parte Hincks* (1992) 1 BMLR 93. However, the *Child B* case was the first to attract significant public and media attention: for discussion of which, see V Entwistle et al, 'Media coverage of the Child B case' (1996) 312 British Medical Journal 1587; and C Burgoyne, 'Distributive justice and rationing in the NHS: framing effects in press coverage of a controversial decision' (1997) 7 Journal of Community and Applied Social Psychology 119–136.

6 C Newdick, 'Can judges ration with compassion? A priority-setting rights matrix' (2018) 20 Health and Human Rights 107–120.

context; but also that it needs to be supplemented by further analysis in order to identify plausible reasons *why* the judicial approach taken in these cases may differ from that adopted elsewhere.

THE EVOLUTION OF JUDICIAL REVIEW OF HEALTHCARE RESOURCE ALLOCATION

During the decade which separates the two editions of *Who Should We Treat?*, there was a distinct alteration in the approach of the courts to allocative questions in healthcare, which is neatly encapsulated by the following extracts from the respective texts:

> Judges have been extremely reluctant to become involved in the assessment of priorities and the allocation of health service resources.[7]

> Today, however, there is much greater willingness to scrutinise resource allocation decisions and, if needs be, to overturn them and to refer them back for reconsideration.[8]

Newdick illustrates this 'dramatic increase in the willingness of the courts to scrutinise the reasonableness of rationing decisions' by particular reference to two cases in which allocative choices were deemed unlawful.[9] In *R v North Derbyshire Health Authority, ex parte Fisher*,[10] the health authority had failed to give effect to Department of Health guidance on the provision of beta interferon for the treatment of multiple sclerosis, offering no reasons for so doing. And in *R v North West Lancashire Health Authority, ex parte A, D and G*,[11] the Court of Appeal, while noting that the setting of priorities for allocation of scarce resources was in principle lawful, ruled against the health authority on the bases that its policy with regard to provision of gender reassignment surgery effectively amounted to a 'blanket ban' which did not admit of the possibility of the presentation of exceptional circumstances, and that it had failed to indicate 'in broad terms' why this form of treatment had been assigned a low priority.[12]

To the decisions analysed by Newdick might also be added the legal challenge to the decision of the then Secretary of State for Health, Frank Dobson, to exclude sildenafil (Viagra) from availability on the

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7 Newdick (n 1 above) 122.

8 C Newdick, *Who Should We Treat? Rights, Rationing and Resources in the NHS* 2nd edn (Oxford University Press 2005) 93.

9 Ibid 102.

10 *R v North Derbyshire Health Authority, ex parte Fisher* (1997) 8 Med LR 327.

11 *R v North West Lancashire Health Authority, ex parte A, D and G* [2000] 1 WLR 977.

12 Ibid 1000 (Buxton LJ).

NHS, save in exceptional circumstances.[13] Here, the primary issue was compliance with EU law, in the form of the so-called 'Transparency Directive' which required 'a statement of reasons based on objective and verifiable criteria' in any instance in which a medicinal product was excluded from coverage on a national health system.[14] The Government's failure to provide this was deemed unlawful by the High Court when the matter was first litigated;[15] however, a subsequent statement which it provided to the European Commission, referring to the cost of providing the drug on the NHS but not establishing its priority vis-à-vis treatments for other non-life-threatening conditions, was held by the Court of Appeal to suffice to meet the 'fairly modest' degree of explanation required by the Directive.[16]

What unites these decisions is a judicial commitment to fair process in decision-making on the allocation of healthcare resources, an approach the origins of which lie in the *dictum* of Laws J (as he then was) in the High Court in the *Cambridge Health Authority* case, that health bodies making allocative decisions must 'do more than toll the bell of tight resources. They must explain the priorities that have led them to decline to fund the treatment'.[17] Courts will require rationing choices to be transparent and properly reasoned on the basis of evidence (albeit stopping short of comprehensive justification), and open to challenge by those who can demonstrate that they fall into an exceptional category.[18] Various explanations have been proffered for what Newdick calls this 'striking' expansion in judicial scrutiny,[19] the principles of which were subsequently given statutory effect in secondary legislation,[20] as well as being enshrined (in England) in the *NHS Constitution*.[21]

Newdick himself looks to jurisprudential evolution in public law, viewing the stance of the courts in these cases as amounting to a species of 'hard look' scrutiny informed by a judicial trend towards requiring

13 Discussed in K Syrett, 'Impotence or importance? Judicial review in an era of explicit NHS rationing' (2004) 67 Modern Law Review 289–304.

14 Directive 89/105/EEC, art 7(3).

15 *R v Secretary of State for Health, ex parte Pfizer Ltd* [1999] Lloyd's Med Rep 289.

16 *R (on the application of Pfizer Ltd) v Secretary of State for Health* [2003] 1 CMLR 19, para 27 (Buxton LJ).

17 *Cambridge Health Authority* (n 4 above) at 1065.

18 Discussed further below: see nn 95–97 and accompanying text.

19 Newdick (n 8 above) 98.

20 The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, SI 2012/2996, regs 34(2)(b), 35.

21 Department of Health and Social Care, *The NHS Constitution for England* (last updated August 2023). For further discussion, see n 118 below and accompanying text.

the giving of reasons for administrative decisions, a move away from the extreme deference of the *Wednesbury* test towards a more searching standard of review in which courts scrutinise the internal logic of the choices made, and a shift towards proportionality stimulated by the enactment of the Human Rights Act 1998.[22] By contrast, Syrett, while not overlooking these normative developments,[23] has suggested that prominent drivers were the changing nature of allocative decision-making in the NHS, coupled with the rise of evidence-based medicine, particularly in the form of clinical guidelines.[24] This is to say that the courts responded to the move towards explicitness in rationing choices grounded upon scientific evidence by imposing explanatory obligations upon allocative decision-makers which were consonant with this altered environment.[25] Finally, something of a middle ground is taken by Wang, who notes that the changed approach to judicial review was 'concomitant to a move towards explicit rationing in the NHS',[26] but notes that 'correlation is not causation',[27] preferring the view that:

> that courts interacted within a 'soup of influences' that created a context that made rationing more explicit 'about what' and that, through their rulings, they established a continuous policy dialogue with decision-makers in the NHS that contributed to make rationing explicit 'about why and how'.[28]

These authors, however, are all united in agreement that this judicial development is consistent with the framework of procedural justice devised by Norman Daniels and James Sabin to address the so-called 'legitimacy problem' which arises when decision-makers make difficult choices about the allocation of scarce healthcare resources.[29] This 'accountability for reasonableness' model posits that compliance with certain procedural criteria – namely, publicity, relevance, challenge and revision, and regulation/enforcement – will reduce suspicion, distrust and resistance to rationing decisions, even in situations where an individual may personally lose out. Wang (whose discussion is

22 Newdick (n 8 above) 97–98, 121–125, 127–128.

23 See K Syrett, *Law, Legitimacy and the Rationing of Health Care: A Conceptual and Comparative Perspective* (Cambridge University Press 2007) especially ch 5.

24 For discussion of the latter, see K Syrett, 'Healthcare resource allocation in the courts: a systems theory perspective' (2019) 70 Northern Ireland Legal Quarterly 111–129.

25 See Syrett (n 13 above) 297.

26 D Wang, 'From *Wednesbury* unreasonableness to accountability for reasonableness' (2017) 76 Cambridge Law Journal 642–670, 644.

27 Ibid.

28 Ibid 658.

29 See N Daniels and J Sabin, *Setting Limits Fairly: Learning to Share Resources for Health* 2nd edn (Oxford University Press 2008).

chronologically the latest and who thus addresses the broadest range of cases) expresses matters thus:

> These changes in the administrative decision-making reflect the fact that the denial of funding for a health intervention will hardly ever be upheld by courts if the decision and the grounds for it are not made public ('publicity'), based on sound evidence and reasonable policy considerations ('relevance') and if the opportunity for adequately challenging the policy or presenting a case for an exception is not given ('challenge'). Accordingly, the courts are guaranteeing that health care rationing decisions in the NHS will comply with the first three conditions for 'accountability for reasonableness' and are thus materialising the last condition ('regulation/enforceability').[30]

Read in this manner, the evolution of judicial review of healthcare resource allocation described in this section is a development to be welcomed; the courts may be viewed as facilitating good administrative decision-making in this context by contributing to ensuring enhanced public legitimacy for the 'tragic choices' which arise as a consequence of inevitable scarcity in healthcare.[31]

SOME PROBLEM CASES

However, the trend outlined in the preceding section also carries with it an implicit constraint upon judicial activism. The courts may, and should, act as overseers of *procedural justice* in rationing cases, but should not be drawn into setting priorities themselves. Auld LJ expressed this limitation concisely in the *North West Lancashire Health Authority* case, stating that 'the precise allocation and weighting of priorities is clearly a matter of judgment for each Authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible'.[32]

Dovetailing with the traditionally constrained reach of judicial review in English administrative law in general – that is, that courts should refrain from involvement in the *substance* of administrative decisions, restricting their role to scrutiny of process and assurance that the decision-maker is acting within its constitutionally allotted powers – there are several well-rehearsed reasons for abstinence in

30 Wang (n 26 above) 668. See also Syrett (n 13 above) 297–298; Syrett (n 23 above), *passim* but especially ch 4; K Syrett, 'NICE and judicial review: enforcing "accountability for reasonableness" through the courts?' (2008) 16 Medical Law Review 127–140; Newdick (n 6 above) 111.

31 See, generally, G Calabresi and P Bobbitt, *Tragic Choices* (WW Norton & Co 1978); and, in the particular context of the judicial review cases discussed here, see R James and D Longley, 'Tragic choices: *ex parte B*' [1995] Public Law 367–373.

32 See *R v North West Lancashire Health Authority* (n 11 above) 991.

this particular context. These can be classified under the heads of (lack of) institutional and constitutional competence.

Within the first category lie concerns as to judicial inexpertise in matters of the clinical and cost-effectiveness of treatments which underpin contemporary allocative decision-making in healthcare;[33] and as to the polycentric nature of rationing choices – that is, that enabling a particular individual to access a treatment or service in situations of scarcity carries opportunity costs for multiple unidentified individuals whose interests cannot adequately be represented in the adversarial arena of judicial proceedings. As for the second category, it is argued that decisions on the allocation of resources are inherently political in nature and are therefore properly assigned, under the doctrine of the separation of powers, to officials who are accountable to the public (or, at least, to those who must themselves account to elected representatives), rather than to unelected judges.

However, it is possible to identify a number of cases – each of which was decided subsequent to the publication of the second edition of *Who Should We Treat?* – in which courts, pushing against the boundaries of this restricted role, have seemingly intruded upon aspects of the allocative choice which appear to lie beyond judicial reach. A brief account of these follows.

In the earliest case, *R (Otley) v Barking & Dagenham PCT*,[34] a patient with metastatic colorectal cancer sought access to the drug Avastin, which was not licensed for use on the NHS in England and Wales. The trust's 'Difficult Decisions Panel' determined that the patient did not meet the criteria for exceptional funding. Pronouncing himself 'unimpressed by arguments which go to procedure',[35] Mitting J concluded that the panel had acted unlawfully, in part because it had overlooked a passage in NICE guidance which indicated that, in a small number of cases, 'prescription of Avastin in combination with chemotherapy was capable of reducing secondary tumours in the liver to such an extent as to make them operable and so to give a patient a slim chance of long term survival'.[36] Given that no other treatments were, in practice, available for the patient (a factor also misunderstood by the panel), this oversight was deemed irrational.

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33 For criticisms of this claim, see K Syrett, 'Courts, expertise and resource allocation: is there a judicial "legitimacy problem"?' (2014) 7 Public Health Ethics 112–122; L Morales, 'Judicial interventions in health policy: epistemic competence and the courts' (2021) 35(8) Bioethics 760–766.

34 *R (Otley) v Barking & Dagenham PCT* [2007] EWHC 1927 (Admin).

35 Ibid [25].

36 Ibid [12].

In *R (Ross) v West Sussex PCT*,[37] another cancer patient sought access to the 'relatively new' drug lenalidomide, which had not yet been appraised by NICE, in combination with two other drugs. Again, the High Court ruled that a failure to provide access to the treatment was unlawful. Here, the unlawfulness arose from misapplication of a policy which, in effect, required evidence of 'uniqueness' rather than exceptionality;[38] but also because of the manner in which the panel which reviewed individual funding cases had interpreted the evidence of the clinical efficacy and cost-effectiveness of the drug. In respect of the former, Grenfell J held that there had been a mistake of fact in a failure to appreciate that the results of a randomised controlled trial demonstrated much stronger evidence of effectiveness than the panel had acknowledged.[39] In turn, this error made it impossible to correctly assess the cost-effectiveness of the treatment. Furthermore, this evaluation was also irrational as a consequence of a failure to comprehend that the treatment would probably not be continued beyond four cycles if the patient failed to respond, by 'double counting' of those with partial and full responses to the treatment, and by a failure to consider the savings made by discontinuing the previous treatment given to the patient.[40]

In *S v NHS England*, there was similarly 'an altogether too restrictive application of exceptionality',[41] in respect of the provision of sodium oxybate for narcolepsy and cataplexy. The patient's individual funding request (IFR)[42] was rejected on the basis that, although there was evidence of a deterioration in her condition, it could not be determined 'what absolute benefit she might expect to receive nor how absolute benefit would compare with other patients, some of whom might be experiencing a deterioration'.[43] The commissioning body, NHS England, also noted that there was a need to guard against 'patients, patient groups or services who lobby being given undue priority'.[44] For his part, Collins J considered this 'to be a very rare case in which the decision-making has gone wrong',[45] taking the view that progressive deterioration in the patient's physical and mental health meant that

37 *R (Ross) v West Sussex PCT* [2008] EWHC 2252 (Admin).
38 Ibid [78].
39 Ibid [83]. This arose because the randomised controlled trials had demonstrated that lenalidomide was so effective that it was offered to patients in the control group, thus skewing the statistical results in a manner which was misunderstood by the panel.
40 Ibid [88].
41 *S v NHS England* [2016] EWHC 1395 (Admin) [35].
42 For further discussion of this process, see n 96 below and accompanying text.
43 *S* (n 41 above) [26].
44 Ibid [28].
45 Ibid [37].

she would benefit from the drug to a greater extent than others who did not respond to usual forms of treatment for the condition and that, as a consequence, the treatment would be cost-effective since her needs for other forms of medical treatment would correspondingly be reduced.[46] Unusually, rather than merely quashing the decision, the judge issued an interim order requiring the drug to be provided to the patient for a three-month trial period on the basis that any further 'decision to refuse the treatment could not be supportable'.[47]

The same policy on IFRs was at issue in the final case to be outlined here, *R(SB) v NHS England*,[48] in which access was sought to the drug Kuvan, which was not routinely commissioned by NHS England. In this instance, although the patient was deemed to have made out exceptional circumstances, NHS England's IFR panel argued that there was insufficient evidence of the drug's clinical effectiveness. Andrews J deemed this decision to be irrational, in that it was 'informed by error upon error',[49] notably a confusion between clinical effectiveness and the issue of how long a drug might work for;[50] relatedly, a consideration of 'benefit' (eg upon nutritional status and cognitive development) as distinct from 'effectiveness' in the achievement of clinical outcomes;[51] and a failure properly to comprehend the clinical evidence which was being presented by the patient, which resulted in the panel asking itself the wrong questions when evaluating the application.[52]

This brief account of case law should make it apparent that courts do not always restrict themselves to a role of oversight of fair allocative decision-making procedure, as proponents of the conjunction between judicial review and accountability for reasonableness, including the present author, have tended to suggest. Rather, the intervention of the courts in these cases is premised upon a (mis)understanding and (mis)interpretation of the evidence which informs the allocative choice (this is particularly evident in the first two cases discussed here); and a failure upon the part of the decision-maker to ask itself the 'right' questions based upon the information with which it has been presented (especially pertinent to the latter two cases).

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46 Ibid [34].
47 Ibid [36].
48 *R(SB) v NHS England* [2017] EWHC 2000 (Admin).
49 Ibid [67].
50 Ibid [56]–[59].
51 In this instance, a reduction in the levels of the amino acid phenylalanine in the blood: ibid [62]–[64].
52 Ibid [67], [85].

WHAT IS THE PROBLEM?

For Wang, these cases are explicable as part of 'an almost linear narrative … about how the case law has evolved from a very self-restrained review of health care rationing decisions towards one in which courts have constantly added new boxes that authorities had to tick for a rationing decision to withstand judicial review'.[53] He appears content to fit the two of the four cases which he covers, *Otley* and *Ross*, within the 'accountability for reasonableness' framework while not specifying precisely how they can be accommodated: it would appear, however, that he considers that judicial scrutiny that the decision is based in 'sound evidence' amounts to enforcement of the 'relevance' condition.[54]

The doctrinal vehicle through which this task is accomplished is the judicial review ground of (ir)rationality. As Newdick argues, the scope of this ground has itself expanded such that, in addition to the egregious, barely comprehensible decision with which this head of review has traditionally been concerned, 'a decision which can be seen to have proceeded by flawed logic' may be deemed to be unlawful.[55] This development can readily be explained because, within the contemporary law of judicial review, the ground of irrationality is not interpreted in a 'monolithic' manner,[56] but rather admits of variable standards of review beneath its 'ample cloak'.[57]

What is clear, however, is that arguments of this type bring courts much closer to the evaluation and weighing of those factors which contribute to the eventual allocative choice, and to matters about which there is often scope for reasonable disagreement between experts. That is, to utilise Auld LJ's terminology, many of the issues raised in these cases would appear to be 'matters of judgment'.[58] The frequency with which judges in these cases seek to deny that they are engaged in impermissible merits review might, paradoxically, be seen as indicative of their awareness that a fine line is being trodden.[59]

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53 Wang (n 26 above) 651.

54 Ibid 668. See also A Ford, 'Accountability for reasonableness: the relevance, or not, of exceptionality in resource allocation' (2015) 15 Medicine, Health Care and Philosophy 217–227.

55 Newdick (n 8 above) 97, citing *R v North & East Devon Health Authority, ex parte Coughlan* [1999] EWCA Civ 1871, [65] (Lord Woolf MR).

56 See Sir John Laws, '*Wednesbury*' in I Hare and C Forsyth (eds), *The Golden Metwand and the Crooked Cord: Essays in Honour of Sir William Wade QC* (Oxford University Press 1998) 186–187.

57 J Jowell and A Lester, 'Beyond Wednesbury: substantive principles of administrative law' [1997] Public Law 368, 371.

58 See n 32 above and accompanying text.

59 See *Otley* (n 34 above) [26]; *Ross* (n 37 above) [35]; *S* (n 41 above) [33], [35]; *SB* (n 48 above) [29].

This may also be viewed as controversial given that 'accountability for reasonableness' is a 'classic appeal to procedural justice',[60] whose very existence is premised upon the assumption that agreement upon the substantive basis of priority-setting decisions is unattainable (at least, in the absence of broad public deliberation upon the need for difficult choices in healthcare). As discussed further below,[61] the 'relevance' condition fits somewhat awkwardly within this model, but it should be noted that, in its original articulation, it relates to factors that '"fair-minded" people can agree are relevant to pursuing appropriate patient care under necessary resource constraints'.[62] This elastic formulation seems to correlate more closely to the traditional *Wednesbury* standard than the modified version of irrationality noted by Newdick: that is, it admits of a wide variety of potentially relevant values or evidence which might legitimately inform priority-setting choices, only excluding those which would be rejected by the 'fair-minded', in similar fashion to the notorious 'red hair' example cited by Lord Greene MR in that case.[63] Conversely, it is not designed to be so fine-grained as to rule out certain outcomes because of conflicting interpretations of evidence, or differing understandings of the precise priority-setting question which is at play in light of the information available to the decision-maker.

Wang is therefore correct to identify that courts have moved beyond *Wednesbury* as the standard of review in allocative decision-making in healthcare; but, contrary to the analysis he presents, it would seem that, at least in the cases discussed in the preceding section, the courts have also ventured beyond mere enforcement of the conditions of a model of procedural justice.[64] Furthermore, his depiction of the 'linear narrative' of the case law may also be called into question.[65] The intense judicial scrutiny of the decision-making process and the interpretation of evidence which characterises these cases is not always replicated elsewhere. In order to demonstrate this, it will be helpful to consider a further decision concerning availability of the drug Kuvan, which was at issue in the *SB* case.

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60 N Daniels, *Just Health: Meeting Health Needs Fairly* (Cambridge University Press 2008) 109.

61 See n 123 below and accompanying text.

62 N Daniels and J Sabin, 'The ethics of accountability in managed care reform' (1998) 17 Health Affairs 50–64, 51.

63 *Associated Provincial Picture Houses Ltd v Wednesbury Corporation* [1948] 1 KB 223, 229.

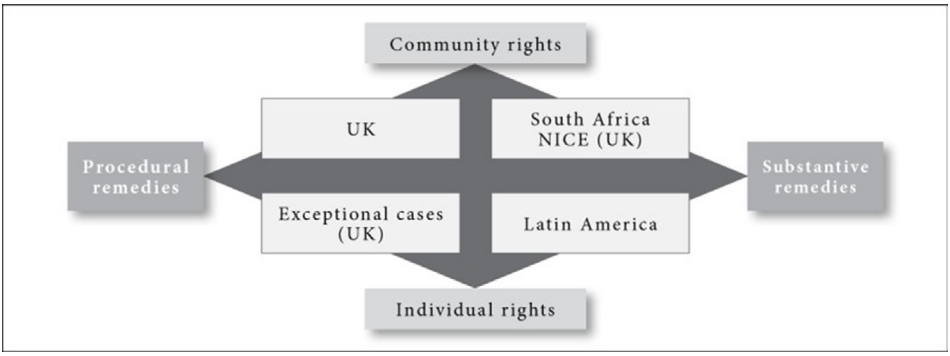
64 Wang (n 26 above) *passim*, but especially at 657–668.

65 Albeit that he qualifies this phrase with the word 'almost': Wang (n 26 above) and accompanying text.

In *R (Cotter) v NICE*,[66] the challenge consisted of an allegation that NICE had erred in law in choosing to evaluate Kuvan through its standard health technology appraisal process as distinct from the highly specialised technology process, the relevance of this being that the latter has a higher cost-effectiveness threshold of £100,000 per quality adjusted life year, meaning that a positive recommendation for use on the NHS is more likely to ensue. The claimant argued that NICE had misunderstood and misapplied criteria which determined which of its processes should be used – these relating to the size of the target patient group for the technology, the clinical distinctiveness of the group and whether the drug was expected to be used exclusively in the context of a highly specialised service – that is, that 'NICE did not ask itself the right questions'.[67] At first instance,[68] Cavanagh J observed that 'there is always a high threshold for irrationality cases'[69] and noted that 'those charged by NICE with taking this decision will generally be in a better position than a judge to make the evaluations that are inherent in the criteria'.[70] Accordingly, the court should show a degree of deference to the Institute's decision as to the process it chose to follow, since this 'require[d] the use of expert judgment, and the use of expert knowledge'.[71] On this basis, the judge held that the claim of irrationality had not been made out.

Aside from the obvious fact that access to the same drug was at issue in both of these cases,[72] there are clear similarities between *SB* and *Cotter*. In both cases, the defendant was a body operating at national level, which could be expected to draw upon a greater accumulation of expertise than is available to a more localised decision-maker such as clinical commissioning groups (or now, integrated care boards). Furthermore, the question of public law raised in each case was, in essence, identical: that is, whether the decision-maker had asked itself incorrect questions based upon its understanding of the evidence available, thus leading it to reach an 'invalid conclusion'.[73] However, the outcomes are strikingly different, with *Cotter* fitting more closely into what Wang labels 'the first stage' in the timeline of judicial review

66 *R (Cotter) v NICE* [2020] EWHC 435 (Admin).
67 Ibid [43].
68 The decision was upheld by the Court of Appeal: [2020] EWCA Civ 1037.
69 See *Cotter* (n 66 above) [70].
70 Ibid [65].
71 Ibid [63].
72 Albeit that, in *Cotter*, the pharmaceutical manufacturer had responded to NICE's decision by withdrawing Kuvan from the appraisal process, meaning that NICE had not yet been able to reach a decision upon whether to recommend it for use on the NHS: ibid [10], [12].
73 See *SB* (n 48 above) [29].



Source: C Newdick, 'Can judges ration with compassion? A priority-setting rights matrix' (2018) 20 Health and Human Rights 107–120, 110.

of healthcare allocation decisions, characterised by deference on the part of the courts.[74]

If this apparent anachronism is read alongside the seeming extension of judicial scrutiny in a more substantive direction, it would seem that the largely teleological analyses previously proffered by Wang and other authors, which connect the evolving case law with a growing judicial commitment to procedural justice consistent with the 'accountability for reasonableness' framework, warrant some reconsideration. In this regard, it is submitted that the 'Newdick matrix' can provide us with assistance in understanding developments.

INTO THE MATRIX

In one of his later works, the article 'Can judges ration with compassion?', Newdick seeks to 'assist clarity in the debate' on the appropriate role for judges in determining allocative questions in healthcare,[75] especially in light of concerns about the judicialisation of health which have particularly been expressed in relation to Latin America.[76] In order to do so, he devises a 'priority-setting rights matrix' by means of which differing ways in which the courts may supervise health service resource allocation can be visualised. The matrix is reproduced above:

In this matrix, the vertical axis differentiates between types of rights, with 'community rights' at the top, and individual rights at the bottom. The meaning of the latter term is relatively clear; by the former term,

74 Since this was not a direct challenge to an allocative recommendation by NICE (see n 72 above), the deferential stance adopted by the court is even more notable since the standard arguments for judicial reticence outlined in the previous section would seem to apply much less strongly.

75 Newdick (n 6 above) 108.

76 On this see O Ferraz, 'Health in the courts of Latin America' (2018) 20 Health and Human Rights 67–77.

Newdick is referring to collective interests of a solidaristic character which connect to notions of social citizenship,[77] including – but not necessarily restricted to – the familiar canon of social, economic and cultural rights. The horizontal axis denotes differing types of judicial remedy, procedural and substantive. Newdick writes that the former 'are more often appropriate to accommodate the politics inherent in promoting social welfare policy ... When others also have legitimate interests in the same resource, the courts must reflect our human interdependence by accommodating the competing rights and interests of other people.'[78]

As can be seen, this schematic enables Newdick to place certain jurisdictions within certain quadrants. He notes, however, that the United Kingdom (UK) system 'comfortably occup[ies] more than one compartment, depending on the circumstances of the individual case'.[79]

What can the matrix tell us about the 'problem cases' discussed herein and how these may be classified? A useful starting point is by means of the same comparison between the two cases concerning access to Kuvan which was drawn in the preceding section, although the absence of a finding of unlawfulness in *Cotter* makes this somewhat problematic, since no remedy was in fact awarded in that instance.

Nonetheless, it would appear that this case best fits within the top-left, collective-procedural quadrant. This is because it is to this category that Newdick assigns judicial review which 'acknowledges the constraints on the judiciary in terms of accountability and technical capacity'.[80] This clearly corresponds to Cavanagh J's expression of the need for deference given relative levels of institutional expertise.[81] In this context, the judicial approach taken is one which is consonant with 'accountability for reasonableness': 'the "right" is a guarantee of a fair and reasonable procedure ... Recognizing the opportunity costs inherent in public health promotion, the objective is to ensure that fair procedures have identified relevant matters and weighed and balanced them properly.'[82]

In contrast, Newdick himself assigns the *SB* case to the bottom-left, individual-procedural quadrant of the matrix.[83] He explains this category in the following terms:

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77 See C Newdick, 'The European Court of Justice, trans-national health care and social citizenship — accidental death of a concept?' (2009) 26 Wisconsin International Law Journal 844–867.

78 Newdick (n 6 above) 109.

79 Ibid 111.

80 Ibid 112.

81 See nn 70–71 above and accompanying text.

82 Newdick (n 6 above) 111.

83 Ibid 114.

> A comprehensive resource allocation system must also be capable of reassuring *individual* patients as to its competence and, essentially, its compassion and humanity … This is an *individual-procedural* right in the sense that it cannot guarantee access to treatment irrespective of cost. Yet it can reassure individuals that their individual circumstances have been considered properly in a way that is not possible when decisions are made at the community level.[84]

For Newdick, the remedy awarded in *SB* is 'strictly procedural' in that the court referred the decision back to NHS England for reconsideration, rather than granting access to the drug in question.[85]

This conclusion warrants some dissection for a number of reasons. First, the qualifying word 'strictly' hints at some hesitation as to the classification under the 'procedural' head. In part this is conceded by Newdick, who points out that the 'procedural' remedy in *SB* had a substantive *impact* in so far as the finding of unlawfulness prompted a reversal of the original decision to deny the claimant access to the treatment.[86] This taxonomical ambiguity is further compounded by the fact that Newdick places the case of *R (Rose) v Thanet Clinical Commissioning Group* within the 'community-substantive' quadrant notwithstanding that the remedy granted in that case was identical to that issued in *SB* (a quashing order, which necessitated reconsideration of the matter by the original decision-maker).[87]

Relatedly, and notwithstanding Newdick's reading of *Rose*, if we consider that reference back to the original decision-maker signals that a remedy is 'procedural' in character, it might be observed that this will generally be the case in the English law of judicial review given that courts are proscribed under the separation of powers doctrine from substituting their view for that initially reached.[88] It is different in a system in which some form of right to health receives constitutional protection, as Newdick acknowledges in reference to South Africa and Columbia, which he assigns to the substantive end of the axis.[89]

Hence, a classification according to *types of remedy* may not be sufficiently discriminating to distinguish between differing cases in this jurisdiction, although it should be noted that this is not Newdick's primary objective in his article. Arguably, the matrix needs to be three- or four-dimensional to capture the various nuances of the English

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84 Ibid emphases in original.

85 Ibid.

86 Ibid 114 and fn 44.

87 [2014] EWHC 1182 (Admin). See Newdick (n 6 above) 115.

88 In this regard the remedy awarded in *S* (n 41 above), which mandated that funding for the treatment be provided (albeit on an interim basis), appears problematic. See further n 127 below.

89 Newdick (n 6 above) 115–116.

case law since, in addition to the *impact* of the case, noted previously, the *standard of review* adopted by judges in allocative adjudication sometimes tends more towards the substantive than the procedural, as I have contended is the case in the instances discussed above.

Notwithstanding these concerns, the matrix can still function as a valuable analytical tool in respect of case law in the English courts. It serves to draw attention to the fact that, in certain cases, judges tend to construe the subject-matter of the claim as more collective or 'macro'-level in character; whereas in others they are much more attentive to the individual interests which are impacted by the particular allocative choice. Assignment to the former category (the top-left quadrant) tends to result in judicial deference, while adoption of a more individualistic focus (the bottom-left category) is more likely (although this is not inevitable) to result in judicial intervention in the allocative choice and accordingly carries with it the possibility that judges might stray towards impermissible merits review.

Application of the matrix thus permits for greater differentiation between allocative cases than the more linear, 'one size fits all' explanations that were discussed previously. This seems more congruent with the evolution of the jurisprudence itself.

However, there are important limitations to the utility of the matrix. In particular, while it is helpful in drawing distinctions between allocative cases, and can thus provide some insight into likely judicial responses, it does not enable us straightforwardly to comprehend *why* cases might be categorised in a particular manner. To return to the example discussed in this section, why is *SB* considered to be an 'individual-procedural' case, whereas *Cotter* seems more naturally to fall within the 'community-procedural' category? Both cases are brought to court by individuals whose important health interests have been adversely affected by the choice made by the decision-maker.[90] In both cases (as in every decision of this type, given the inevitability of scarcity of resources), there are collective consequences, in so far as any decision to allocate resources to the individual in question carries opportunity costs – that is, the 'alternative investments [that] could be made with the same healthcare resources'.[91] This therefore disrupts the collective activity of rational priority-setting for the benefit of the community as a whole, this being especially noticeable in instances such as these, where national-level bodies are involved. In sum, both cases necessitate the striking of a balance by the court between an

90 Cf *R v North West Lancashire, ex parte A, D and G* (n 11 above), per Buxton LJ at 997, describing 'a citizen's health' as an 'important interest'.

91 M Meltzer, 'Introduction to health economics for physicians' (2001) 358 The Lancet 993–998, 994.

individual claim and a wider collective interest. Yet, the two cases yield distinct outcomes.

It is, of course, plausible that these two cases are treated differently because the judges engage in backwards reasoning; that is, that the choice made in *Cotter* is upheld simply because it appears to be a more acceptable exercise of judgement on the part of the decision-maker than was the case in *SB*. It is certainly true, as Andrews J identified,[92] that there appeared to be multiple deficiencies in the decision-making of NHS England in the latter case, which would be likely to dispose the court to be much less sympathetic towards the position which it reached.

Nevertheless, the notion that cases can be 'retrofitted' into certain categories of the matrix depending upon the judge's preferred outcome feels unsatisfactory. Although such a conclusion does not divest the model of its value in demonstrating that all allocative cases should not be regarded as identical in character – and recalling that the matrix was not formulated primarily for the purpose of analysis of judicial review cases in England and Wales – the impact and quality of Newdick's scholarship is such that this author feels compelled to venture a further step. In the following section, I draw upon but develop the matrix, moving from the issue of classification of allocative cases and further exploring the complex question of why judges decide in particular ways.

A STEP BEYOND: SEEKING TO UNDERSTAND THE PROBLEM CASES

Importantly, the four problem cases outlined previously in this article share a common characteristic. In each case, the applicant had sought to argue that they amounted to an exceptional case, warranting a departure from the general policy not to fund the particular treatment which they had requested (with the support of their treating clinician). By contrast, in *Cotter*, no such argument was made: here, the claimant wished to gain access to the drug following her successful participation in a clinical trial.

The challenge from exceptionality, which is rooted in the hoary administrative law principle that there should be no fettering of discretion,[93] had its common law origins in the healthcare allocation context in the *North West Lancashire Health Authority* case, noted

92 See n 49 above and accompanying text.

93 See *R v Port of London, ex parte Kynoch Ltd* [1919] 1 KB 176; *British Oxygen Co Ltd v Minister of Technology* [1970] UKHL 4.

above,[94] and was given statutory effect in 2012.[95] In the NHS in England, it now takes the form of the IFR process, operated both by local decision-makers and, in relation to the specialised services which it nationally commissions (and which were at issue in both the *S* and *SB* cases), by NHS England.[96]

Of course, the activation of an IFR does not divest an allocative decision of its collective consequences; there remain significant opportunity costs in according resources to the applicant, as NHS England notes in respect of its commissioning responsibilities:

> Funding for additional treatments outside the prioritisation process can only be done by reducing the funding that is available for other established treatments. There is no allocated separate budget to meet the costs of providing treatments agreed through the IFR process. It is because of this that very careful consideration is required before the decision is taken to fund a treatment that is not usually available for an individual.[97]

In short, IFR cases still necessitate the striking of a balance between the individual claim and the broader collective interest. In each of these cases, the original allocative decision-maker has, in effect, opted for the latter over the former.[98]

Turning now to consider treatment of these cases in court, the matrix assists us in understanding the probable orientation of the judges. The IFR encourages a focus upon the circumstances presented by the individual. While the courts have been clear that it is not necessary for the applicant to demonstrate that they are in a unique position,[99] there must nonetheless be a departure from the norm which inevitably draws

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94 See n 11 above and accompanying text.

95 The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, SI 2012/2996, reg 34(2)(b), as amended by the Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022, SI 2022/634.

96 For the latter, see *NHS England, Commissioning Policy: Individual Funding Requests*, PR2086 (8 February 2023). Responsibility for such commissioning will lie elsewhere once NHS England is abolished.

97 Ibid 3.

98 Note, however, that in *SB*, the patient's exceptionality claim was (eventually) accepted; but NHS England refused to provide funding given its doubts as to the clinical effectiveness of the treatment. This reflects the decision-maker's preference for the collective interest over the individual in that scarce resources would be better allocated to (likely successful) treatment of other, unspecified, conditions than to an identified individual who was unlikely to benefit.

99 See *Ross* (n 37 above) [77]; *S* (n 41 above) [12].

attention to the clinical particularities of the case.[100] For example, in the *S* case, Collins J noted that the patient was 'suffering from a particularly severe form of her condition. Her condition is rare, and her failure to respond to the usual treatment is also rare. But she is in a very rare situation in that she suffers from a particularly rare form of the condition.'[101] It thus seems appropriate, as already noted in respect of *SB*, to assign the four problem cases analysed in this article to the bottom-left quadrant of the matrix, Newdick's 'individual-procedural' category.

As discussed in the preceding section, judicial decisions in this category tend to be less deferential towards the allocative decision-maker. However, this still begs the question. Since *any* allocative case entails striking a balance between individual and collective, *why* is it that judges appear more likely to favour individuals in situations where the IFR process has been utilised? Addressing this point requires us to consider psychological and doctrinal factors that are not discussed by Newdick.

First, in so far as it effects a degree of individuation in the allocative decision, the IFR may reinforce particular psychological tendencies to which judges, as well as other decision-makers, may be prone. In this context, Hofmann has noted that rational priority-setting choices may be distorted by a number of 'biases' which may lead to 'perceptual distortion, inaccurate judgment, illogical interpretation'.[102] An important example which he cites is the 'identifiability and singularity effect', which he describes as occurring:

> when a single patient in front of the health care professional or on the front-page of the newspaper emotionally 'takes priority' over the many thousands that also may be in need … When the individual and proximate patient trumps all non-present and more remote patients general priority setting principles, such as justice and equity, are undermined … the singularity effect may trump priority setting principles, such as severity, effectiveness, and efficiency, and bypass established procedures and hence distort priority setting.[103]

This phenomenon has its roots in the:

> stronger emotional reactions elicited by an identified individual … empathic emotions, such as sympathy, compassion and distress at the plight of another are preconditioned on adopting the other person's

100 In *R (Condliff) v North Staffordshire PCT* [2011] EWHC 872 (Admin), it was determined that it was lawful to exclude social factors in a consideration of exceptionality.

101 See *S* (n 41 above) [34].

102 B Hofmann, 'Biases distorting priority setting' (2020) 124 Health Policy 52–60, 53.

103 Ibid.

> perspective and imagining how he or she feels. This is more likely to occur when an individual is identified rather than anonymous or statistical.[104]

In respect of allocation of healthcare resources, it connects to the 'rule of rescue', which may be defined as the 'obligation to help an individual whose life is imminently at risk, where the intervention is relatively costly and therefore does not maximise the expected benefit we can produce with the resources at our disposal'.[105] Identifiability has frequently been cited as a rationale for this potent psychological intuition,[106] although it is not clear that this should in fact amount to a morally relevant factor in allocative decision-making.[107]

As Sinclair points out, the IFR process fundamentally entails identifiability, which has the potential to lead to bias in the allocation of resources. Applying his analysis, the initial decisions reached in these four cases can be seen as normatively justified, because 'intuitively it would seem quite reasonable for the [IFR] panel to apply the same cost-effectiveness criteria as are applied in standard commissioning decisions applying to unidentified patients'; any other approach would be unfair to those who have not been identified.[108]

Conversely, the rulings of the courts in these four cases might be read as instances in which the singularity and identifiability effect has led the judges to a 'perceptual distortion' in favour of each claimant.[109] As Lewinsohn-Zamir and colleagues argue, there is no reason to presume that judges are immune from the emotive responses elicited by an identified individual.[110] Indeed, certain statements in these four cases, such as 'No one can completely put aside the human element of a case like this'[111] and 'I have, as anyone would, enormous sympathy for the claimant',[112] point towards exactly such a psychological reaction

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104 D Lewinsohn-Zamir, I Ritov and T Kogut, 'Law and identifiability' (2017) 92 Indiana Law Journal 505–555, 514.

105 S Sinclair, 'Explaining rule of rescue obligations in healthcare allocation: allowing the patient to tell the right kind of story about their life' (2022) 25 Medicine, Health Care and Philosophy 31–46, 31.

106 See eg D Hadorn, 'Setting health care priorities in Oregon: cost-effectiveness meets the rule of rescue' (1991) 265 Journal of the American Medical Association 2218–2225; R Cookson, C McCabe and A Tsuchiya, 'Public healthcare resource allocation and the rule of rescue' (2008) 34 Journal of Medical Ethics 540–544.

107 See Sinclair (n 105 above); J Mckie and J Richardson, 'The rule of rescue' (2003) 56 Social Science and Medicine 2407–2419.

108 Sinclair (n 105 above) 33. Given the outcome in *SB* (see n 48 above), clinical effectiveness is also relevant here.

109 Hofmann (n 102 above) 53.

110 Lewinsohn-Zamir et al (n 104 above) 533.

111 *Ross* (n 37 above) [4] (Grenfell J).

112 *S* (n 41 above) [33] (Collins J).

on the part of the judges, even if they are ostensibly balanced by claims of judicial objectivity.[113]

Moreover, the propensity of judges to succumb to the singularity and identifiability effect is exacerbated by the nature of adjudication as a form of law-making. Distinctly from the act of legislating, the identifiability effect is an inherent facet of the adjudicative process,[114] especially in systems where that process takes an adversarial form. Procedural requirements, such as standing, reinforce a judicial tendency to favour the identified litigant over alternative, unidentified, potential recipients of healthcare resources.[115]

Additionally, there is a significant development of a more doctrinal variety. In their survey of the evolution of the doctor–patient relationship in *Montgomery v Lanarkshire Health Board*, Lords Kerr and Reed observe that 'patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession'.[116] In part, this development is reflected in the discourse of 'rights' which pervades the *NHS Constitution for England*.[117] The 'constitutional right' which is most pertinent to the present context is expressed as follows:

> You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.[118]

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113 In *Ross* (n 37 above), Grenfell J remarked of the 'human element' that 'it cannot be allowed to dictate the result. My approach has to be to decide whether or not the decision can be successfully challenged on clear and laid down principles' (n 111 above). Similarly, in *S* (n 41 above), Collins J said 'I am conscious that it is not for me to strike down the decision in this case because I believe that it was too harsh' (n 112 above).

114 Lewinsohn-Zamir et al (n 104 above) 507.

115 See I G Cohen, 'Identified versus statistical lives in US civil litigation: of standing, ripeness, and class actions' in I G Cohen, N Daniels and N Eyal (eds), *Identified Versus Statistical Lives: An Interdisciplinary Perspective* (Oxford University Press 2015). The relative elasticity of the 'sufficient interest' test in the law of judicial review in England and Wales (as compared with the approach adopted by US courts) has tended to render this factor somewhat less impactful, although a growing turn towards procedural rigour has been recently identified: see L Marsons, 'Crossing the t's and dotting the i's: The turn to procedural rigour in judicial review' [2023] Public Law 29–38.

116 *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [75].

117 Department of Health and Social Care (n 21 above).

118 Ibid.

This 'right' is drawn from the common law cases discussed above,[119] and it appears compatible with Wang's reading of the evolution of the jurisprudence as reflective of 'accountability for reasonableness' in so far as it encompasses both the publicity and relevance conditions of the model.[120] On this analysis, the existence of such a right – which, it should be noted, was not explicitly articulated in any of the four problem cases analysed here – reinforces the classification in the bottom-left quadrant of the matrix. That is, this is an 'individual procedural' right and, as such, judicial intrusion into the merits of allocative decision-making need not follow.

Nonetheless, two factors might tend to push judges towards the right-hand portion of the Newdick matrix (the 'individual-substantive' quadrant). First, awareness of the requirement that local decisions should be made 'rationally' opens up the possibility of a judicial 'hard look' into the understanding, evaluation and application of evidence under the guise of a broader reading of the irrationality ground, as discussed above.[121] This does not appear to be consonant with Daniels and Sabin's original construction of the 'relevance' condition in accountability for reasonableness,[122] and would appear to support the view of certain authors that this condition is sufficiently imprecise and malleable that it can be interpreted and applied in a manner that is not proceduralist in orientation.[123]

Secondly, while as a matter of *legal* status, this and other 'rights' contained in the *NHS Constitution* are more closely akin to 'relevant considerations' for the purpose of judicial review,[124] there is profound *discursive* significance in the particular formulation which has been adopted. This is because, as Nedelsky reminds us, 'rights talk' connects at a fundamental level with a 'powerful legacy of liberal political thought in which rights are associated with a highly individualistic conception

119 See Department of Health and Social Care/Public Health England, Handbook to the NHS Constitution for England (updated 1 October 2023).

120 Wang (n 26 above) and accompanying text.

121 See nn 55–57 above and accompanying text.

122 See Daniels and Sabin (n 62 above) and accompanying text.

123 See eg A Friedman, 'Beyond accountability for reasonableness' (2008) 22 Bioethics 101–112, especially at 107–108; A Rid, 'Justice and procedure: how does "accountability for reasonableness" result in fair limit-setting decisions' (2009) 35 Journal of Medical Ethics 12–16, especially at 13; 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 469–488, especially at 481.

124 See Health Act 2009, s 2, which establishes a duty to have regard to the *NHS Constitution*. For a recent instance in which this duty was held to have been fulfilled, see *R (AA) v NHS Commissioning Board* [2023] EWHC 43 (Admin), [2023] EWCA Civ 902 (long wait times for treatment; Board was 'well aware' of the issue and was taking steps to address it).

of humanity ... indeed the "rights bearing individual" may be said to be the basic subject of liberal political thought'.[125] This serves further to reinforce the identifiability effect, focusing judicial attention on the 'wronged' individual. Moreover, it raises the possibility that, as a 'right', that individual's interest should be understood and enforced as a 'trump over some background justification for political decisions that states a goal for the community as a whole';[126] in this instance, the scarcity-driven need to set priorities for allocation of healthcare resources for the population. This, of course, is the problematic mode of judicial intervention which has been witnessed in jurisdictions in Latin America, as Newdick observes.[127]

To sum up, these problem cases may plausibly be understood as instances in which the judges, operating in a legal and health policy environment in which patients are now constructed as rights-holders, tend to favour an identified individual with particular circumstances articulated through the IFR process, whose plight arouses profound emotions of compassion and sympathy. This can lead them to stray from acceptable procedural review in the direction of more questionable substantive scrutiny, albeit that the inherent pliability of the irrationality ground of judicial review somewhat disguises that this step has been taken.

CONCLUSION

Both in the UK[128] and across the globe,[129] health systems continue to struggle to meet demand, even in 'normal', non-pandemic times. In these circumstances, it seems certain that there will be on-going resort to courts as disappointed patients attempt to secure access to healthcare services and treatments that have been denied or restricted on grounds of cost.

Future analysts of this phenomenon would do well to look to the groundbreaking work of Chris Newdick. As this article has sought to demonstrate, this continues to yield valuable insights which can assist

125 J Nedelsky, 'Reconceiving rights as relationship' (1993) 1 Review of Constitutional Studies 1–26, 12.

126 R Dworkin, 'Rights as trumps' in A Kavanagh and J Oberdiek (eds), *Arguing about Law* (Routledge 2009) 335.

127 Newdick (n 6 above) 116–117. This is not, of course, to suggest that the English courts have engaged in overreach on the scale seen in Latin America. Nonetheless, the drift towards the bottom-right quadrant of the matrix is demonstrated by the award of a substantive remedy in *S*, albeit only on an interim basis for three months: see n 47 above.

128 See eg Audit Scotland, *NHS in Scotland 2023*, AGS/2024/3 (2024).

129 See eg C Rauh, 'Why healthcare systems are in chaos everywhere' *The Economist* 21 January 2023.

greatly in the understanding of this contentious and often complex area of law and public policy. While – as here – there may on occasion be a need for some development and supplementation, the relevance and resonance of Newdick's scholarship is unquestionable and calls for enduring gratitude on the part of those working within this field.

Northern Ireland
Legal Quarterly
Vol. 76 No. 1 (2025) 75–102
Articles DOI: 10.53386/nilq.v76i1.1150

The boundaries and goals of legal scholarship within health of the public research

John Coggon

University of Bristol*

Correspondence email: john.coggon@bristol.ac.uk.

ABSTRACT

This article explains, maps, and critically explores the tasks and aims of legal scholarship within, to use the phrase of the Academy of Medical Sciences, transdisciplinary 'health of the public' research. It does so with a view to explaining what legal scholarship can bring to, and also how it may be shaped by, such research. The article considers developments in understandings and focus of public health law scholarship, especially as these have gained renewed force with *The Lancet*–O'Neill Commission on the legal determinants of health. It presents roles for legal analysis in relation to questions of law as a practice, as well as a discipline that works through social sciences and humanities methods and approaches. In evaluating legal scholarship's place within health of the public research, the article leads to an argument that greater attention should be given to the incorporation of questions concerning values and social justice. These are important – and more widely acknowledged – issues, and ones that are key to the rigour of research agendas that aim directly to promote goals of creating healthier, fairer societies.

Keywords: legal determinants of health; legal scholarship approaches; public health; public health law; transdisciplinary research.

* This work was made possible by the Tackling Root Causes Upstream of Unhealthy Urban Development consortium, award reference: MR/S037586/1, supported by the UK Prevention Research Partnership, which is funded by the British Heart Foundation, Cancer Research UK, Chief Scientist Office of the Scottish Government Health and Social Care Directorates, Engineering and Physical Sciences Research Council, Economic and Social Research Council, Health and Social Care Research and Development Division (Welsh Government), Medical Research Council, National Institute for Health Research, Natural Environment Research Council, Public Health Agency (Northern Ireland), The Health Foundation and the Wellcome Trust.

INTRODUCTION

This article's purpose is to explain and account for the places and roles of legal scholarship within broad, transdisciplinary research agendas that are focused on the health of the public. In so doing, it aims in turn to argue how we should best envisage academic law's place within organised efforts to create socio-structural conditions that are conducive to better, fairer health opportunities and outcomes. In other words, I am not looking centrally here at any and all legal scholarship that addresses questions concerning (public) health. Rather, I am focused primarily on the contribution of, and effect on, legal studies when they are incorporated within research agendas that are designed with both of these two characteristics: first, transdisciplinary research goals; and secondly, practical aims to generate better, fairer health outcomes at societal levels.

I take the article's framing of 'health of the public' research from the agenda-setting report of the Academy of Medical Sciences (AMS), *Improving the Health of the Public by 2040: Optimising the Research Environment for a Healthier, Fairer Future*.[1] I explain what that entails in the next section of this article. I note here, though, how its nature is reflected in the large, transdisciplinary research project from which the current article is an output: *Tackling Root Causes Upstream of Unhealthy Urban Development* (TRUUD).[2] In that project, which is funded by the United Kingdom Prevention Research Partnership (UKPRP),[3] we have engaged legal analysis as just one part of a vast suite of research and applied disciplinary expertise. The span of that expertise includes (but is not exhausted by reference to) economics, engineering, government, health sciences, management, policy studies, real estate, spatial planning, and urban development. The work has incorporated expertise in public engagement and co-production, and both university-based and embedded researchers. It has sought to generate understanding of, and promote better practical outcomes from, the complex systems that shape England's cities (taking Bristol and Greater Manchester as case studies). At the same time, it has also generated reflective and research-led discourses on the *doing* of impact-oriented, transdisciplinary health-focused research.[4] The current article may be seen as a contribution to that latter aspect.

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1 Academy of Medical Sciences, Improving the Health of the Public by 2040: Optimising the Research Environment for a Healthier, Fairer Future (AMS 2016).

2 See TRUUD website for further details.

3 See UKPRP website for further details.

4 See eg Daniel Black et al, 'Operationalising a large research programme tackling complex urban and planetary health problems: a case study approach to critical reflection' (2023) 18 Sustainability Science 2373–2389.

The article may also be viewed as a focused advancement of the applied agendas set in *The Lancet*–O'Neill Institute report, 'The legal determinants of health: harnessing the power of law for global health and sustainable development'[5] (which I describe more fully below). The discussion builds through four sections, which together aim to provide depth in understanding of the tasks of and for law, and some critical challenges that I argue need to be examined in relation to them. In the next section, I briefly outline key points from the AMS report. In the third section, I go on to explain how a focus has developed on the idea of 'legal determinants of health' within broader, longer-established research discourses concerning the social determinants of health. In particular, that section argues that the central conceptual drivers within such research are governance (broadly conceived) and responsibility (conceived by reference to causality, agency/power, and ethical obligation). The fourth section then provides a 'map' of legal scholarship within health of the public research. This highlights how law may be conceived as a practical discipline, social sciences, and humanities, eliciting doctrinal understandings, empirical or 'lived' understandings, and critical and philosophical understandings. These all contribute to what may be known about or by reference to law, including in the framing of practical agendas for change. And they both give to and take from their being embedded within health of the public research programmes. Finally, given this, the fifth section draws from that discussion observations regarding subordinations of law and laws: specifically, a practical subordination to empirical rather than formal concepts of governance; and, more philosophically, a normative subordination of legal justice and principles to broader-reaching claims regarding specific concerns in social justice. It advances this discussion in the spirit of constructive criticism. In particular, I argue how legal scholarship's contribution needs in part (and continually) to address and scrutinise the normative concepts and underpinnings to health of the public research, as well as values relating to health and health inequalities as societal and political goals, and the means of promoting them as such.

In closing this introduction, I note that the article has been developed as part of TRUUD, but also as a part of a celebration of the career of Professor Chris Newdick. Chris has been a pioneer in health law scholarship; one whose contributions' significance has been defined in part by its disruption of 'mainstream', individualistic areas of focus in studies of law and health. His work consistently demands that attention to ethical values be made against appreciation of social,

5 Lawrence O Gostin et al, 'The legal determinants of health: harnessing the power of law for global health and sustainable development' (2019) 393(10183) *The Lancet* 1857–1910.

economic, and political realities. He is one of the field's long-standing and pre-eminent critics of a theoretically impoverished and practically inequitable preoccupation with what amounts, in its generalised essence, to the safeguarding only of civil and political rights. In place of that, he has argued for a focus on broader social and institutional structures and systems, within and far beyond the healthcare sector. He has a keen concern for realisable social justice, looking at power dynamics, and identifying socially (including legally) created inequalities, disempowerments, and disadvantage. I note the influence of papers such as Chris's 2017 essay 'Health equality, social justice and the poverty of autonomy',[6] which I visit in the below analysis. That work exemplifies well many of the ideas concerning legal scholarship that I advance in this article: it provides a model that conveys qualities and aims that I will argue are essential to legal research within transdisciplinary 'health of the public' research agendas.

TRANSDISCIPLINARY 'HEALTH OF THE PUBLIC RESEARCH' AND APPROACHING THE PLACE OF LAW WITHIN IT

In *Improving the Health of the Public by 2040*, the AMS explains what it means by 'health of the public' research, and why it is oriented around novel paradigms:

> Public health research has provided fundamental insights into human health and how it can be improved. …
>
> Yet there remains much we do not know about the complex array of interlinking factors that influence the health of the public, and about how to prevent and solve the many health challenges we face as a population, including obesity, diabetes, dementia, depression, cancer and persisting emerging infections. …
>
> Biomedical research as currently conducted does not have the capacity to address these increasingly diverse and complex issues that transcend disciplinary, sectoral and geographical boundaries. We need to move towards a 'health of the public' approach, involving disciplines that would not usually be considered to be within the public health field; an approach integrating aspects of natural, social and health sciences, alongside the arts and humanities, which directly or indirectly influence the health of the public. We must drive forward an ambitious research agenda to realise the aspirations of successive policymakers and leaders of health and social care—aspirations to shift our focus to prevention and early intervention at scale, and to thereby optimise the use of resources.[7]

6 Christopher Newdick, 'Health equality, social justice and the poverty of autonomy' (2017) 12 Health Economics, Policy and Law 411–433.

7 AMS (n 1 above) 4–5.

As indicated in this article's introduction, there are two aspects to the AMS's framing that are of particular interest. First is the commitment to transdisciplinarity, and the second is its having a view to particular sorts of demonstrable, real-world impact. Regarding transdisciplinarity, the AMS urges, for instance, that health of the public research 'should draw on the skills and expertise of a wide range of disciplines outside the traditional sphere of public health research, from environmental sciences to law to ethics to engineering.'[8] In clarifying understanding of transdisciplinary research, the report's glossary explains how we might contrast, respectively, multidisciplinarity, interdisciplinarity, and transdisciplinarity:

- Multidisciplinarity: An 'additive' approach; uses knowledge from different disciplines but remains within their boundaries.
- Interdisciplinarity: An 'interactive' approach; analyses, synthesises and brings together links between disciplines into a coordinated whole.
- Transdisciplinarity: A 'holistic' approach; integrates the natural, social and health sciences in a humanities context, working across traditional discipline boundaries.[9]

As regards societal impact, we see even within the title of the report the aim: better and fairer health outcomes. Emphatically, these are value-driven goals, demanding assumptions both about political priorities (ie that health itself is a political value, and so is addressing unfair health inequalities) and practical epistemological understandings (ie that influences on health, for better and worse, exist within a distal causal framework of socially generated and amendable systems and structures). Finally, it should be noted that as a paradigm-shifting, agenda-setting work, the AMS report is not a merely hopeful statement of ambition. It is a transformative document. Part of its subsequent realisation is found in the establishment of the UKPRP; an ambitious, multi-funder scheme that supports large-scale development of impactful, transdisciplinary, health of the public research.[10]

The aims of generating health of the public research programmes is revolutionary. But this is not to deny the pre- or concurrent existence of a vast web of research on the public's health from 'non-public health' disciplines. Nor is it to deny the reality of more diffuse and (as it were) independently organic and gradually emerging scholarly

8 Ibid 56.

9 Ibid 116. In advancing these characterisations, the AMS report cites Bernard C K Choi and Anita W P Pak, 'Multidisciplinarity, interdisciplinarity and transdisciplinarity in health research, services, education and policy: 1. Definitions, objectives, and evidence of effectiveness' (2006) 29(6) Clinical and Investigative Medicine 351–364.

10 See UKPRP website.

developments that were and would anyway have been in train. Some matters, methods, and approaches that are new within 'public health research' are not new to the 'not usually considered' disciplines that are drawn in. Similarly, it is just plain that more traditional 'public health research' has not held an exclusive grip on questions concerning the public's health: even if underplayed within perceptions of public health research, sustained and long-standing scholarly attention has been given to the health of the public from across academic disciplines.[11]

My focus in this article is on the 'shaping' done to and by legal scholarship within concerted, health of the public research agendas as presented in these opening paragraphs. In approaching the idea of shaping to and by legal scholarship, I am influenced by the framing of Mathias Siems and Daithí Mac Síthigh, who present legal research as overall covering three domains: law, respectively, considered as a practical discipline, as social sciences, and as humanities.[12] In this sense, when taking an *intra*disciplinary view of legal scholarship, I envisage law as an area of study that implicates methods and approaches from distinct and – when looking across the piece – radically diverse non-legal disciplines; with that radical diversity extending to understandings of evidence or data, and thus the foundation of epistemological claims that lie across quite distinct planes.[13] And I envisage law as a discipline that evidences selectivity – whether this is concerted or not – in relation to *which* practical matters get looked at, and what gets ignored.

More antagonistically, against this framing, law is an area of study within which tussles for predominance between different methods, approaches, and topics of practical concern play out. This includes tussles over understandings and characterisations of the idea of law and the meanings and import of laws themselves. It also includes tussles over which extra-legal framings and understandings might be brought to bear; for instance, different commitments regarding questions of political morality or social justice, or different points of empirical focus, such as on differential impacts of laws amongst different groups and communities. Perhaps more benignly, the framing that I am giving also presents law as an area of study within which different scholarly zeitgeists and wider socio-political

11 Cf 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).

12 Mathias Siems and Daithí Mac Síthigh, 'Mapping legal research' (2012) 71(3) Cambridge Law Journal 651–676.

13 Cf John Coggon, 'Legal, moral and political determinants with the social determinants of health: approaching transdisciplinary challenges through intradisciplinary reflection' (2020) 13(1) Public Health Ethics 41–47.

circumstances themselves can capture and direct programmes of research. Such may certainly be said of the space that 'health law' occupies. In topic, it has predominantly seen a focus on individual-level questions within health*care*, and primarily there in narrower relation to medical practice.[14] In methods and approaches, a privileged place has been given to framings and assumptions from moral philosophy; particularly as found in biomedical ethics. And that, in turn, has presented presumptive prominence to negative rights (ie rights of non-interference), has stimulated commitments to formal equality of opportunity over a focus on inequalities in substantive experiences and outcomes, and has accordingly galvanised conflations of 'empowerment' with an absence of imposed legal obligations and constraint.[15]

In short, I see legal studies writ large, and scholarship within health law more specifically, as radically diverse, but also subject both to internal trends and extrinsic forces that come to define its aims, ambitions, approaches, and understandings. And, as indicated, it is applied across a vast but never exhaustive practical domain. Legal scholarship is its own social phenomenon, And it plays out within structures of political economy inside the university sector and more broadly. It is shaped by the more and less visible hands that all that implies. My analysis of its engagement with health of the public research should be considered against that outlook.

'LEGAL DETERMINANTS' WITHIN HEALTH OF THE PUBLIC RESEARCH THAT CENTRES ON RESPONSIBILITY AND GOVERNANCE

Our natural and socially generated (including built) environments all influence our health outcomes and opportunities, both in the immediate and across longer-term time frames. The importance of health as an individual but also a collective value prompts questions of when and how potential or amendable influences on health give rise to political imperatives. It invites analysis of the philosophical question 'what makes health public?',[16] and in more concrete terms

14 See further Anne-Maree Farrell et al, *Health Law: Frameworks and Context* (Cambridge University Press 2017).

15 John Coggon and Beth Kamunge-Kpodo, 'The legal determinants of health (in)justice' (2022) 30(4) Medical Law Review 705–723; John Coggon and Beth Kamunge-Kpodo, 'Health inequalities, law, and society' in Chloe Romanis, Sabrina Germain and Jonathan Herring (eds), *Diverse Voices in Health Law and Ethics: Important Perspectives* (Bristol University Press 2025).

16 John Coggon, *What Makes Health Public? A Critical Evaluation of Moral, Legal, and Political Claims in Public Health* (Cambridge University Press 2012).

a scheme of explaining what is needed practically in 'making health public'.[17] Insofar as we are focused on how social structures, norms, and institutions are implicated in the exploration of these questions, a key concern is directed at the actors, embedded within systems and structures, that determine 'upstream causes' or the 'causes of causes' of better and worse health. Within this domain, we see an urgency in focusing on 'primary preventive' measures; namely, measures that would forestall or limit the onset of ill health in the first place.[18]

It should be noted that understanding and recognition of the import of avoidable, upstream determinants of ill health are long established in national and global policy discourses.[19] By taking 'population approaches' in health sciences research, causal factors are discernible that are invisible at individual levels; for instance, the health effects of smoking tobacco or higher-level consumption of salt.[20] Works in social epidemiology, furthermore, allow such population-level research to track the incidence of disease across different *axes* of social positionality: historically, with a view especially to relative health opportunities and outcomes by reference to socio-economic position, but with increasing focus over time on other factors and characteristics,

17 John Coggon and Lawrence O Gostin, 'The two most important questions for ethical public health' (2020) 42(1) Journal of Public Health 198–202; Peter Littlejohns et al, *Making Health Public* (Bristol University Press 2023).

18 Primary prevention is contrasted in the health sciences literatures with secondary and tertiary prevention. The AMS report (n 1 above) 117 provides the following definitions: 'In terms of health, prevention involves a range of interventions aimed at reducing risks or threats to health. Primary prevention aims to prevent disease or injury before it occurs, for example by immunisation, health education and preventing exposure to hazards. Secondary prevention aims to reduce the impact of a disease or injury which has already occurred, for example by detecting, diagnosing and treating as soon as possible as well as taking steps to prevent reoccurrence. Regular screening programs, such as mammograms for detecting breast cancer, are an example. Tertiary prevention aims to reduce the impact of a disease or illness which is ongoing and has long-term effects, by helping people to manage often complex health problems and injuries to maximise their quality of life and life expectancy. Rehabilitation programs and support programs are forms of tertiary prevention.'

19 See eg *Inequalities in Health: Report of a Research Working Group* (Department of Health and Social Security 1980); Commission on Social Determinants of Health, *Closing the Gap in a Generation: Health Equity through Action on the Social Determinants of Health – Commission on Social Determinants of Health Final Report* (World Health Organization 2008); Michael Marmot et al, *Fair Society, Healthy Lives: The Marmot Review* (The Marmot Review 2010); Michael Marmot et al, *Health Equity in England: The Marmot Review 10 Years On* (Institute of Health Equity 2010).

20 Geoffrey Rose, 'Sick individuals and sick populations' (1985) 14(1) International Journal of Epidemiology 32–38; 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).

such as geographical positioning,[21] age, disability, ethnicity, gender, and race (giving rise in turn to questions then of intersectionality and compounded inequity).[22] As may perhaps be implicit in this, developments in relation to research on social determinants of health have come with a broad expansion to its disciplinary inclusiveness.[23] In its sum, scholarship in this area allows a vision and well-established understanding of the social determinants of health as a question for (amongst many others) researchers in fields as ostensibly diverse as population health sciences, policy studies, and social justice.[24]

With the social determinants of health as an overarching idea, research efforts have in turn emerged that focus in on more specified strands or 'sub-strata' determinants, defined by reference to particular sectors, systems, and institutions, or different sorts of social actors, agencies, and organisations.[25] Across the different disciplinary approaches and perspectives that are taken, we do well to envisage all of these exercises as spanning – and interweaving – *three central ideas of responsibility*, as represented in Table 1. They cover, respectively: *causal responsibility*, looking to practical forms of evidence regarding the generation of different health outcomes (eg by demonstrating that higher consumption of salt across a population leads to a higher incidence of cardiac disease); *agentic responsibility*, looking to establish questions of which actors hold, or lack, (degrees of) control

21 Beth W Kamunge, *Place and Health Inequalities: An Ethical Framework for Evaluating and Developing Policy* (UK Pandemic Ethics Accelerator 2022).

22 Sarah Hill, 'Axes of health inequalities and intersectionality' in Katherine E Smith, Clare Bambra and Sarah E Hill (eds), *Health Inequalities: Critical Perspectives* (Oxford University Press 2015); Beth Wangarĩ Kamunge, *Which Inequalities Should We Focus on in Evaluating Health Policy Before, During, and Following Covid-19?* (UK Pandemic Ethics Accelerator 2021).

23 As well as the AMS report (n 1 above) and Venkatapuram and Bibby (eds) (n 11 above), see Richard Horton, 'Offline: apostasy against the public health elites' (2018) 391(10121) *The Lancet* 643; Ted Schrecker, 'What is critical about critical public health? Focus on health inequalities' (2022) 32(2) Critical Public Health 139–144; Michelle Kelly-Irving et al, 'Falling down the rabbit hole? Methodological, conceptual and policy issues in current health inequalities research' (2023) 33(1) Critical Public Health 37–47.

24 See further the works cited in the previous footnote. See also how this plays out in ranging styles of general introductions to public health, but each with broad disciplinary reach, as eg Smith et al (n 22 above) or Ichiro Kawachi, Iain Lang and Walter Ricciardi (eds), *Oxford Handbook of Public Health Practice* 4th edn (Oxford University Press 2020). See also John Coggon, *What is Public Health?* (Faculty of Public Health 2023).

25 Cf Jennifer Karas Montez, Mark D Hayward and Anna Zajacova, 'Trends in US population health: the central role of policies, politics, and profits' (2021) 62(3) Journal of Health and Social Behavior 286–301; Haik Nikogosian, 'The interface of multisectoral and multilateral dimensions of public health policy: what's new in the 21st century' (2022) 44(2) Journal of Public Health 349–355.

Complementary understandings of responsibility at the heart of health of the public research	
Causal responsibility	A question for health and social sciences, asking how we establish causal factors regarding better or worse health, and the continuation, worsening, or lessening of health inequalities.
Agentic responsibility	A question for social and political sciences, seeking to establish who (potentially) has power/influence over those causes, and what forms that power takes.
Ethical responsibility	A question focused on arguments regarding moral responsibility, but demanding consideration of associated questions of social, political, and legal responsibility; questions both of who holds rights and duties in relation to health, and of accountability, scrutiny, and who has responsibilities to oversee or ensure the vindication of such rights and enforcement of such duties.

Table 1: Understanding responsibility in health of the public research[26]

and power as regards the frameworks of causal responsibility (eg by identifying who can influence the levels of salt that people eat, whether individual consumers, producers or sellers of food products, those who (might) regulate the sector, and so on); and *ethical responsibility*, looking to establish questions of what different actors should do, and whether and how they may be subject to distinct forms of scrutiny, accountability, and enforceability (eg by asking, as a question of social justice or political morality, whether legislators, governments, or commercial actors ought to use their influence to lessen the use of salt, and if so through what permissible means).[27]

Amongst substrata studies within health of the public research on the social determinants of health, of especial note for the current article are those regarding the *political*[28] and *commercial*[29] determinants. Within such substrata, a careful balance is required between identifying particular sources of responsibility (as indicated by the respective designations) whilst avoiding a problematic (and ironic) generation of silos through the inadvertent understatement of other causal factors and actors. Such balancing is key in an area that

26 Adapted from John Coggon, 'Global Health' in Tuija Takala and Matti Häyry (eds), *Concise Encyclopedia of Applied Ethics in the Social Sciences* (Edward Elgar 2024) 116.

27 For the general framing, see ibid. For an excellent example of a work that combines these approaches, see Anne Barnhill and Matteo Bonotti, *Health Eating Policy and Political Philosophy: A Public Reason Approach* (Oxford University Press 2022).

28 See, especially, Ole Petter Ottersen et al, 'The political origins of health inequity: prospects for change' (2014) 383(9917) *The Lancet* 630–667.

29 See, especially, Anna B Gilmore et al, 'Defining and conceptualising the commercial determinants of health' (2023) 401(10383) *The Lancet* 1194–1213.

is defined by a focus on complex, distal causal sources and structures, and which espouses a practical and disciplinary breadth of embrace. *The Lancet*–Oslo Commission on Global Governance for Health report on *The Political Origins of Health Inequity* demonstrates well how such balance works.[30] As the report's title suggests, it has government and public actors as a core concern (ie its ostensible focus is on 'political determinants'). However, its pivotal conceptual apparatus comes not, I would argue, in the sectoral boundaries of 'public sector' or 'government', but rather in the practically directive boundaries encapsulated through the idea of *governance*; as indicated in the Commission's name. And as regards governance, the Commission employs a definition of global governance, initially advanced by Ramesh Thakur and Thomas Weiss, that captures the influence of market forces, private citizens, and organisations that are not 'public' in the sense of governmental. They conceive of global governance as:

> The complex of formal and informal institutions, mechanisms, relationships, and processes between and among states, markets, citizens, and organisations, both intergovernmental and non-governmental, through which collective interests on the global plan are articulated, rights and obligations are established, and differences are mediated.[31]

In relation to questions regarding (global) health, *The Lancet*–Oslo report goes on to explain that such a governance focus, combined with aims to account for the sweep of influences on health, requires looking beyond actors whose primary sector or agenda concerns health: namely, actors involved in what is widely labelled 'global health governance'. Instead, *The Lancet*–Oslo Commission looks at governance across the piece and its effects on health: a contrast it captures by employing the alternative term 'governance for global health'.[32] To emphasise again, this is all very open-textured and broad in reach:

> The Commission builds on existing work in defining the global political determinants of health as the transnational norms, policies, and practices that arise from political interaction across all sectors that affect health. *This definition can include all rules that guide behaviour, from broad social norms to specific policies* (eg, trade agreements) *and practices* (eg unregulated activities of transnational corporations).[33]

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30 Ottersen et al (n 28 above).

31 Ibid 632, quoting words cited as originally from Ramesh Thakur and Thomas G Weiss, *The UN and Global Governance: An Idea and its Prospects* (Indiana University Press 2006).

32 Ibid. See also Lawrence O Gostin, *Global Health Law* (Harvard University Press 2014).

33 Ottersen et al (n 28 above) 633 (emphases added).

The key point for current purposes is that the salience of *governance* arrives as a result of stipulating definitions that are characterised more by studying responsibility for outcome effects than by line-drawing between (say) private and public sector actors; specifically, governance is more fundamentally about practical effect than a specific form or source of governance.[34]

In relation to the specifics, we thus in *The Lancet*–Oslo report (quite appropriately, I would suggest) come to see an intertwining of political determinants and commercial determinants research *within* political determinants research, rather than anything approaching an outright separation (or 'siloing') of them. This observation can as easily be made if we come (as it were) from the other direction. Research regarding the commercial determinants of health is not simply – or even primarily – focused on the population health impacts of (say) cheap foods with high salt, fat, or sugar content that may be found on the open market. Rather, it looks to matters such as the advertising of such products, the absolute and relative ease of their availability to consumers (thinking economically, geographically, and otherwise practically), political lobbying by industry actors, engagement in litigation processes to challenge regulation, and overall looking to the exercise of influence by commercial organisations over social actors and political decision-makers.[35]

It is only with the above points made that I would introduce the legal determinants of health as a research area that has found its own discrete but connected space within research on the social determinants of health. Again, the centrepiece publication here is a globally oriented work: *The Lancet*–O'Neill Commission's 2019 report, led by Lawrence Gostin and noted in the introduction of this article, 'The legal determinants of health: harnessing the power of law for global health and sustainable development'.[36] Building on the discussion in this section, legal determinants scholarship should be seen as intertwined with wider analyses regarding social determinants, rather than siloed or considered wholly separable. Laws and legal institutions of course reflect their own (broadly) distinct type of normative system (or more

34 We find this underscored in efforts to define and redefine 'public health'; notably when that means advancing definitions that assign alternative labels such as planetary health, One Health, or EcoHealth: see Coggon, *What is Public Health?* (n 24 above) 19–24. See also John Coggon, 'Defining global health law' (2024) 1(2) Journal of Global Health Law 150–176.

35 See eg Martin McKee and David Stuckler, 'Revisiting the corporate and commercial determinants of health' (2018) 108(9) American Journal of Public Health 1167–1170; Nason Maain et al, 'Corporate Practice and the Health of Populations: A Research and Translational Agenda' (2020) 5(2) Lancet Public Health e80–e81.

36 Gostin et al (n 5 above).

accurately, types of systems). But importantly, *The Lancet*–O'Neill Commission itself represents legal normativity within the broader concept of governance found in the earlier *Lancet*–Oslo report.[37] This is significant for how it relates law more narrowly to governance more widely, but also for the *empirical*, outcome-focused manifestations of 'law' that it thereby brings into analysis because of a concern to account for outcome effects. Law is not treated as some sort of purely positivist or exclusively specialist phenomenon. Instead, *The Lancet*–O'Neill Commission presents law as mutable both in how it is viewed and in its effects: it is something that can change over time even when formally it remains the same, and that at any one point in time may be subject to plural, simultaneously effective, mutually contradictory understandings. Taking 'law' in this way, legal determinants research is in part about explanation of how 'the legal' intertwines with other determinants of health that also serve ultimately to centre questions of responsibility and governance.

However, consistent with social determinants literatures more widely, *The Lancet*–O'Neill report does not simply look to legal determinants descriptively. It is also agenda driven: it looks to change the world; to 'make the case for better, more strategic linkages between health and law'.[38] The report explains its approach in the following terms:

> The term law throughout is used to mean legal instruments such as statutes, treaties and regulations that express public policy, as well as the public institutions (e.g., courts, legislatures, and agencies) responsible for creating, implementing, and interpreting the law. By establishing the rules and frameworks that shape social and economic interactions, laws exert a powerful force on all the social determinants of health. Well-designed laws can help build strong health systems, ensure safe workplaces, and improve the built and natural environments. However, laws that are poorly designed, implemented, or enforced can harm marginalised populations and entrench stigma and discrimination.[39]

It is, of course, plain that such an approach is not one to which all public health-focused legal scholars would or do subscribe.[40] It assumes normative commitments regarding health as a political value, as well as particular and instrumental conceptions of the idea of law itself.[41] However, it is a clear consolidation of growing bodies of scholarship

37 Ibid 1859.

38 Ibid 1857.

39 Ibid 1857.

40 See eg Richard A Epstein, 'In defense of the "old" public health: the legal framework for the regulation of public health' (2004) 69 (4)Brooklyn Law Review 1421–1470. See also Coggon, *What Makes Health Public?* (n 16 above) ch 8.

41 Coggon, 'Legal, moral and political determinants' (n 13 above).

within public health law across the past decades. In particular, beyond Gostin's own marked contributions, the synergies with agendas set by Scott Burris and colleagues are evident. This includes the move beyond 'law on the books', through methodologies in socio-legal studies, to appreciating the 'salience of law as it is implemented in practice and experienced by those it targets'.[42] At a conceptual level, this (to reaffirm the point) firmly engages ideas of governance more widely, and invites scholarship that looks to empirical questions both about how things are and how they could be made to be.

To be clear, insofar as I have touched on questions of governance and responsibility in the above discussion, the key conceptual anchors might be observed to have been in literatures on *global* health. However, governance – conceived in the same way – is no less pertinent in relation to national and sub-national public health law.[43] It should be stated first of all that *The Lancet* reports that I have cited engage with their subject matter at national and sub-national levels too.[44] And to make the point more concretely, within the TRUUD project, our focus is on the upstream systems and structures that lead to the creation and form of urban environments in England. This has included looking to the place of law and laws. In that regard, our research and analysis have focused on applied ideas in ways that are very much consistent with the agenda set by *The Lancet*–O'Neill report. We have incorporated a focus on broad, empirical understandings of governance that neither assume that legal governance manifests as some sort of singular and coherent phenomenon, nor that legal governance can be understood without looking to governance more widely. Our inquiry has looked at the interweaving of legal, commercial, and political forms of power.[45] Notably, a key frame that coincided with our work on legal determinants, as it developed, was a paper by Scott Burris and Vivian Lin, which even in its title puts law and governance together within the context of (sub-)national public health concerns regarding cities.[46] In that paper, Burris and Lin say:

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42 Scott Burris et al, 'Making the case for laws that improve health: a framework for public health law research' (2010) 88(2) Milbank Quarterly 169–210.

43 John Coggon, Keith Syrett and A M Viens, *Public Health Law: Ethics, Governance, and Regulation* (Routledge 2017) ch 4.

44 See also Coggon, 'Defining global health law' (n 34 above).

45 See, especially, Lisa Montel, '"Harnessing the power of the law": a qualitative analysis of the legal determinants of health in English urban planning and recommendations for fairer and healthier decision-making' (2023) 23 BMC Public Health 310.

46 Scott Burris and Vivian Lin, 'Law and urban governance for health in times of rapid change' (2021) 36(S1) Health Promotion International i4–i12.

> 'Governance' encompasses both the formal organization of management capacity, responsibility and authority within local government and the broader networks of influencers—NGOs, businesses, informal citizen groups—that shape policy decisions and implementation.[47]

As regards the idea of law itself, they stipulate that it:

> [I]ncludes legal texts like constitutions and statutes, but also the formal policies of public and private institutions, the implementation/enforcement practices of legal agents and the *beliefs about the law prevailing among those subject to it*.[48]

In consistent vein, within the legal team on TRUUD we have focused (*inter alia*) on 'law' as it featured (or did not) within the decision-making and actions of different actors within the overall systems of urban planning.[49] This meant adopting, in essence, a legal consciousness approach:[50] namely, one that would allow us to see what law is taken to mean in its real-world points of practical application, and in turn to generate understandings of how the 'legal' in legal determinants itself was subject (or not) in different ways to the influence of political and commercial consolidations of power. This approach accords with Lynette Chua's and David Engel's representation of legal consciousness, which is defined by a central concern with 'the ways in which people experience, understand, and act in relation to law'.[51] Rather than focus just on 'legal awareness', it entails too eliciting understanding of 'the absence as well as the presence of law in people's understanding of the social world and their place in it'.[52] Methodologically, this works in concert with approaches advocated for in the context of public health law research by Burris and colleagues.[53] Or in the words of Gostin and colleagues' overarching mission, it allows an understanding first of who best 'harnesses the power of law',[54] whether through positive assertion of what law demands, or by assuring that legal concerns are ignored.

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47 Ibid i4–i5.

48 Ibid i5 (emphasis added).

49 For an overall description of what this has entailed within our empirical research, see Montel (n 45 above).

50 Patricia Ewick and Susan S Silbey, *The Common Place of Law: Stories from Everyday Life* (University of Chicago Press 1998); Dave Cowan, 'Legal consciousness: some observations' (2004) 67(6) Modern Law Review 928–958; Lynette J Chua and David M Engel, 'Legal consciousness reconsidered' (2019) 15 Annual Review of Law and Social Science 335–353.

51 Chua and Engel (n 50 above) 336.

52 Ibid.

53 Burris et al, 'Making the case for laws that improve health' (n 42 above). See also Scott Burris et al, *The New Public Health Law* 2nd edn (Oxford University Press 2022).

54 Gostin et al (n 5 above).

To conclude this section, I have above sought to present a picture of legal determinants research and to explain how this fits within wider studies on the social determinants of health; which in turn may be seen as core to the shape, impetus, and impact-orientation of 'health of the public' research. Necessarily, this is a partial picture, and readers who are unfamiliar with it are encouraged to visit and make their own appraisal of the systematised representations and recommendations of *The Lancet*–O'Neill report, as well as critical responses to it. They may also consider practical initiatives that have sought directly to 'harness the power of law': for instance, through the creation of partnerships between legal services and healthcare better to address law itself as a determinant of (ill) health.[55] For present purposes, I have elected to describe the analytical context in the above terms to highlight some peculiar aspects of legal scholarship in this area. Amongst these are the mission-driven nature and framings of scholarship. This is not hidden: a political commitment to health is a value-based commitment (as, of course, would be shunning health as a political value); and it is a political, value-based commitment that assigns responsibility to socio-political and legal institutions and actors to address health inequalities.

Nevertheless, as explored in the following two sections of the article, these points give rise to particular questions that legal scholarship is apt to address but which may also make it in some senses vulnerable. In relation to those, as within health of the public research writ large, it would be mistaken to allow the 'scientific' or empirically oriented research to speak over or minimise regard for critically oriented and philosophical research in relation to the values-questions themselves.[56] Put more bluntly, we cannot coherently obfuscate that research on values is its own essential part of the picture here, and such research incorporates methods, evidence, and reasoning that are distinct but no less important. Such a point is not lost within works such as *The Lancet*–O'Neill report, and is all the more prominent, for instance, in Gostin's independent work.[57] It does, however, become under-scrutinised to the extent, within health of the public research, that the values-questions become treated as self-evident in nature, or

55 Hazel Genn, 'When law is good for your health: mitigating the social determinants of health through access to justice' (2019) 72(1) Current Legal Problems 159–202.

56 As well as the long-established field of critical public health, note contributions in the philosophy of public health: eg Ruth Faden, Justin Bernstein and Sirine Shebaya, 'Public health ethics' in Edward N Zalta (ed), *The Stanford Encyclopedia of Philosophy* (Stanford University Press spring 2022); Sridhar Venkatapuram and Alex Broadbent (eds), *The Routledge Handbook of Philosophy of Public Health* (Routledge 2023).

57 See eg Lawrence O Gostin and Lindsay F Wiley, *Public Health Law: Power, Duty, Restraint* 3rd edn (University of California Press 2016) ch 1.

arguments in their favour are treated as already well enough made.[58] The following section of the article accordingly aims to present a vision of the overall expert contributions that legal scholarship can make, with an equal view to analysis regarding ethics, equity, and social justice in relation to responsibility and governance as to the empirical effects and potential of law and laws.

AN OVERARCHING REPRESENTATION OF LEGAL SCHOLARSHIP AND ITS 'FIT' WITH HEALTH OF THE PUBLIC RESEARCH

In this section I give an overview of four threads of scholarly inquiry that I see as necessarily interwoven in the conduct of the practical and analytical goals of legal scholarship within health of the public research. In a way that I hope can help structure and guide future research, I aim to provide a map of applicable legal expertise. I would add, in setting this up, that although the practical examples in this article primarily concern non-communicable diseases (NCDs), what follows speaks as well to legal scholarship that focuses on other areas concerning the public's health, such as health security (ie protection from threats such as contagious disease or chemical threats), prevention of injury (eg within the domain of occupational health), or healthcare public health (ie looking to population-level questions concerning the healthcare system). A visual representation of the mapping exercise is provided in Table 2.

As per the discussion in the preceding section, to be part of health of the public research agendas – meaning that it can both inform and be informed by them – we find two overarching contextual domains that ought to feature within legal scholarship (if in places inchoately).[59] First, and more obviously, such scholarship should apply to questions that are well defined with a 'health of the public' focus. Here, we are interested in health as a practical phenomenon and particular value to feature within analysis, and its situation and dynamics when viewed at a population level. Secondly, and perhaps less obviously in the abstract, but as explained in the previous section of this article, we are interested in governance. In line with the quite general characterisations of governance given above, suffice to say that

58 Cf Sridhar Venkatapuram, 'Global health without justice or ethics' (2021) 43(1) Journal of Public Health 178–179.

59 It may seem bizarre to suggest that the first of these may feature only inchoately. The reason I cast the point as I do is because we can and do find public health law scholarship that looks eg at 'big-picture' philosophical questions or systems-structures without in terms speaking to specific applied questions. Nevertheless, to serve as analysis in this area, it should be possible that it could find application.

<table>
<tr><th colspan="5">The practical and critical landscape of public health law scholarship</th></tr>
<tr><th colspan="2">Broad contexts</th><th colspan="2">Analytical approaches defined by tasks for legal studies</th><th></th></tr>
<tr><td rowspan="4">A. Health of the public focus
Prevention of ill health and injury, provision of healthcare, cross-sector promotion of good health and well-being</td><td rowspan="4">B. Focus on sources and systems of governance
Social coordination and influence through e.g. politico-administrative, socio-structural, and commercial systems</td><td rowspan="2">Practical inquiry</td><td>1. Description and explanation
What effects do (perceptions of) law and laws have on the public's health and why/how; both in terms of constraint and limits on, and the advancement of, the provision of favourable conditions for health?</td><td rowspan="4">⬅ Each area able to inform the others ➡</td></tr>
<tr><td>2. Strategy and impact
How might law and laws be used to improve the public's health and address health inequities?</td></tr>
<tr><td rowspan="2">Critical inquiry</td><td>3. Evaluation and critique given basic legal values, principles, and norms
How might basic legal values, principles, and norms – e.g. the rule of law, respect for human rights, legality – inform critical analysis of health of the public activities and agendas?</td></tr>
<tr><td>4. Evaluation and critique beyond law as a contained normative system
How do wholesale theories of ethics and social justice inform understanding of the place and use of law in health of the public activities and agendas?</td></tr>
<tr><td colspan="5">Combining the outcome-oriented aims, methods, and insights of health of the public research with law as a discipline embedded in practice, social sciences, and humanities</td></tr>
</table>

Table 2: The practical and critical landscape of public health law scholarship

as a basic idea this term draws attention to wide-ranging sources and systems of action-guidance. These may be created by design, or arise as unplanned, systemic realities. And across their totality, they may emanate from multiple actors; governmental and otherwise. When reflecting on governance conceptually, we do well to keep in mind specifically as regards *legal* governance that laws themselves do not function within a single, contained, or impervious system. But more fundamentally, anyway, a practical and critical appreciation of law in the context of health of the public research requires understanding as well of non-legal forms of governance.

Within the broad reach of these two pervasive contextual domains, we may imagine a fourfold scheme of 'tasks' for legal studies. The first two are defined by *practical* analytical aims and are more straightforwardly identified from legal determinants scholarship as outlined in the

previous section. The latter two centre on *critical* analytical aims. As indicated above, their existence is accounted for in works such as *The Lancet*–O'Neill report, but invite more sustained attention insofar as health of the public research is concerned. In outlining these four 'tasks', I should be clear that, whilst each can be conceived discretely, they must each be able (at least in principle) to inform and relate to analysis from the others. Importantly, the tasks identified as practical should not be taken as impliedly untouched by values-based questions; and those presented as critical are still to be brought to bear on real-world phenomena. As such, the scheme is presented to exemplify the overall analytical scope within a given piece of health of the public legal scholarship. Some will do it all, while others will do just one, two, or three parts of it. All of these, I have noted, are represented within *The Lancet*–O'Neill report. However, the third and especially the fourth invite and demand greater emphasis and attention, both from legal scholars and from those with whom they collaborate in health of the public agendas.[60]

In line with the preceding summary, regarding practical tasks, we may observe two functions for legal scholarship. First, it seeks to generate understanding of how law and laws in practice influence health opportunities and outcomes. Although multiple methods may be employed within this, the field of *legal epidemiology* might (with due qualifications)[61] be seen as the 'gold standard'.[62] This combines doctrinal legal understanding ('law as practice') with methods drawn from health and social sciences to adduce observations about the effects of law and laws. However, legal epidemiology is not exhaustive here. As well as other forms of social science methods that may also be applied (borrowing eg from studies in criminology),[63] there is clear scope for looking at the effects of law against methods from humanities disciplines such as history[64] or philosophy.[65] Secondly, the practical

60 See also Coggon, 'Legal, moral and political determinants' (n 13 above).

61 Cf Horton (n 23 above).

62 Scott Burris et al, 'A transdisciplinary approach to public health law: the emerging practice of legal epidemiology' (2016) 37 Annual Review of Public Health 135–148; Scott Burris, Lindsay K Cloud and Matthew Penn, 'The growing field of legal epidemiology' (2020) 26 Journal of Public Health Management and Practice S4–S9.

63 See eg Naomi Finch et al, 'Undermining loyalty to legality? An empirical analysis of perceptions of "lockdown" law and guidance during COVID-19' (2022) 85(6) Modern Law Review 1419–1439.

64 See eg Janet Weston, 'Paternalism in historical context: helmet and seatbelt legislation in the UK' (2023) 16(1) Public Health Ethics 64–76.

65 See eg John Coggon, 'Smoke free? Public health policy, coercive paternalism, and the ethics of long-game regulation' (2020) 47(1) Journal of Law and Society 121–148.

application of legal scholarship on public health can move from describing and explaining to having a role in the generation of strategy. In the phrase employed by Gostin and colleagues, as suggested above, we find here a focus on law and public health that includes seeing law as 'a tool'[66] – that is, a form of power to be used instrumentally – to 'achieve better health with justice'.[67] This can span questions informed by law as practice: for instance, to lend experience-based understanding to methods of instrumentalising law such as may be done through strategic litigation.[68] It can draw too on ranging methods, against commensurately ranging evidence bases, in the development of legal regulatory tools.[69] But more subtly, it can involve as well developments in understandings of the practical scope and effect of legal obligations; for instance in the formulation of understandings and use of health impact assessments in administrative decision-making.[70] And even more subtly still, drawing from methods captured under the idea of legal consciousness, strategic efforts can be about mobilising understandings of law as they play out far away from questions of litigation or law-making; that is, through finding how 'law in action' – for instance as applied by, or operating as perceived constraint by, actors within public authorities – may better serve public health aims and agendas.[71]

Regarding critical inquiry, again I suggest two frames for tasks of legal scholarship. These draw more centrally from the domain of law as humanities, and thus far have been more muted in the article's discussion. Nevertheless, their work is essential. As we have seen, insofar as health of the public research (including on legal determinants) is about practical agendas, these are driven by normative ideas and ideals: most strikingly concerning political obligations to protect and promote good health, and to respond to unfair, structurally determined

66 Gostin et al (n 5 above).

67 Ibid.

68 See eg David Patterson and Farhang Tahzib, From Analysis to Action: Climate Change Litigation – A Guide for Public Health Professionals (Faculty of Public Health 2023).

69 We might think here of the generation of regulations under powers provided in the Public Health (Control of Disease) Act 1984, as well as the consolidation of evidence bases and their presentation in support of the development of primary legislation: eg Department of Health and Social Care, *Tackling Obesity: Empowering Adults and Children to Live Healthier Lives* (DHSC 2020). For critical analysis of how evidence might 'translate' or otherwise into legislation, see John Coggon and Jean Adams, '"Let them choose not to eat cake …" Public health ethics, effectiveness and equity in government obesity strategy' (2021) 8(1) Future Healthcare Journal 49–52.

70 See eg Edward Kirton-Darling, 'Law, health and planning: using health impact assessments to improve urban health' (TRUUD Intervention Briefing 2023).

71 Montel (n 45 above).

health inequalities. Yet there is work to do in exploring and explaining the relevant questions concerning values and justice. And these are key applied areas for (amongst others) legal scholars.

First of all, within these, we may look, as it were, at the 'internal' values and norms of law itself. We appeal here to the wisdom and application of normative legal concepts, considering them at both formal or procedural levels as well as substantive levels. Three examples will suffice for present purposes. First, we may look to principles for the legitimacy that they lend in and of themselves; for instance, public law concepts of legality in relation to executive public health powers. Secondly, we may look to legal principles for the indication of legitimacy that consistency with them implies; for instance, compliance with conditions of the rule of law. Or thirdly, we may look to higher-level, substantively 'thicker' normative values, such as are entrenched in more foundational or fundamental legal instruments, such as instruments that enumerate constitutional rights or enshrine human rights through international law.

Such ideas find prominence within *The Lancet*–O'Neill report. However, as we move to the fourth task for legal scholars, we find attention at a headline level that enjoys relatively less detail on specifics. Here, we are concerned with measures of normative validity that are extrinsic to (positive) law itself: to questions of what justifies assertion of political obligation and of claims in social justice. In other words, we are concerned to know, fundamentally and in practical detail, what 'with justice' actually means. Within works in legal philosophy, we may (if only heuristically) imagine here the legal domain as presented by scholars such as Joseph Raz, and the contrasts he then provides for extra-legal evaluation and practical understanding when legal normativity is cast against non-legal measures of understanding and critiquing socio-political norms, structures, and institutions.[72] Both as regards the missions and agendas of health of the public scholarship, and evaluation and reflection against critical concerns of social justice, there is a vital role here: for wider framing, conceptual development, and analytical theorising; and for explication of how laws, legal institutions, and laws in practice may and should feature with reference to the matters raised.

To make these representations a little less abstract, having presented these four 'tasks' of legal scholarship, we can consider Newdick's 2017 paper on NCDs, law, governance, and social justice. Although that was not written (to my knowledge) as a direct part of a health of the public research programme, it clearly addresses its aims and analysis in a way that is consistent with the ideas as I have presented them

72 See eg Joseph Raz, *The Authority of Law: Essays on Law and Morality* 2nd edn (Oxford University Press 2009).

in this section. It combines structural and causal considerations with normative critiques that ultimately are underwritten by non-legal approaches to understanding social justice and equity. These apply at the level of individual freedom, commercial responsibility, and the role of government, with ideas of population health and governance at the centre. Within Newdick's framing, this means challenging questions of responsibility and governance by reference to the normative burdens that may be ascribed to individuals, while also not exceptionalising or presumptively privileging the power and influence of private corporate actors. And it involves evaluations of the application and justification of different methods of governance. In his words:

> The point of reappraising [personal] autonomy is not to impose the burden of non-communicable diseases upon those least able to shoulder it. It is to encourage the development of systems of governance, nationally and internationally, to promote equality of people's capabilities. For example, if paternalism is to limit public policy to merely 'nudging' us towards healthier lives, it should be equally concerned to engage with the private, commercial forces nudging us towards ill health. Accepting behavourial psychologists' findings that we are constantly nudged from all directions, the question is not simply how governments should behave, it is which 'nanny' do we prefer – publicly accountable government or self-interested private corporations? Yet, by permitting the 'nanny industry' to dominate the debate, we impose vast personal and social cost on the community.[73]

In short terms, we find an example here of legal scholarship that seeks to ask and answer, in the same spirit, the matters set out in Table 2 and the discussion in this section of the article. In the following section, I consider what doing so means when it is taken as a contributing part of the broad and guiding health of the public research agenda.

LAW'S PLACE IN HEALTH OF THE PUBLIC RESEARCH: SUBORDINATION TO GOVERNANCE AND SOCIAL JUSTICE?

As the ideas have emerged over the previous sections' analysis, we have seen the mapping of a scholarly agenda – 'health of the public research' – with specific regard to its inclusion of law. Within that agenda, I would suggest that there comes a double subordination of ideas of 'law' and 'the legal'. Although I present these 'subordinations' under two headings, they are fundamentally intertwined. First, as a practical method of governance defined by source and form, we see distinct limitations in the recognition of any special attributes of law and the legal. Secondly, insofar as we may wish to engage law in more

73 Newdick (n 6 above) 427.

philosophical senses, especially through appeal to legal concepts of justice and 'virtues' of ('good') law, such as rule-of-law ideas, these may be characterised as valued instrumentally, insofar as they are consistent with or serve some much broader, extra-legal idea(s) of social justice. In this final substantive section of the article, I will reflect on this double subordination and its significance for legal scholarship.

First, then, health of the public research pushes back against any practical presumptive pre-eminence being given to law and legal regulation as a distinct form of governance. It disrupts – perhaps even denies – law's special significance as a consolidation of coercive power. This contrasts with what we might call 'standard' or 'mainstream' representations, which place law as the 'highest' or most firmly directive method of governance on a linear spectrum of regulatory interventions (or, in a different metaphor, a last resort to be invoked when 'softer' methods of governance fail).[74] Notably within these, governance overall, and degrees of coerciveness, are defined by reference to form and source rather than effect. Notably too, such perspectives found (clumsy and reductive) echoes in the much-vaunted, simplistic, binary framing of 'freedom day', when 'lockdown' regulations were discontinued during the Covid-19 pandemic; an idea that suggested, as regards questions of governance, normative analysis, and justification, that an exhaustive account of responsibility and governance was provided by legal responsibility *versus* no legal obligation.[75] But even within the more subtle, linear framings that permit for distinct methods of directing behaviour (eg through public information campaigns, the imposition of structural amendments to economic (dis)incentives, and so on), we find a 'liberal' presumption that straightforwardly, along that linear pathway, holds that the 'heavier' the *form* of obligation, the heavier the burden of normative justification.

Yet, the practical and analytical reality within health of the public research, and the policy and practice that follow from it, is that law's place is subordinated both analytically and practically to outcome-focused, empirically oriented concepts of governance. The measure of these is determined by reference to effect and effectiveness; a graded and defined-as-experienced concept of coercion rather than a binary one or – more importantly – one that looks to form and source.[76] A practical goal (say, to reduce rates of smoking) is approached strategically; with

74 This may be seen as reflected, for instance, in the influential idea of the 'intervention ladder' and its surrounding rationalisation in Nuffield Council on Bioethics, *Public Health – Ethical Issues* (Nuffield Council on Bioethics 2007).

75 John Coggon, 'Personal responsibility versus legal obligation? Why simplistic binaries make for bad pandemic responses' (*Nuffield Council on Bioethics Blog* 12 July 2021).

76 Cf Cass Sunstein, *Why Nudge?* (Yale University Press 2014) 57.

considered reference to a structured array of governance methods, including but not limited to legal regulation. And it is tempered by considerations of effectiveness and acceptability, rather than any normative understanding that is informed by a liberal philosophical interest in law and its distinct normative authority (such as that may be). This simultaneously calls into question special justificatory demands for the imposition of legal obligations, and – more urgently – the putatively less (and in reality no less) demanding task of justifying non-legal methods of governance.[77]

Secondly, any pre-eminence to normative values within or 'of' law – legal principles such as legality, the rule of law, or human rights – become potentially subordinated to political values-commitments that arise from a 'public health perspective'. As with social determinants research generally, it is hard (perhaps impossible) to imagine measures and analyses that do not rest on the engagement of contestable values at some juncture.[78] But this is not just about potentially *hidden* values: the 'public health perspective' I refer to here rests firmly on *expressly stated* (if also incompletely stated) political commitments: mandates, through social architecture, to generate conditions of better, fairer health. The perspective demands its own normative steers and constraints. So beyond it being a mistake to assume that unstated values means an absence of values, we find a steer in health of the public research agendas that is directly oriented towards particular political commitments: specifically, the importance of protecting and promoting health as a socio-politically shared endeavour; and concurrently, (more or less clearly specified) conceptions of social justice that prioritise the amelioration of unequal health outcomes and opportunities. This results in a situation where legal inquiry and advocacy are not (which of course perhaps they never were) simply about finding 'the' legal answer, but rather about best shaping law as a 'tool' that can advance (non-legal) agendas of social justice. This may be exemplified, for instance, by having regard to climate change litigation under international human rights law.[79]

When presented within the pages of a law journal, these apparent subordinations of law might seem striking for being unremarkable. There are well-established literatures that look to effective regulation or governance, both analytically and as methods of achieving and assuring social coordination, which clearly subordinate law, or purport to circumvent moral demands that are taken as read for the formal

77 Coggon, 'Smoke free?' (n 65 above).

78 Sam Harper et al, 'Implicit value judgments in the measurement of health inequalities' (2010) 88(1) Milbank Quarterly 4–29.

79 Contrast eg the majority and minority reasoning in *Verein Klimaseniorinnen Schweiz and Others v Switzerland* App no 53600/20 (ECtHR, 9 April 2024).

imposition of legal coercion.[80] The place of behavioural sciences and the regulatory effects of our environments demonstrably create redundancies and irrelevancies for legal norms and law as practical phenomena conceived as being at the heart of social coordination.[81] And all the more, there must be very few – if any – legal scholars who would assume that all positive laws should be unquestionably followed no matter what, even should they hold a more abstract position that people should obey 'the law'. But of course, it does not follow from any of these observations that specifically 'public health values' should provide the normative bottom line instead. Indeed, we might here take the example of former Supreme Court Justice Lord Sumption, who spoke expressly against the practically binding authority of public health laws during the Covid-19 crisis against – as he saw it – more fundamental moral and practical considerations.[82]

So it is precisely the *non-sequitur* in a claim that 'public health values' are properly foundational that opens up the two subordinations as more remarkable observations after all. It invites the question not of whether legal obligation may be lesser (whether generally or in a specific instance) than (say) moral obligation. Rather, and much more directedly, it demands scrutiny of how much discordance – or equivocation or silence – there can be on the normative aspects of health of the public research with regard to the pre-eminence of the values it represents to be meaningful and workable. How non-specific can we be about the meanings of health and equity, or about the health costs themselves of a health policy, and questions more widely about value trade-offs that emerge?

With these sorts of questions in mind, we see a vital place for legal scholarship *within* health of the public research in articulating, challenging, refining, and *justifying* the questions of applied values. I hope, given even the *intra*disciplinary reach of legal scholarship that I have outlined above, it is clear that this scholarship is not the exclusive preserve of people whose primary discipline is law. As a reviewer of this article noted, the scholarship that I discuss here may be done, for instance and in different parts, by criminologists or political philosophers or sociologists with interests in law. The rigour comes through the quality of the scholarship measured against the different

80 Most notably, perhaps, Richard H Thaler and Cass R Sunstein, *Nudge: Improving Decisions about Health, Wealth and Happiness* (Penguin 2008).

81 Cf William Lucy, 'The death of law: another obituary' (2022) 81(1) Cambridge Law Journal 109–138.

82 For a critical and more widely contextualised account of Lord Sumption's doing of this, see John Coggon, 'Lord Sumption and the values of life, liberty, and security: before and since the Covid-19 outbreak' 48(10) Journal of Medical Ethics (2022) 779–784.

'tasks' that I have outlined. And to enjoy the rigour that they require, health of the public research agendas need to allow for this. This is not to suggest that there should be, or that we should act is if there were, a single, knock-down theory of (health) justice. It is rather to acknowledge and engage with the political realities of values-disagreements even within teams of transdisciplinary researchers. Strikingly, against the framings above, independent (ie independent of health of the public research) research in public health law talks in clear and direct terms to these matters. We see explorations of the relationships between law and governance and these questions of subordination: practical and normative.[83] Such normative analysis sits shoulder-to-shoulder with wider, policy and practice-focused works in critical public health, the philosophy of public health, and public health ethics. And it is part of what *The Lancet*–O'Neill report is about. But – without coming at the cost of the descriptive and strategic analyses – it needs to have a surer and more robust place. Exploring and explaining the reasons in support of the agendas is key to their intellectual and moral integrity. And it cannot just be about big picture battles as pitched (say) between 'libertarians *versus* paternalists'. Rather, it means looking to the more subtle reasons and disagreements *within* a more general accord on the position that governments should protect and promote health, and reduce health inequalities, as a matter of social justice.

Within health of the public research agendas, we need to talk about the contestable meaning of health, and about health/health trade-offs.[84] We need to talk about the *axes* across which we measure (or do not measure) health inequalities.[85] We need to clarify what values beyond health matter, and why (or explain how and why health is *the* basic value of concern).[86] We need to talk about what sorts of

83 For a good example of a standalone analysis of law's relationship with governance for public health more widely, and an account of law's proper standing in that context, see Mark Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Hart 2018). For an overview of how public health law scholarship has addressed and incorporated governance, see Coggon et al, *Public Health Law* (n 43 above) ch 4.

84 Consider eg the conceptual and analytical questions and challenges, and consequent practical policy implications, raised in Cass R Sunstein, 'Health–health tradeoffs' (1996) 63(4) University of Chicago Law Review 1533–1571.

85 Consider eg the conceptual and analytical questions and challenges, and consequent practical policy implications, raised in Jasmine N Olivera et al, 'Conceptualisation of health inequalities by local healthcare systems: a document analysis' (2022) 30(6) Health and Social Care in the Community e3977–e3984.

86 Contrast the approaches and reasoning of eg Madison Powers and Ruth Faden, *Social Justice: The Moral Foundations of Public Health and Health Policy* (Oxford University Press 2006); Jennifer Prah Ruger, *Health and Social Justice* (Oxford University Press 2009).

interventions – what methods of governance – are justified, and why.[87] We need to ask whether we are focused on opportunities, or outcomes, or both; about how these are measured; and across what time frames.[88] We need to talk about the meaning of assigning responsibility, and applying methods of scrutiny and accountability, to different sorts of actors within the diffuse structures that define the social determinants of health.[89]

In short, we need to be ready to articulate and defend substantive positions on justice, if we are to engage openly in research agendas that aim to provide for better, fairer health with justice. There already exist good literatures on this. They can and should develop. The very nature of their subject matter means there will never be a last word. And health of the public research will be depleted if it fails to account for and contribute to these discourses; to speak to questions of ethics and justice as regards the aims of law and policy, as regards the procedures of determining law and policy, and as regards the methods of governance – including legal governance – in effecting health policy.

CONCLUSIONS

This article has presented a view to understanding and steering the direction of a sub-domain of legal scholarship, *and* to understanding and steering the wider agendas of health of the public research. I regard these two as necessarily developing in symbiotic connection: as public health law scholarship moves forward, it adds to and draws from health of the public research, each informing and enriching the other. Against the framings in the opening section of the article, I am particularly interested in how this impacts on the (necessarily impinged) autonomy of legal scholarship; in the place and engagement of methods, respectively, from law as practice, as social sciences, and as humanities, and their further embedding with insights and even methods from the health and natural sciences.

With a view to ensuring that attention to legal determinants of health is not an exercise in problematic siloing, I have provided above a 'map' of the tasks of legal scholarship in this area. That has enabled me, in turn, to orient the ideas against considerations concerning social justice. And, in the end, that is where I envisage the most

87 Consider eg the conceptual and analytical questions and challenges, and consequent practical policy implications, raised in Nuffield Council on Bioethics (n 74 above).

88 Consider eg the conceptual and analytical questions and challenges, and consequent practical policy implications, as advanced in Jonathan Wolff and Avner de-Shalit, *Disadvantage* (Oxford University Press 2007).

89 As eg in Newdick (n 6 above).

heavily understated area of health of the public research, and call for the expertise of legal scholars (amongst others) to bring more to the table. None of that is to deny or displace a predominant focus on broad concepts of governance and structured concepts of responsibility. Nor is it a challenge to the specific aspects that legal scholarship can bring to these; in descriptive analysis, and in the development of strategy. But, as *per* the questions listed at the end of the previous section, it is a challenge to agendas that rest too easily on under-theorised, vague, or very thin accounts of the political values and claims in social justice that ultimately provide the impetus for their existence in the first place. To be founded on solid evidence bases, health of the public research needs firmly to incorporate ongoing analysis of fundamental questions of the meaning and import of moral values and social justice.

Northern Ireland
Legal Quarterly
Vol. 76 No. 1 (2025) 103–117
Articles DOI: 10.53386/nilq.v76i1.1134

Contract, social relations and the outsourcing of publicly funded healthcare

Kenneth Veitch

University of Sussex
Correspondence email: k.j.veitch@sussex.ac.uk.

ABSTRACT

A prominent and consistent element of Chris Newdick's work can be understood as a focus on the nature of relations in healthcare and healthcare law. Specifically, he has emphasised and defended the importance of social solidarity and community as core values against the dominant focus on and championing of an individual sense of autonomy in those areas. This article takes up the theme of relations in a different context, exploring the nature of the social relations underpinning the increasing role played by the private sector in delivering publicly funded healthcare. It does so by considering two instances of outsourcing – the private finance initiative and the United Kingdom (UK) Government's awarding of contracts as part of its response to the Covid-19 pandemic. It is argued that those examples disclose relations between the state, citizens, and what the sociologist Wolfgang Streeck calls the *marktvolk* (the people of the market) that cannot be comprehended via the notions of solidarity and community traditionally associated with a publicly funded healthcare system like the UK's National Health Service. Indeed, the social relations involving the *marktvolk* – including, for instance, the importance of one's status and duties of loyalty based on acquaintance – tend to have the effect of, in Newdick's phrase, 'corroding [the traditional form of] social solidarity'. Thus, while important, it is not only the stress on individual autonomy and rights that has this corrosive effect; other forms of social relations – including those involving elites and revolving around capital – have this impact too and demand exploration.

Keywords: contract; social relations; outsourcing; publicly funded healthcare; Covid contracts; private finance initiative.

INTRODUCTION

An enduring feature of Chris Newdick's work has been its focus on the nature of relations in healthcare and healthcare law. Specifically, against the dominant focus on and championing of an individual sense of autonomy in those areas, he has emphasised and defended the importance of social solidarity and community as core values. We see this, for instance, in

his analysis of the *Watts* case,[1] in which he notes a development – namely, individual rights to access healthcare in European Union member states – that may, in Newdick's words, be 'likely to damage the sense of social solidarity essential to any public, social welfare system'.[2] In another article, and in line with Newdick's advocacy of a communitarian approach to healthcare issues, he urges us to think of autonomy in a more relational way than is traditionally the case, stressing the importance of understanding and acknowledging the circumstances and environments within which individuals live. And rather than placing too much emphasis on individual responsibility when it comes to promoting and protecting health, he argues that we need to pay heed to 'the social and commercial determinants of inequality and dependency'.[3] Newdick's suggested way forward is to strive for a 'public health "ethics"' which exemplifies 'non-ideal theory' and manifests itself in a call for 'an acceptable balance of competing outcomes and aspirations [including "between public and private interests"]'. – 'to rebalance the relationship between [what Wolfgang Streeck calls the] *staatsvolk* and *marktvolk*'.[4] That is, between 'the general citizenry' (citizens have a duty of loyalty to the state in return for it protecting them through the existence of social rights) and the 'people of the market' (the state increasingly seeks to sustain this constituency's confidence and the relationship between this group and the state is defined by contractual ties; in other words, unlike citizens, the *marktvolk* do not owe a duty of loyalty to the state, though maintaining their confidence in the ability of states to service the debts they owe the *marktvolk* is crucial). Newdick's suggestion, then, is that there has been a shift away from 'public interests'/solidarity/ the *staatsvolk* in favour of 'private interests'/individual autonomy/the *marktvolk* and that this constitutes an imbalance in need of redress.[5]

This article takes up Newdick's emphasis on the relational dimension of healthcare and healthcare law by considering the phenomenon of the outsourcing of publicly funded healthcare in the United Kingdom (UK).

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1 *R (on the application of Watts) v Bedford Primary Care Trust and Another* [2006] All ER (D) 220 (May)

2 C Newdick, 'Citizenship, free movement and health care: cementing individual rights by corroding social solidarity' (2006) 43 Common Market Law Review 1645–1668, 1645.

3 C Newdick, 'Health equality, social justice and the poverty of autonomy' (2017) 12(4) Health Economics, Policy and Law 411–433, 427.

4 Ibid 427–428. See W Streeck, *Buying Time: The Delayed Crisis of Democratic Capitalism* (Verso 2014).

5 For some suggestions as to how this rebalancing might occur, see C Newdick, 'Global capitalism and the crisis of the public interest – sleepwalking into disaster' in S C Breau and K L H Samuel (eds), *Research Handbook on Disasters and International Law* (Edward Elgar 2016).

It does so by focusing on the mechanism through which outsourcing has occurred – namely contract. In one sense, contract is apposite as a focal point as it enables reflection on the growing role in healthcare of the *marktvolk*. As contract is traditionally understood as being central to the operation of markets, it would seem like an appropriate place to look to try to understand the role the 'people of the market' play in the context of publicly funded healthcare. Simultaneously, it will be argued that contract presents an opportunity to identify and explore the kinds of social relations at play, and at stake, in contemporary publicly funded healthcare as well as their effect on the solidary notion of social relations underpinning an institution such as the UK's National Health Service (NHS). This kind of exploration involves digging down beneath the surface appearance of contract and the particular exchange between the contracting parties to reflect on the character of the relations between, say, the state and the *marktvolk*, and the *staatsvolk* and the *marktvolk*. With the introduction of the private sector and the profit motive into a publicly funded healthcare system, such as the NHS, which was founded on anti-market principles and values, it involves thinking about what types of relations need to be in place for capital to flourish in this sector, as well as the distinctive form of social relations that capital introduces into the system. Using the private finance initiative (PFI) and the Covid-19 pandemic as examples, the article identifies a variety of forms of relations that structure the contracts in those areas. Moreover, it is argued that those relations tend to have the effect of, in Newdick's phrase, 'corroding social solidarity' – that is, the notion of social solidarity traditionally associated with a publicly funded healthcare system such as the NHS. It is suggested that this form of corrosion is not only caused by the contemporary stress on individual autonomy and individual rights, but is also the result of capital and elite relations too. To begin, however, let us first turn to consider the principles underpinning Aneurin Bevan's vision of the NHS at its founding. This will then allow for a consideration of the impact on these of subsequent developments.

BEVAN, THE NHS AND SOLIDARITY

To contextualise the discussion of contract and the *marktvolk* that follows later in the article, reference will be made to the ideas and principles underpinning Aneurin Bevan's vision of and for the NHS, which was established in 1948. The Labour Minister of Health at the time, Bevan viewed the NHS as an institution founded on socialist principles of community, universalism, and need. As he said: '[M]edical treatment and care should be a communal responsibility that … should be made available to rich and poor alike in accordance with medical

need and by no other criteria.'[6] This 'collective principle', as he called it, was designed to create a healthcare service in which universal access to healthcare, hitherto absent from the pre-NHS patchwork system of healthcare, became a reality. Moreover, access to treatment was not to be conditional upon the payment of charges by patients; rather, it would be funded via general taxation, thus reflecting the communal and progressive nature of the institution. Essentially, Bevan's vision for the NHS was one in which the profit motive and commodification were to be banished from the world of medical treatment and care. In terms of social relations, the NHS was not akin to the market exchange traditionally associated with contract, which predominantly characterised the relationship between doctor and patient prior to the founding of this institution – namely, payment in return for a service. Nor, relatedly, was the legitimation underpinning its mode of financing – general taxation – to be understood in a transactional, utilitarian sense (what Leroy describes as 'exchange tax' – I expect to receive the amount of healthcare equivalent to the amount of tax I have paid).[7] Rather, the idea of social relations inherent in Bevan's NHS can be thought to equate to a notion of solidarity synonymous with the principle underpinning the Roman law concept of *obligatio in solidum* – that each member of a group is 'liable for the reversals of fortunes of another'. This idea of all for one and one for all is consistent with a healthcare system driven by the common good in which nobody needing it should be denied access to medical treatment just because they lack the means to pay for it. Moreover, as noted, liability is the binding force of the *obligatio in solidum* rather than, say, blood or love. Thus, citizens are liable to those in need of medical treatment and care, irrespective of the fact they are not blood relatives or friends. Those founding and guiding principles of solidarity and the common good find expression in Leroy's notion of 'contribution tax', the legitimacy of which is synonymous with progressive, redistributive welfare policies that are supported by taxpayers despite no immediate, or indeed any, return in exchange for one's contribution.

Bevan's notion of communal responsibility is synonymous with ideas of social justice and fairness that, it is suggested here, characterise at least part of what Newdick means when, in the context of the *Watts* case for example, he talks of social solidarity. There is a sense that the emphasis on individual rights in that case compromises the carefully constructed solidary elements – waiting lists, for example – of a healthcare system like the NHS. Newdick's take on solidarity, however, is presented in the context of the dangers of a system driven

6 A Bevan, *In Place of Fear* (Heinemann 1952) 75.

7 M Leroy, *Taxation, the State and Society: The Fiscal Sociology of Interventionist Democracy* (Peter Lang 2011).

by individual rights. Thus, allowing the latter to dominate may mean that finite resources are diverted to the 'affluent' or 'articulate' with detrimental consequences for others and the idea of social solidarity underpinning the institution.[8] While important, it is not only in this context that questions arise about solidarity, the promotion of the public interest, and how these are being affected. Other forms of relationship need to be brought into the mix too if we are to think about those issues in the round. Those relationships are not just those of individual to community, but of state to finance, and citizens to both finance and state. Reflecting on these latter forms of relationship is crucial to both developing an understanding of the kinds of social relations at play in the context of contemporary publicly funded healthcare systems and identifying their effects on the notion of solidarity synonymous with Bevan's vision of the NHS. The remainder of this article makes a start in pursuing this form of enquiry. As indicated earlier, it does so by considering the role that contract increasingly plays as an important mechanism through which several features of the NHS and publicly funded healthcare are planned and delivered today. The next section begins this enquiry in the form of a discussion of two examples of contract – PFI contracts and so-called 'Covid contracts'.

TWO CONTRACTS – PFI AND COVID-19

PFI contracts

First, let us turn to what are here called private finance initiative (PFI) contracts. With such contracts, a private finance company – known as a special purpose vehicle (SPV) – is established and it finances, builds and maintains, for example, an NHS hospital for the duration of the contract term (typically in the range of 25–40 years). Clinical commissioning groups (CCGs)[9] lease the hospital and staff, such as cleaners, from the SPV, and during the contract term pay unitary charges, which cover services provided by the SPV, debt repayment, and financing costs (including often very high interest payments on the original loan, usually from a bank to the SPV). Those payments come out of the NHS budget. While the Government announced in 2018 that it would no longer use PFI for future building projects, given the duration of the existing contracts, the high levels of payments will continue for many years to come.[10] In 2022, it was reported that 101

8 Newdick (n 2 above) 1652.

9 As a result of the Health and Care Act 2022, CCGs, which were created by the Health and Social Care Act 2012, have been abolished and replaced with integrated care boards.

10 L Booth, 'Goodbye PFI' (House of Commons Library October 2018).

NHS trusts still owed around £50 billion in future unitary payments.[11] In 2020–2021, of the £2.3 billion the trusts spent on PFI projects, £457 million was used to pay interest charges to private companies, the equivalent of 15,000 newly qualified nurses' salaries. Some trusts spent more than half of their total unitary payments on interest charges.[12] As indicated, this means less money for patient care and staffing, which is compounded by the prospect of NHS trusts having to make future cost savings. The unitary payments, on the other hand, are guaranteed and rise in line with inflation, thereby compromising further the resources available for healthcare. From the perspective of those private sector actors involved in the funding, construction and management of PFI contracts, there are definitely profits to be made. A 2017 report by the Centre for Health and the Public Interest (CHPI) found that the vast majority of PFI healthcare contracts overseen by the Department of Health and Social Care (DHSC) and in existence at the time (107 of 125) had, over the previous six years, produced £831 million in pre-tax profits for the PFI companies involved.[13] This was on top of the profits made by others from those contracts, such as banks and construction companies. In addition, £480 million in dividends was also paid out on those contracts, amounting to almost 5 per cent of all the money the NHS paid under the contracts. Finally, the report notes that, by 2017, only eight companies had equity stakes in 115 (or 92%) of the 125 DHSC PFI contracts. As the report's authors note, this raises doubts over the claimed competitive basis/rationale of the PFI tendering process and questions about the possibility of abuse of market power in the context of existing contracts.[14]

In the context of this article, two questions arise from such data. First, what are its possible implications for the notion of solidarity underpinning the NHS? Secondly, what can PFI contracts reveal about the forms of social relations at play in today's NHS? As those questions are inextricably linked, the analysis that follows will not admit of clear demarcations when responding to each question in turn. An initial response is that the PFI does not have much of an effect on the idea of solidarity underpinning the NHS. For, despite PFI, general taxation still funds this public healthcare system and grounds its operation in accordance with principles such as access to treatment being based on one's need rather than ability to pay. Millions of people continue to receive treatment free at the point of need, including those unable,

11 M Goodier, 'NHS hospital trusts paying hundreds of millions in interest to private firms' *The Guardian* (London 25 October 2022).

12 Ibid

13 Centre for Health and the Public Interest, PFI: Profiting from Infirmaries (August 2017) 4.

14 Ibid 4.

for whatever reason, to pay tax. It therefore retains its communal and progressive character.

As noted above, however, PFI contracts have the effect of diverting some of the NHS budget away from the treatment and care of patients (reducing the money available to recruit more healthcare staff, for instance), thereby, in Newdick's term, corroding the original sense of solidarity discussed above and undermining its foundational principles. But, if this is the effect of PFI contracts, how might we explain the manner in which it occurs? What forms of relations underpin this type of corrosion? The following are two possible, and related, ways of approaching those questions. First, rather than the solidarity amongst citizens envisaged by Bevan, the PFI contract creates another form of social relation – namely that between creditor and debtor; the creditor (putting up the money) being the SPV and the debtor (accepting that money as a loan with interest that must be repaid) being the public body, or more broadly we could say, the state. And if citizens' taxes are the source of the debt repayments to the private sector, citizens might also be characterised here as debtors in a relationship with creditors. If liability for our fellow citizens in need of medical treatment (liability 'for the reversals of fortune of another') is the bonding force at the heart of the NHS as Bevan imagined it, the bonding force in the context of PFI contracts, while still liability, is a communal liability of debtors (the state and its citizens) to creditors (finance capital) – in other words, to a group outside of the solidary group (citizens) at the heart of the original vision of the NHS. Thus, despite the importance to it of citizens and the presence of a form of communal liability, this debtor–creditor relation is not a solidary one. Rather, it is a relation of power, driven by the needs and imperatives of capital and its constituency – the *marktvolk*. In the context of PFI contracts, at least, it is those needs and imperatives, rather than the demands of patients or claims of individual rights to medical treatment or the political objective of patient empowerment via increased choice, which result in the corrosion of Bevan's notion of solidarity. For the diversion of the NHS budget to the *marktvolk* contributes to the provision of fewer services, resulting in longer waiting lists, which, as seems to be occurring presently, lead to increasing numbers of citizens paying privately for treatment.[15] This, in turn, further jeopardises the NHS's solidary basis. Decisions to look for treatment outside of the NHS are predominantly driven by a lack of adequate state funding, a state of affairs to which PFI contracts will continue to contribute for the foreseeable future.

15 P Duncan and D Campbell, 'One in eight UK adults using private medical care due to NHS delays' *The Guardian* (London 15 December 2022).

Another, related, way of comprehending this erosion of solidarity in the context of PFI contracts is by reference to Brett Christophers' analysis in his book *Rentier Capitalism*.[16] Rent, as Christophers defines it, is '*income derived from the ownership, possession or control of scarce assets under conditions of limited or no competition*'.[17] Christophers' argument is that contracts (including PFI contracts) used to outsource the provision of services fit this definition insofar as the contracts themselves are the scarce assets over which certain companies – the rentiers of the outsourcing sector – have monopoly control. As he says:

> These contract assets are scarce in the sense that each is unique, and they are by nature limited in number … [T]hey frequently encompass the delivery of services for a period of years – even, in some cases, decades – and the income they generate thus takes the form of rent: income guaranteed by virtue of possession of an asset that insulates the contractor from all competition for the contract duration.[18]

Christophers' analysis prompts several points that are pertinent to the present discussion. First, beyond the scarce (NHS) resources, identified earlier, that function as the pool of money from which rentiers derive their income, Christophers identifies a further layer of scarcity in the context of what he terms 'contract capitalism' or 'contract rentierism' – namely, the scarcity of the contracts themselves. This scarcity tends towards the existence of monopoly power, with a limited number of companies being awarded contracts for outsourced services, something that would seem to be borne out by the CHPI's findings, cited earlier, showing that, by 2017, only eight companies had equity stakes in 115 of the 125 DHSC PFI contracts. As noted, those findings tend to confound claims about the competitive basis/rationale of the PFI tendering process and thus lend support to Christophers' point about the lack, rather than strong presence, of competition in the context of contract rentierism generally.

Secondly, 'contract capitalism' points to the central role of the *marktvolk* in the private and public sectors today, and, for present purposes, specifically within the sphere of publicly funded healthcare. Of course, as we have already seen by reference to Newdick's work and the discussion above, one way of characterising this is as a relationship between the *staatsvolk* and *marktvolk*, skewed in favour of the latter. But what Christophers' analysis alerts us to is not only the crucial consequences of 'contract rentierism' for the *staatsvolk* but, equally, the importance of understanding the nature of the relationships

16 B Christophers, *Rentier Capitalism: Who Owns the Economy, and Who Pays for It?* (Verso 2020).

17 Ibid xxiv. Emphasis in original.

18 Ibid xxxiv.

between the state and the *marktvolk* that are generative of the very existence of rentierism, of which contract capitalism is one example. The nature of those relationships is apparent in a 1965 essay by E P Thompson, which Christophers cites as evidence of the character of rentierism's revival in the UK during the 1960s and 1970s. Thus, Thompson identified one of the core characteristics of what he called a new 'predatory [rentier] complex' as being 'its interpenetration of private industry and the State (Government contracts, especially for war materials, of an unprecedented size, subsidies, municipal indebtedness to private finance, etc.) ...'.[19] Another was the state's central role in the revival of rentierism, a theme stressed in Christophers' account of the phenomenon. For instance, he argues that the growth of financial rentierism in the UK in recent times has been spearheaded by governments and powerful groups within them 'that have actively privileged the financial sector and financial activities'.[20] This focus on agency is also apparent in relation to the scarcity mentioned above and its production. Christophers cites John Maynard Keynes, who argued that earning interest on loaned funds depended on the existence of a scarcity of loanable capital. This scarcity, however, was not a natural phenomenon, but, Keynes argued, the result of a class project – capital had to be made scarce in order for the lucrative interest rates charged to access it to be possible. This focus on the active role played by the state dovetails with Streeck's notion of the debt state insofar as one of its key roles is to continue to borrow the *marktvolk*'s money and pay interest on it. Moreover, as noted earlier, as an important constituency that contemporary debt states must keep on side, Streeck argues that the state must actively seek to maintain the confidence of the *marktvolk* as well as demonstrating to this group its credibility in the form of being able to service its future debts. This important relationship between the state and the *marktvolk* will be taken up further in this article's final substantive section.

Finally, PFI contracts have a certain temporal dimension; as noted above, they can endure, often for several decades. Consequently, for those companies holding the contracts, they function as a steady stream of income over a period of time extending long into the future. As Christophers says, the contract of 'contract rentierism' should be characterised as an asset as 'it embodies futurity: the contract refers to future rather than historic or immediate ("spot market") exchange, and the value of the asset to its holder is the value of the future net cash flows it will elicit'.[21] PFI contracts are therefore often not ephemeral entities; rather, they bind the state and its citizens in for the long term.

19 Quoted in Christophers (n 16 above) 22.
20 Ibid 54.
21 Ibid 229.

What emerges from the foregoing discussion of PFI contracts is that, if we are to understand Newdick's contention that the idea of solidarity traditionally underpinning the NHS is being corroded, it is necessary to focus on the types of relations that are having this effect. Doing so means looking behind the surface appearance of such things as PFI contracts as mere entities of exchange to explore the nature of the relations between, on the one hand, the *marktvolk* and the state, and on the other, the *marktvolk* and the *staatsvolk*. This enables identification of the kinds of conditions required for the existence and maintenance of such contracts, as well as for the corrosive effects that flow from those conditions. The following section continues this type of analysis by reference to the example of what are here called 'Covid-19 contracts'.

Covid-19 contracts

At the outset, it is important to note the scope of Covid-19 contracts. On the one hand, they cover matters directly related to healthcare, such as contracts for the supply of personal protective equipment (PPE) to the NHS. Covid-19 contracts also include the Government's broader management of the pandemic – for instance, the award of contracts to firms that ran focus groups to assess the best way for Government to communicate important information about the pandemic to the public. For the avoidance of doubt, reference to Covid-19 contracts in this article includes both types of contract.

Several controversies have, and continue to, surround Covid-19 contracts. Two of these will form the focus of attention here. First, there have been much-publicised allegations of cronyism – that is, of those working in government effectively awarding contracts to their acquaintances. The second concerns the amount of PPE items that are unfit for purpose and thus designated as waste. Is there evidence pointing in these directions; if so, what might this tell us about the relations at play in Covid-19 contracts, as well as the possible implications for the notion of solidarity? These are the questions to which the discussion in this section is directed.

Taking allegations of cronyism first, reference to a couple of recent judicial review cases brought by the Good Law Project (GLP) can assist here. The argument advanced is that the cases point to the presence of personal and social relations/connections at different stages of the process leading to the award of contracts. Thus, in one case concerning the award of a contract (to a company called Public First) for the provision to the Government of focus group and communications support services without public notice or competition, the High Court upheld the GLP's ground of challenge that the award gave rise to

apparent bias contrary to principles of public law.[22] As the defendant had not produced objective criteria which they could show had been used to select Public First over other research agencies, the High Court found that it had not been demonstrated that the procurement was fair and impartial and that there was, consequently, 'a real possibility, or a real danger, that the decision-maker was biased'.[23] Although O'Farrell J was at pains to stress that Mr Cummings's (who was, at the time, the Chief Adviser to the Prime Minister) professional and personal connections with Public First did not mean he was unable to make an impartial assessment as to which organisation could deliver the required services, it is difficult to divorce the finding of apparent bias from those connections, which the defendant (the Rt Hon Michael Gove (then Minister for the Cabinet Office and Chancellor of the Duchy of Lancaster)) also had with Public First's owners and directors. Indeed, the GLP's 'apparent bias' ground of challenge was founded on the existence of those personal connections, the nature of which are set out in detail in the High Court's ruling.

Another case concerns the so-called high priority (HPL) or VIP lane, whereby various groups – Members of Parliament (MPs), ministers, and senior officials, including those in the NHS – could email a dedicated email address indicating opportunities from people who had contacted them wanting to supply PPE.[24] One concern with the VIP lane was that it functioned as a mechanism by which officials could recommend the businesses of acquaintances as suppliers of PPE and fast-track their interests in being awarded contracts. The importance played by personal relations, at least insofar as getting onto the HPL was concerned, seems to be borne out by this case, in which the GLP sought judicial review of decisions by the Secretary of State for Health and Social Care to make direct awards of contracts for the supply of PPE and medical devices to three companies. The company director of one of the companies – Pestfix – contacted the Chief Commercial Officer

22 *R (on the application of The Good Law Project) v Minister for the Cabinet Office* [2021] EWHC 1569 (TCC).

23 This ruling was subsequently reversed by the Court of Appeal as it found that there was no requirement on the decision-makers to conduct any procurement process and thus no requirement on them to identify objective criteria that had been applied in selecting one rather than another research agency. Mr Cummings was able to award the contract directly. See *R (on the application of The Good Law Project) v Minister for the Cabinet Office* [2022] EWCA Civ 21. Despite the ruling, the Court of Appeal reiterated the evidence of the personal, social and professional connections between Public First and the decision-makers, especially Mr Cummings. GLP's request for permission to appeal the Court of Appeal's ruling to the Supreme Court was refused in December 2022.

24 *R (on the application of Good Law Project Limited and Everydoctor) v The Secretary of State for Health and Social Care* [2022] EWHC 46 (TCC).

at the DHSC indicating that he was a good friend of his father-in-law's and that they had met at the father-in-law's recent 80th birthday party. In subsequent emails to staff, the nature of the relationship – that the director is an old friend of his father-in-law's – is relayed by the Chief Commercial Officer. As a result of the referral, the company was placed onto the HPL, subsequently being awarded a number of lucrative contracts for the supply of PPE. Another of the companies – Ayanda, which is engaged in private equity, trading, asset management and trade financing – was awarded lucrative PPE contracts worth £252.5 million. Ayanda was allocated to the HPL after an adviser to its board, who formerly was an adviser to the Board of Trade for the Department of International Trade (DIT), contacted the Director of Global Trade and Investment at the DIT suggesting that the PPE deal he was proposing 'really needs Ministerial attention'. The Director of Global Trade and Investment suggested to other officials that it 'should be fast tracked through the system', which it was.

Beyond those legal cases, evidence of the importance of connections and acquaintances to successful referrals to the VIP lane, and to securing subsequent contracts, continues to mount.[25] This obviously raises the issue of potential conflicts of interest, something identified by the Public Accounts Committee (PAC) in the context of the award by the DHSC to Randox Laboratories Ltd of contracts for Covid-19 testing services and goods worth almost £777 million.[26] It found that the DHSC did not demonstrate 'any evidence of taking any care over potential conflicts of interest when it awarded contracts to Randox' despite the then Secretary of State for Health and Social Care – Matt Hancock MP – having received hospitality from Randox in 2019, and Owen Patterson MP, who had contacts with the Secretary of State for Health and Social Care, having been one of Randox's paid consultants. The PAC also expressed concern about the disproportionate (high) value of contracts for testing services having been awarded to testing suppliers on the VIP lane, that had been referred by, *inter alia*, government ministers, MPs and the Prime Minister's office.

As noted above, the second area of controversy concerns the vast amount of PPE which is currently in storage as it cannot be used by frontline staff. The following data from the National Audit Office provides details about this issue.[27] More than 3.6 billion PPE items,

25 See, for example, the following items on the GLP's website: 'LEAKED: The Conservative politicians who referred companies to the PPE "VIP lane"'; 'REVEALED: Greg Hands referred close political contact for £25m VIP contract'.

26 Committee of Public Accounts, G*overnment's Contracts with Randox Laboratories Ltd* (House of Commons 27 July 2022) 28.

27 National Audit Office, *Investigation into the Management of PPE Contracts* (House of Commons 30 March 2022) 1144.

costing £2.9 billion to purchase, are in storage because they cannot currently be used for frontline services, which is 11 per cent of all PPE the Government has received: 1.5 billion of these have expired (passed their sell by date); and 1 billion items of PPE, costing £439 million, are wastage, meaning that it cannot be used for any purpose. From March 2020 to October 2021, the DHSC paid £737 million to store PPE, which included penalty charges of £436 million for having to store it for longer than they envisaged. The DHSC annual accounts for 2021–2022 show that the department was spending an estimated £24 million each month on PPE storage costs.[28] Exemplary of the controversies surrounding PPE, the GLP cites the case of Uniserve, a company assigned to the VIP lane after referral by the Conservative peer, Lord Agnew. The company was awarded PPE contracts worth £300 million and subsequently provided £178 million of PPE which the Government classified as 'do not supply' (to frontline workers). Uniserve was then awarded a contract worth £138 million to store PPE.[29]

What might the two foregoing controversies, and related information, disclose about the relations at play in the context of Covid-19 contracts? Let us return to one element that Streeck stresses in his analysis of the relationship between the state and *staatsvolk* – namely, a duty of loyalty. As we saw earlier, he argues that citizens owe the state a duty of loyalty in return for the protection of social rights afforded to them. Of course, we might think such a duty was present during the pandemic – people generally abided by the regulations set by the state and expressed loyalty to the NHS and its founding principles, including in the form of solidarity with its workers and those citizens requiring access to treatment as a result of having contracted the virus. Thus, some with non-Covid related illnesses may have held off attending hospital to ensure priority was given to those with the virus. And it could be argued that longer waiting lists demonstrated the existence of a more pressing health need and an instance of a communal liability for the reversal of fortunes of others (Covid-19 patients). It is suggested here, however, that the controversies cited above point towards the existence of two other duties of loyalty at play, but this time in the context of the relationship between the state and the *marktvolk* (here, those companies/firms that secured government contracts for the provision of materials and services related to Covid-19). The first resides at the micro level. This takes the form of a duty of loyalty on the part of state officials to market players in the context of specific contracts. This duty of loyalty may arise, for instance, out of friendship

28 Department of Health and Social Care, *Annual Report and Accounts 2021–22* (26 January 2023).

29 See 'REVEALED: PPE storage costs hit £1bn as "VIP" firm Uniserve's profit soars'.

or having been a former colleague, especially where the person could demonstrate links to government in the sense of having contributed to it in some form. Here, then, we might note the importance to the award of Covid-19 contracts of certain sets of social relations or networks, which themselves exhibit a sense of community or even solidarity between state officials and the *marktvolk*. The ties that bind here might not be so much grounded in liability but in something more akin to status and, if not blood or love, then acquaintance. It is who you are, whom you know, whom you have worked with, that seem to matter. The second duty of loyalty lies at the macro level. In July 2020, the British Medical Association (BMA) produced a report indicating the vast scale of the outsourcing of work and tasks by the Government in the course of the pandemic, as well as the use of large sums of public money that sometimes did not produce high-quality products and technology (they give the example of test and trace).[30] The examples cited earlier would seem to confirm both the extent of this outsourcing and its results. It is argued here that what this scale of outsourcing discloses is a state loyalty, in a more general sense, to the market and capital, rather than to provision of services by the public sector.

The two foregoing duties of loyalty differ from Streeck's characterisation as, firstly, they are not manifestations of loyalty owed *to* the state in the context of the relationship between the state and the *staatsvolk*, but rather *by* the state to the *marktvolk*. And, secondly, the return on this form of state loyalty does not necessarily equate to the protection of citizens' or indeed public healthcare workers' health, as confirmed, for instance, by the BMA's findings and the vast amount of wasted PPE. Rather, it enhances the profit margins of the companies/firms to whom the work was outsourced and produces large amounts of debt, the repayment of which will potentially further affect the resources available for, among other public services, the NHS. As noted earlier, diminishing resources affect this institution's solidary basis as the principle of universal access based on need alone is compromised, together with Bevan's notion of communal liability, as those able to afford it feel increasingly compelled to resort to the private sector. That other sense of communal liability that was encountered in the discussion of PFI contracts above – a liability of citizens to the *marktvolk* in the form of repayment of debt – will, however, be reinvigorated.

30 British Medical Association, *The Role of Private Outsourcing in the COVID-19 Response* (July 2020).

CONCLUSION

Chris Newdick's work has contributed significantly to putting the ideas of community and solidarity squarely on the agenda of healthcare lawyers and those researching healthcare more generally. In doing so, he has opened up for discussion and analysis the broader theme of the nature of relations in the context of publicly funded forms of healthcare and the ways in which these may have changed, and be changing, today. Taking the outsourcing of such healthcare as its point of departure, this article has sought to identify and analyse the kinds of relations underpinning and flowing from some of the contracts associated with this phenomenon. Two conclusions emerge.

First, the contracts explored here mark something of a shift in the kinds of social relations underpinning the NHS. While this institution still displays evidence of Bevan's vision of it as a solidary, collective entity founded on the principle of access based on need rather than ability to pay, the PFI contract illustrates the partial erosion of this notion of solidarity and its replacement by a non-solidary communal liability of the *staatsvolk* to the *marktvolk*. Here, it is the debtor–creditor relation and the emerging significance of the *rentier* that is important.

Secondly, and relatedly, the discussion of Covid-19 contracts in this article raises the issue not merely of the corrosion of traditional understandings of solidarity and community underpinning publicly funded healthcare, but of how that may occur precisely via the operation of other forms of solidarities, communities, and/or networks – specifically those fostered in the context of the relationship between the state and the *marktvolk*. As Ralph Miliband wrote of economic elites, they exhibit 'a high degree of cohesion and solidarity, with common interests and common purposes which far transcend their specific differences and disagreements'.[31] Those other forms of solidarity and community, and the nature of the ties and bonds they exhibit, demand further research if we are to grasp the changing state of publicly funded healthcare and the steadily increasing role of capital and the *marktvolk* within it.

31 R Miliband, *The State in Capitalist Society* (Merlin 2009) 35.

Northern Ireland
Legal Quarterly
Vol. 76 No. 1 (2025) 118–139
Articles DOI: 10.53386/nilq.v76i1.1141

Developing product liability networks for AI systems in the medical context

James Devenney
University of Reading*
Geraint Howells
University of Galway†
Correspondence emails: j.devenney@reading.ac.uk; geraint.howells@universityofgalway.ie.

ABSTRACT

Product liability is again a matter of contemporary discussion due to the increased integration of technology into products. In particular, artificial intelligence (AI) has come to the fore, with machines, for example, using big data to make decisions faster and often with greater accuracy than humans. AI is being used at all stages of medicine. Such advances in technology have the potential to provide great benefits. However, there are potential risks. Many of these risks relate to data privacy but even in the field of safety uncertainty about the risks remain. This has led, in part, to reform of the European Union (EU) Products Liability Directive. The United Kingdom (UK) is, of course, no longer bound to follow, but it is likely it will also in time feel the need to do something in this space. In 2021 the Law Commission tentatively suggested 'product liability and emerging technology' for its programme of Law Reform, but concluded the time was not right. Subsequently, the Government has alluded to the need for modernising product liability law, but has only mentioned the possibility of extending the definition of product to include software and taking AI into account when assessing defectiveness. The context is a country hamstrung by Brexit, without a real vision for the future of UK consumer law nor for achieving the competitive advantages which Brexit promised to deliver. On the other hand, the EU has considered both a strict liability regime for high-risk AI products and a revised negligence regime for AI, as well as a revised strict product liability regime adapted to the AI context. This article will, first, consider how negligence might apply. Then, liability under the product liability regime, the EU's amended regime and the proposed strict liability regime for high-risk AI will be considered. The advantages and disadvantages of negligence and strict liability will be discussed with a preference being for strict liability for all products. Finally, a plea to consider network liability or an even more ambitious insurance-based solution will be made.

Keywords: product liability; AI; Brexit; medical arena.

* Professor of Transnational Commercial Law, University of Reading; Visiting Full Professor, UCD, Ireland; Professor, Neapolis University of Pafos, Cyprus; and Visiting Professor, Dalian Maritime University, China.

† Established Professor, University of Galway; and Visiting Professor, University of Manchester.

INTRODUCTION

It is an honour to contribute to this celebration of the work of Professor Christopher Newdick, one of the leading medical law thinkers of our generation. As private lawyers, the most obvious intersection of our interests with Chris's fields of expertise lies in product liability; an area to which Chris directed his customary incisive critique in relation to the emerging strict product liability regime in the 1980s.[1] Fortunately for us, product liability is again a matter of contemporary discussion due to the increased integration of technology into products.[2] Moreover, artificial intelligence (AI) has come to the fore in the medical arena, with machines, for example, using big data to make decisions faster and often with greater accuracy than humans (even medics!).[3] AI is being used at all stages of medicine: it can help triage patients to assist doctors with determining the order of priority for treatment; it can assist with clinical risk prediction; it can assist with diagnosis; it can help develop drugs and match drug regimes to patients; and it can assist in surgery, including through the use of robots.[4]

Such advances in technology have the potential to provide great benefits.[5] However, there are also potential risks. Many of these risks relate to data privacy,[6] but, even in the field of safety, uncertainty about

1 See, for example, C Newdick, 'The future of negligence in product liability' (1987) 103 LQR 288–310; C Newdick, 'The development risk defence of the Consumer Protection Act 1987' (1988) 47 Cambridge Law Journal 455–476; and C Newdick, 'Risk, uncertainty and "knowledge" in the development risk defence' (1991) 20 Anglo-American Law Review 309–326.

2 See, for example, Law Commission, *Automated Vehicles: Joint Report* (Law Comm No 404, 2022); European Law Institute, Guiding Principles for Updating the Product Liability Directive for the Digital Age (2021); and European Commission, *Expert Group on Liability and New Technologies – New Technologies Formation: Liability for Artificial Intelligence and Other Emerging Digital Technologies* (2019).

3 Cf M Prictor, 'Where does responsibility lie? Analysing legal and regulatory responses to flawed clinical decision support systems when patients suffer' (2023) 31 Medical Law Review 1–24.

4 A Oliva et al, 'Management of Medico-legal risks in digital health era: a scoping review' (2022) 8 Frontiers in Medicine 1; S Jassar et al, 'The future of artificial intelligence in medicine: medical-legal considerations for health leaders" (2022) 35 Healthcare Management Forum 185–189; M Morris et al, 'Ethical, legal and financial consideration of artificial intelligence surgery' (2023) 89 The American Surgeon 55–60.

5 See, for example, NHS England, Artificial Intelligence (AI) and Machine Learning (updated 13 March 2023).

6 See B Murdoch, 'Privacy and artificial intelligence: challenges for protecting health information in a new era' (2021) 22 BMC Medical Ethics 122. See, generally, Information Commissioner's Office, Guidance on AI and Data Protection (updated March 2023).

the risks remains.[7] The program may be developed using inadequate data. There may be flaws in the data. The data may fail to take account of all categories of patients based on gender or ethnicity. There may be design errors causing abnormal system behaviour. The AI system may not be used in the original design context. There may be impact from permanent or transient hardware defects, such as 'bit flip' linked to radiation particles.[8] Furthermore, there is a risk that doctors are deskilled if they rely automatically on AI results (which may be wrong) or at least overdevelop some skills (such as interpreting AI outputs) at the risk of not recognising, for example, normal images. Education is clearly needed.[9] Equally there may need to be a 'surgeon in the loop' principle to ensure the surgeon remains responsible for all decisions, and these are not outsourced to an AI.[10] The 'black-box' algorithm is also potentially problematic as it often provides an answer, but without any supporting rationale. Should the doctor just trust the machine? If things go wrong the injured party may not know on what basis the machine acted due to intellectual property law keeping the basis of the algorithm secret.

This has led, in part, to reform of the EU Products Liability Directive.[11] The United Kingdom (UK) is, of course, no longer bound to follow such initiatives, but it is likely the UK will also in time feel the need to do something in this space. Indeed, in 2021 the Law Commission tentatively suggested 'product liability and emerging

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7 Compare H Smith and K Fotheringham, 'Exploring remedies for defective artificial intelligence aids in clinical decision-making in post-Brexit England and Wales' (2022) 22 Medical Law International 33–51. See also Medicines and Healthcare Products Regulatory Agency, Software and Artificial Intelligence (AI) as a Medical Device (updated 3 February 2025).

8 Oliva et al (n 4 above).

9 Ibid.

10 Ibid. See also C Jones, J Thornton and J C Wyatt, 'Artificial intelligence and clinical decision support: clinicians' perspectives on trust, trustworthiness, and liability' (2023) 31 Medical Law Review 501–520.

11 Directive (EU) 2024/2853 of the European Parliament and of the Council on liability for defective products and repealing Council Directive 85/379/EEC. Consumers will rarely directly buy complex medical devices, so we leave out of this account the reform of the law for contractual liability for digital content and services found in the UK Consumer Rights Act 2015 and Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services. See G Howells and C Twigg-Flesner, 'Interconnectivity and liability' in L DiMatteo, C Poncibo and M Cannasa (eds), *The Cambridge Handbook on Artificial Intelligence* (Cambridge University Press 2022); and A De Franceschi and R Schulze (eds), *Digital Revolution: New Challenges for Law* (Beck International 2020).

technology' for its programme of Law Reform.[12] Yet, in February 2023 the Law Commission concluded that the time was not right to establish a new programme of reform, noting that it had 'taken this decision in view of the Government's focus on priorities for the remainder of this Parliament'.[13] Subsequently, in a report mainly concerned with product safety reform, the Government has alluded briefly to the need for modernising product liability law, but concretely has only mentioned the possibility of extending the definition of product to include software and taking AI into account when assessing defectiveness.[14] The context, we would suggest, is a country hamstrung by Brexit, without a real vision for the future of UK consumer law nor for achieving the competitive advantages which Brexit promised to deliver.[15]

On the other hand, the EU has proposed both a strict liability regime for high-risk AI products (which would encompass medical devices) and a revised negligence regime for AI (though recently withdrawn) as well as a revised strict product liability regime adapted to the AI context. This article will, first, consider how negligence might apply, including under the revised EU regime. Then, liability under the product liability regime, the EU's amended regime and the proposed strict liability regime for high-risk AI will be considered. The advantages and disadvantages of negligence and strict liability will be discussed with a preference being for strict liability for all products. Finally, a plea to consider network liability or an even more ambitious insurance-based solution will be made.

NEGLIGENCE

Introduction

In many cases, medical use of AI systems will be under the supervision of trained medics. For example, there may be computerised systems for determining the best mix of medicines to be administered, robots may

12 See Law Commission, 'Generating ideas for the Law Commission's 14th programme of law reform'.

13 See Law Commission, 'An update on the 14th programme of law reform' (15 February 2023).

14 Department for Business, *Energy and Industrial Strategy, Smarter Regulation: UK Product Safety Review* (August 2023) 42.

15 Compare general policy statements such as wanting 'a more active pro-competition strategy to deliver more targeted and effective pro-competitive interventions' (Department for Business, Energy and Industrial Strategy, *Reforming Competition and Consumer Policy: Driving Growth and Delivering Competitive Markets that Work for Consumers* (2021) para 0.15). See also the UK Government policy paper *Establishing a Pro-innovation Approach to Regulating AI* (CP 728, 2022).

be used in surgery and AI systems may guide anaesthetists, but the final call will normally be with the trained medic.[16] Medical liability is likely to remain negligence based outside those few systems that adopt no-fault liability;[17] and so the starting point is that AI liability in medicine will continue to be judged on a negligence basis, taking into account the availability and performance of AI devices. However, in the context of negligence and AI systems, some interesting questions are posed, particularly around the complicated interaction between the person using the AI system and the performance of the product. For example, a well-known phenomenon is automation bias under which people sometimes trust machines more than personal judgement.[18] Whether this is due to a belief that the machine is really likely to be accurate, or simply due to pressure of workload, there is a risk that doctors will rely too much on machines and not use their independent judgement to question it.[19]

Conversely, there is also the risk of being found negligent for not using, or following, an available AI system. What, for example, if a doctor reflects on the advice of the AI device and decides not to follow its instructions, but it turns out the patient would have benefited from the doctor following them? Or an AI system is found to perform better than humans, for example in reading X-rays, but it is decided not to use it? Or a surgeon prefers to deactivate an automated tool when the outcome can be shown to have been more likely to be successful if automation had continued? It may in fact be hard to allocate blame and prove negligence.[20] That is why some authors have favoured strict liability over negligence when AI is involved.[21] Also, the difficulty for the injured party in assigning liability to a particular actor where AI devices are involved, relying on data feeds and used by professionals, has also been a factor in calls for network liability. We will return to

16 F Pasquale, 'Liability standards for medical robotics and AI' in L DiMatteo, C Poncibo and M Cannasa (eds), *The Cambridge Handbook on Artificial Intelligence* (Cambridge University Press 2022).

17 Compare S Holm, C Stanton and B Bartlett, 'A new argument for no-fault compensation in health care: the introduction of artificial intelligence systems' (2021) 29 Health Care Analysis 171–188.

18 See, for example, M Grissinger, 'Understanding human over-reliance on technology' (2019) Pharmacy and Therapeutics 320–321.

19 See D Lyell and E Coiera, 'Automation bias and verification complexity: a systematic review' (2017) 24 Journal of the American Medical Informatics Association 423–431.

20 See, generally, C Witting, *Street on Torts* 16th edn (Oxford University Press 2021) 410–411.

21 On policy considerations generally, see H Zech, 'Liability for AI: public policy considerations' (2021) 22 ERA Forum 147–158.

these broader policy questions after surveying the current law and reform initiatives.[22]

If AI systems develop in such ways that once deployed they operate autonomously without the ability for a medic to intervene, then the decision to use such an autonomous device will itself be subject to judgment for reasonableness.[23]

EU proposal on adapting non-contractual civil liability rules to artificial intelligence

The EU proposed to adapt the rules of Member States in respect of non-contractual fault-based liability and AI.[24] The proposal, now withdrawn, sought to make it easier to recover for fault-based liability by introducing rules relating to the disclosure of evidence with a rebuttable presumption of non-compliance with duty of care if not complied with and a rebuttable presumption of a causal link in the case of fault.[25] The proposal differentiated high-risk AI (as defined in the then proposed AI Act).[26] Indeed, the rules on disclosure of evidence would have only applied to high-risk AI.[27] The operation of AI systems can be very opaque so that claimants are unable readily to assess whether there has been, for example, any negligence. The phrase 'black-box' is often used to describe the secrecy surrounding the algorithms used in AI systems.[28] These proposals were intended to make it easier to bring claims by making the AI more transparent. On presenting facts and evidence to support the plausibility of a claim, national courts would have been empowered to require the disclosure of relevant risks.[29] Steps could have been taken to preserve the confidentiality of any alleged trade secret, such as the algorithms underpinning the AI operation.[30] The requirements of the AI Act would have ensured such

22 See below at 135ff.

23 See J Herring, *Medical Law and Ethics* 9th edn (Oxford University Press 2022) paras 3.2.2ff.

24 Proposal for a Directive of the European Parliament and of the Council on Adapting Non-contractual Civil Liability Rules to Artificial Intelligence (AI Liability Directive), COM/2022/496 final. On withdrawal, see Legislative Train Schedule: AI Liability Directive.

25 See O Dheu and J De Bruyne, 'Artificial intelligence and tort law: a "multi-faceted" reality' (2023) 31 European Review of Private Law 261–298.

26 See art 2, cross-referring to art 3 of the now Regulation (EU) 2024/1689 of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act).

27 Art 3(1).

28 See Y Bathaee, 'The artificial intelligence black box and the failure of intent and causation' (2018) 31(2) Harvard Journal of Law and Technology 899–938.

29 Art 3.

30 Art 3(4).

information was readily accessible to the defendant.[31] The claimant would first have needed to take all proportionate efforts to gather the information from the defendant. Failure to disclose such information would have led to the presumption of fault.[32] This was significant as it also led to a rebuttal presumption of a causal link.[33]

A rebuttable presumption had also been proposed as regards the causal link between the fault of the defendant and the output of the AI system or the failure of the AI to produce an output.[34] For this presumption to arise, three conditions need to be met. First, the claimant had to have demonstrated fault, or this must have been presumed by breach of a duty to disclose.[35] In the case of high-risk AI systems, there must have been a failure to comply with certain rules in the then proposed AI Act aimed at risk management, design and development or there must have been a failure to take required corrective measures.[36] Second, it needed to be likely that the fault influenced the output produced by the AI system or its failure to produce an output.[37] Failure to comply with record-keeping requirements are unlikely, for example, to have influenced the functioning of the AI system. Third, it had to be demonstrated to be reasonably likely that the output produced by the AI system or the failure of the AI system to produce an output gave rise to damage.[38] These rules did not apply to high-risk AI systems where there was sufficient evidence and expertise was reasonably accessible.[39] This might be possible based on the documentation and logging requirements of the AI Act. This presumption of causality would only have applied for non-high-risk systems when courts considered it would be excessively difficult for the claimant to prove the causal link. It was not clear how serious a barrier this would have been given that the recitals note that the claimant should not be required to explain the characteristic of the AI system or how these characteristics make it harder to establish the causal link.[40] It was noted that the claimant had the difficult task of pointing to the human act or omission that constituted fault leading to the output or failure of output from the AI system causing damage. Also, whilst it was called a rebuttable presumption, there was built-in a requirement

31 See art 13.
32 Art 3(5).
33 Art 4(1)(a).
34 Art 4.
35 Art 4(1)(a).
36 Art 4(2).
37 Art 4(1)(b).
38 Art 4(1)(c).
39 Art 4(4).
40 Recital (28).

to show likelihood of a causal link, so it was uncertain how reduced the burden would have been. This is discussed further below in relation to similar rules in the Product Liability Directive. AI that has been found suitable for use by non-professionals would not normally have been subject to the presumption of causality.[41] This would have been unfair on non-professional end users. The presumption would only have arisen where they materially interfered with the operation of the AI system or failed when required to determine the conditions of operation of the AI system.

Even if medical liability remains fault based, there remains the question of the distinct liability under other liability systems. If this is a product it may already be subject to the distinct strict product liability regime. Indeed, the proposal on adapting non-contractual liability to AI was specifically stated not to affect any rights the injured person may have under the Product Liability Directive 85/374/EEC.[42] Now the proposal on AI liability has been withdrawn, product liability will become even more central to many. It is to that Directive and its reform that we now turn.

PRODUCT LIABILITY DIRECTIVE

Introduction

The previous Product Liability Directive (85/374/EEC) was transposed in the UK by part 1 of the Consumer Protection Act 1987.[43] That Act included an explicit reference to the purpose of part 1 being to comply with that Product Liability Directive, a reference which has survived Brexit albeit with a change from the present to past tense.[44] Thus, it is still legitimate in the UK to refer to the previous Product Liability Directive.

At first glance, that Product Liability Directive's stated aim of achieving a 'fair apportionment of the risk in modern technological production'[45] seems well suited to resolving the problem of AI liability. Unfortunately, there was no clarity about what the precise underlying

41 Art 4(6).

42 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

43 Part 1 of the Consumer Protection Act 1987 applies to England, Wales and Scotland. For Northern Ireland, see part 2 of the Consumer Protection (Northern Ireland) Order 1987.

44 The amendment was made by the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2019/696, sch 3.

45 Recital 2.

policy was seeking to achieve. One model was to see product liability as sharing the risks so that if new developments go wrong those affected are compensated.[46] Without unduly pre-empting later discussion, it could be seen as a form of insurance. However, in practice there is a danger that it can become a matter of avoiding liability by simply warning the user of potential risks. Burton J's concern in *A v National Blood Authority*[47] that warnings should not slip into being exclusion clauses[48] (which are not allowed)[49] is at risk of not being heeded.

Whatever the underlying policy, there are doubts that this Product Liability Directive, and the Consumer Protection Act 1987 regime enacting it into law in England, Scotland and Wales, had the scope and definitions to deal appropriately with AI systems. In particular, is an AI system a 'product'? A product is defined in the Consumer Protection Act 1987, section 1(2), and is primarily defined as goods, the definition for which is found in section 45 as including:

> substances, growing crops and things comprised in land by virtue of being attached to it and any ship, aircraft or vehicle ... .

Two challenges thus arise for bringing AI systems under the ambit of the Consumer Protection Act 1987. First, the purpose of some AI systems might be to provide information. In *VI v KRONE – Verlag Gesellschaft mbH & Co KG*,[50] incorrect paramedical advice was printed in a newspaper and subsequently followed by a reader, causing injury to the reader. The Court of Justice of the European Union (CJEU), noting that the then Product Liability Directive did not apply to services, held that the situation did not come within the scope of that Product Liability Directive. However, the CJEU did note:

> In the present case, it must be observed that the service in question, namely the provision of inaccurate advice, is unrelated to the printed newspaper, which constitutes its medium. More specifically, that service does not concern either the presentation or the use of the latter. Therefore, that service is not part of the inherent characteristics of the printed newspaper which alone permit an assessment as to whether the product is defective.[51]

Thus, an AI diagnostic system is, perhaps, more likely to come within the Consumer Protection Act 1987 than an AI system merely conveying information.

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46 See, generally, S Deakin and Z Adams, *Markesinis and Deakin's Tort Law* 8th edn (Oxford University Press 2019) 584ff.

47 *A v National Blood Authority* [2001] 3 All ER 289.

48 Ibid [70].

49 Consumer Protection Act 1987, s 7.

50 Case (C-65/20) ECLI:EU:C:2021:471.

51 Ibid at [36].

Secondly, does software come within the definition of 'goods' under the Consumer Protection Act 1987? A similar debate, of course, has been simmering under the Sale of Goods Act 1979,[52] where the fairly widely accepted view has been that software is not *per se* 'goods' but defective software installed on hardware may render the hardware of unsatisfactory quality.[53] By contrast the CJEU held, in the context of the Commercial Agents Directive,[54] that goods 'can cover the supply, in return for payment of a fee, of computer software to a customer by electronic means where that supply is accompanied by the grant of a perpetual licence to use that software'.[55]

The EU reform of the Product Liability Directive includes software allowing an AI system producer to be liable for the system or as a component of the final products.

Defects

Assuming a particular AI system is subject to the (UK) strict liability regime, the next issue is to determine whether the product is defective. The definition of defect – 'there is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect'[56] – has been subject to many criticisms. In particular, it has been criticised for circularity as the answer to what is a defect depends upon answering the question of what safety a person is entitled to expect.[57] Indeed, Herbert Zech describes this strict product liability regime as a 'de facto negligence' regime.[58] He suggests this is the case on the ground that the defect requirement entails negligence and the injured party has the burden of proving defectiveness. Although many[59] have hinted at the regime risking collapsing back into a negligence regime, especially if the development risks defence is allowed, few have gone this far.

52 See, generally, S Green and D Saidov, 'Software as goods' (2007) Journal of Business Law 161–181.

53 *St Albans City and DC v International Computers Ltd* [1997] FSR 251.

54 Council Directive 86/653/EEC of 18 December 1986 on the coordination of the laws of the Member States relating to self-employed commercial agents.

55 *Software Incubator Ltd v Computer Associates (UK) Ltd* (C-410/19) [2022] 2 CMLR 3 at [52].

56 S 3.

57 J Stapleton, *Product Liability* (Butterworths 1994) ch 10.

58 Zech (n 21 above).

59 Including C Newdick, 'The future of negligence in product liability' (n 1 above); Newdick, 'The development risk defence' (n 1 above); and Newdick, 'Risk, uncertainty and "knowledge" (n 1 above).

The key question is what safety a person is *entitled* to expect, rather than what they actually expect.[60] Only a few clues are given to the factors to be taken into account on how those expectations should be assessed. Nevertheless, it may involve the courts (and indeed potentially reformers) in questions of policy around, for example, risk-benefit analysis.[61]

The very open-textured nature of the standard[62] means that it could be applied to AI systems, even if the Consumer Protection Act 1987 is not reformed to expressly make reference to factors specifically relevant to AI. The age-old problem remains of determining what standard a person is entitled to expect. Would we, for example, always be entitled to expect AI systems to have better outcomes than human interventions, so that if it does not reach that standard it does not offer the safety we are entitled to expect? Can we always be entitled to expect AI to take account of social factors such as race and ethnicity and so a failure to do so would render it less safe than we are entitled to expect?[63] To the extent that AI is self-learning, do we have to accept that comes with risks that it may learn in ways that create additional risks?

At this point we will limit ourselves to highlighting three further issues. First, at what point in time are safety expectations judged? The traditional view would be at the time the product is supplied,[64] but how does this apply in the context of any ongoing software updates or, indeed, development of the AI system through self-learning?

Secondly, at least in the context of high-risk AI used in the medical setting, the EU's AI Act proposes a raft of regulatory requirements.[65]

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60 See, for example, *Richardson v LRC Products Ltd* [2000] Lloyd's Rep Med 280 (consumers not entitled to expect that condoms will never fail).

61 See Witting (n 20 above) 416, citing C Newdick, 'Strict liability for defective drugs in the pharmaceutical industry' (1985) 101 Law Quarterly Review 405–430.

62 Consumer Protection Act 1987, s 3(2) states: '(2) In determining for the purposes of subsection (1) above what persons generally are entitled to expect in relation to a product all the circumstances shall be taken into account, including—(a) the manner in which, and purposes for which, the product has been marketed, its get-up, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product; (b) what might reasonably be expected to be done with or in relation to the product; and (c) the time when the product was supplied by its producer to another; and nothing in this section shall require a defect to be inferred from the fact alone that the safety of a product which is supplied after that time is greater than the safety of the product in question.'

63 See, for example, P Noseworthy et al, 'Assessing and mitigating bias in medical artificial intelligence: the effects of race and ethnicity on a deep learning model for ECG analysis' (2020) 13(3) Circ Arrhythm Electrophysiol e007988.

64 Compare Consumer Protection Act 1987, s 3(2)(c).

65 AI Act (n 26 above).

Would compliance with such requirements provide a defence to an allegation that the product was defective? This is not based on reliance on the very narrow compliance with mandatory requirement defence,[66] but would rely on the argument that if the AI system is designed and built according to the best contemporary standards then it must offer the standard of safety people are entitled to expect. This argument has been run and accepted in principle in case law in England and Wales, but even in generally pro-defendant judgments there was a reluctance to make it an automatic defence.[67] The weight given to compliance would depend upon the context and might take into account whether the standards had addressed the particular issue and how recently the standards had been updated. In a fast-changing area like AI, one might expect the courts to be slow to accept that mere compliance with regulatory requirements would provide an effective shield against liability. At a more general level, the function of regulation and the *ex post* assessment by a court are very different tasks that should not be unduly confused.

Thirdly, warnings are clearly relevant to the presentation of the product and should, therefore, be taken into account in determining appropriate safety expectations. However, the precise effect the warning will have on the assessment of safety expectations remains unclear. For example, simply warning a consumer that AI is being used and therefore the producer might not be able to control the way the product acts presumably should not be an excuse. French case law has been sceptical of the role of warnings in avoiding liability. The new Product Liability Directive also sounds a similarly cautionary note about warnings, stating in recital that:

> warnings or other information provided with a product cannot by considered sufficient to make an otherwise defective product safe, since defectiveness should be determined by reference to the safety that the public at large is entitled to expect. Therefore, liability under this Directive cannot be avoided simply by listing all conceivable side effects of a product.[68]

Of course, medical AI systems are often used under the guidance of medical professionals. Warnings or instructions may be given to such professionals. In *A v National Blood Authority*,[69] Burton J had held that this information was not relevant when assessing the expectations of the general public. Other cases have taken a different view,[70] which is probably the correct approach with the blood decision being assessed

66 See Consumer Protection Act 1987, s 4.
67 See *Gee v DePuy* [2018] EWHC 1208.
68 Recital 31.
69 [2001] 3 All ER 289.
70 See, for example, *Worsley v Tambrands Ltd* [2000].

in the unique context of the facts of that case. Thus, the public would expect its medic to be informed of the risks and look to them to assess the product and ensure informed consent to the use of the AI system.

Development risks

A controversial[71] feature of the previous Product Liability Directive was the presence of the development risks defence. This was intended to protect industries against risks which could not be discovered given the state of scientific and technological knowledge when the product is put into circulation. At first glance, this might seem to be applicable to autonomous AI as it is not known how the AI will develop. However, we would suggest that this misses the point. When one uses autonomous AI, it is known that the system will develop in ways it determines itself based on its learning from the data and possibly in ways which are hard to predict. In a sense this involves risks which are unknown. However, the inherent risk of the AI taking a decision which creates a safety risk is known. If one follows the logic of *Commission v United Kingdom*,[72] once a risk is known about the trader should be responsible and decide whether to investigate further to reduce risk or take out insurance against the risk.

Revised Directive on liability for defective products

The preamble to the 2024 Product Liability Directive[73] notes 'life-sustaining medical devices, entail an especially high risk of causing damage to people and therefore give rise to particularly high safety expectations'.[74] It adds certain factors which would need to be considered when assessing defectiveness and which seem to be relevant to the safety assessment of AI systems. For example, the effect on the product of any ability to continue to learn after deployment is a factor clearly aimed at AI products that have the ability to act autonomously based on their learning.[75] Here, the distinction between AI systems that simply follow coded instructions and those that have the ability to learn from data and make autonomous decisions is crucial. The recitals provide guidance on how this should be interpreted, noting the 'expectation that a product's software and underlying algorithms are

71 See, for example, S R Ghasemzadeh, 'The economic and legal bases of the development risk defence in European product liability: a critical approach to proponents' bases of the defence' (2019) 27 European Review of Private Law 1023–1050.

72 (C-300/95) [1997] ECR I-2649.

73 Directive (EU) 2024/2853 (n 11 above).

74 Recital 30.

75 Art 7(2)(c).

designed in such a way as to prevent hazardous product behaviour.'[76] It does not seem that a producer can blame rogue post-product conduct on the AI device, but rather should take responsibility for it.[77]

Equally, the effect on the product of other products that can reasonably be expected to be used together with the product should be considered.[78] This is clearly intended to cover the internet of things, where products interact with one another. However, as a product will cover software under the proposal,[79] it will cover the interaction between software and hardware which is common in AI products. This protective approach is further underlined by the safety assessment not only being when the product is placed on the market but for as long as the manufacturer retains control over the product after that moment.[80] So if a manufacturer continues to provide updates, or feed data to the AI product, they will be responsible for any resulting defects. This reform also maintains the development risks defence but would extend the time for assessing knowledge for as long as the manufacturer controls the product.[81]

Some of the new innovations are intended to make redress more practicable. As the explanatory memorandum to the proposal explained, 77 per cent of respondents considered that technically complex products created difficulties in respect of the injured person's burden of proof. This went up to 95 per cent among consumer organisations, non-government organisations and members of the public, with even 38 per cent of business and industry organisations sharing this concern. Industry stakeholders were more open to information disclosure obligations and easing the burden of proof in complex cases than to reversing the burden of proof.[82] This perhaps explains why the EU Commission was keen to stress that a presumption of defect or causation is not the same thing as a reversal of the burden of proof.[83] Whilst formally the burden may remain on the claimant, in practice the presumption will have a very similar effect to reversing the burden of proof.

The courts will be given powers to order disclosure of evidence where there is evidence of a plausible claim. The disclosure would have to be necessary and proportionate and would take into account

76 Recital 32.
77 Ibid.
78 Art (7)(2)(d).
79 Art 4(1).
80 Art 7(2)(e).
81 Art 11(1)(e).
82 Com/2022/495 Explanatory Memorandum, p 8.
83 Recitals 42 and 46.

confidentiality and trade secrets.[84] From a common law perspective familiar with discovery rules, this seems unremarkable.

Presumptions of defectiveness are introduced where there has been a failure to comply with the disclosure obligations, or non-compliance with mandatory safety requirements, or an obvious malfunction. There is clearly here an intention to incentivise compliance with disclosure orders and to follow safety requirements.[85] Recital 46 explains the inclusion of obvious malfunction on the ground that it is unnecessarily burdensome to require a claimant to prove defectiveness when the circumstances are such that its existence is undisputed. With respect, if it was so obvious there would be no need for the provision but it may stop defendants entering technical defences. There is a presumption of causality where it is established the product is defective and the damage is consistent with that type of defect.[86] There is a presumption of defectiveness or causality where the claimant faces excessive difficulty and is able to establish it is likely the product was defective/caused damage. The recital gives the following examples of factors giving rise to excessive difficulty as including:

> the complex nature of the product, such as an innovative medical device; the complex nature of the technology used, such as machine learning; the complex nature of the information and data to be analysed by the claimant; and the complex nature of the causal link, such as a link between a pharmaceutical or food product and the onset of a health condition, or a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system.[87]

What is quite perplexing though is that the claimant will still have to show the defect or causation was likely, and the question is how much more claimant friendly is that than proving the case on the balance of probabilities?

STRICTER LIABILITY FOR HIGH-RISK AI SYSTEMS?

Introduction

The AI Act[88] does not directly address the liability of AI systems. Direct rules on liability are limited to the requirement of notified bodies to have compulsory insurance[89] and the continued liability under national

84 Art 9.
85 Art 10(2).
86 Art 10(3).
87 Recital 48.
88 AI Act (n 26 above).
89 Art 31(9).

law of AI involved in regulatory sandboxes.[90] It notes the problems that different approaches to liability can pose for the development of the single market and favours harmonising measures, but leaves this for other legislative initiatives.[91] Fenwick and Wrbka[92] also note that, indirectly, the AI Act may make it easier to identify potential defendants due to the *ex ante* conformity assessment obligations and registration requirements for high-risk AI systems.

European Parliament Resolution of 20 October 2020 with Recommendations to the Commission on a Civil Liability Regime for Artificial Intelligence

The EU Parliament has also proposed a form of strict liability for high-risk AI, backed up by compulsory insurance.[93] This would be additional to any other liability such as under the Product Liability Directive and would impose liability on operators of AI systems. This covers both frontend operators (who benefit from an AI operation and exercise a degree of control over a risk connected with the operation) and backend operators (who exercise control over a risk on a continuous basis, define the features of the technology and provide data and essential backend support services).[94] Strict liability would apply to all AI systems listed in an annex to the regulation. However, this certainty for operators is to some extent undermined by the exception mentioned in the Resolution whereby AI systems, which have not yet

90 Art 57(12).

91 See Explanatory Memorandum, para 2.1.

92 M Fenwick and S Wrbka, 'AI and legal personhood' in L DiMatteo, C Poncibo and M Cannasa (eds), *The Cambridge Handbook on Artificial Intelligence* (Cambridge University Press 2022).

93 European Parliament Resolution of 20 October 2020 with recommendations to the Commission on a Civil Liability Regime for Artificial Intelligence (2020/2014 (INL) OJ C 404, 6.10.2021, p 107) (the Resolution). This was informed by, and largely based on, Committee on Legal Affairs, *Draft Report of 27 April 2020 with Recommendations to the Commission on a Civil Liability Regime for Artificial Intelligence* 2020/2014(INL) (JURI AI draft report).There had been a background study: see E Karner et al, *Comparative Law Study on Civil Liability for Artificial Intelligence* (European Commission 2021). See also A Bertolini, 'Artificial intelligence and civil law: liability rules for drones – study for the JURI Committee' (2018); M van Lieshout et al, 'Study on safety of non-embedded software; service, data access, and legal issues of advanced robots, autonomous, connected, and AI-based vehicles and systems – study for the Commission/DG CONNECT' (2019); BEUC, 'Product liability 2.0: how to make EU rules fit for consumers in the digital age' (2020); A Bertolini, 'Artificial intelligence and civil liability – study for the JURI Committee' (2020). These are excellently discussed in Fenwick and Wrbka (n 92 above).

94 Para 12.

been assessed for high risk, could be made subject to strict liability if they caused repeated incidents resulting in serious harm or damage.[95]

The liability would be strict and arise for any harm or damage *caused* by a physical or virtual activity, device or process driven by that AI system.[96] It would be no defence to have acted with due diligence or that the harm was caused by an autonomous activity, device or process driven by their AI system. *Force majeure* would be a defence.[97] This sort of strict liability regime based on causation has been mooted before, notably by the Australian Law Reform Commission for product liability.[98] Whilst it seems in principle both stricter and simpler, the risk is that litigation will then get drawn into abstract causation debates that can be as complicated as determining defectiveness. That is not to say the idea should not be considered and the UK's Automated and Electric Vehicles Act 2018[99] might serve as a model. Under that law the insurer is required to pay the victim of an accident caused by an autonomous car with the driver and car manufacturer and their insurers left to fight over where the actual liability lies. The proposal does not go quite that far. It does require operators to have insurance,[100] but that would only kick in to compensate once liability is established.

There are maximum limits for strict liability of €2 million for personal injury and €1 million for property damage with a threshold of €500. One suspects this lower threshold mirrors the then Product Liability Directive and will be removed in line with its removal from the Product Liability Directive.

For non-high-risk AI, the proposal would maintain a fault-based regime. This would not have any limits on the amount of compensation. The rules provide two ways in which the operator would be able to prove the harm or damage was caused without being their fault.[101] There would be no liability where the AI system was activated without their knowledge and all reasonable and necessary measures to avoid such activation outside the operator's control had been taken. Liability can also be avoided by showing due diligence was observed by selecting a suitable AI system for the right task and skills, putting the AI system duly into operation, monitoring the activities and maintaining the operational reliability by regularly installing all available updates. However, the operator will not be able to escape liability simply by

95 Para 21.
96 Art 4(1) of the proposed Regulation contained in the Annex to the Resolution.
97 Art 4(3) of the proposed Regulation contained in the Annex to the Resolution.
98 Australian Law Reform Commission, *Product Liability* (ALRC Report 51 1989).
99 See also L Clinch, 'A long road ahead for automated vehicles' (2022) 172 New Law Journal 13–14.
100 Art 4(4).
101 Art 8(2).

arguing that the harm or damage was caused by an autonomous activity, device or process.

The EU is unlikely to take this strict liability initiative forward after the reform to the Product Liability Directive and the withdrawal of rules on AI non-contractual liability. It seems at least that the question of adopting no-fault liability for AI not covered by the Product Liability Directive will be kicked down the line.[102]

REFLECTIONS

Negligence or strict liability?

Strict product liability has been a terrain for fierce policy debate with competing (moral and economic) arguments for and against strict liability.[103] Some consider it unfair to impose liability on a party that has done everything they could reasonably have been expected to do.[104] Equally, some suggest it makes no economic sense to require more than foreseeable steps to prevent harm.[105] Negligence for them provides a fair and rational liability standard. By contrast, those who favour strict liability suggest it should be seen as the entry price for

102 Note original proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM/2022/496 final, Recital 31: 'It is necessary to provide for a review of this Directive [five years] after the end of the transposition period. In particular, that review should examine whether there is a need to create no-fault liability rules for claims against the operator, as long as not already covered by other Union liability rules in particular Directive 85/374/EEC, combined with a mandatory insurance for the operation of certain AI systems, as suggested by the European Parliament. In accordance with the principle of proportionality, it is appropriate to assess such a need in the light of relevant technological and regulatory developments in the coming years, taking into account the effect and impact on the roll-out and uptake of AI systems, especially for SMEs. Such a review should consider, among others, risks involving damage to important legal values like life, health and property of unwitting third parties through the operation of AI-enabled products or services. That review should also analyse the effectiveness of the measures provided for in this Directive in dealing with such risks, as well as the development of appropriate solutions by the insurance market. To ensure the availability of the information necessary to conduct such a review, it is necessary to collect data and other necessary evidence covering the relevant matters.'

103 See, generally, G Howells, *Product Liability* 2nd edn (Butterworths 2007).

104 D Owen, 'Product liability: principles of justice for the 21st century' (1990) 11 Pace Law Review 63–86 and 'The Moral Foundations of Products Liability Law: Towards First Principles' (1993) 68 Notre Dame Law Review 427–506.

105 See, generally, R Posner, *Economic Analysis of Law* 9th edn (Aspen 2014).

being allowed to enter the market for profit.[106] Internalisation of costs for the harm flowing from the use of the products is seen as a way for ensuring only the optimum amount of the product is used.[107]

Similar divides emerge in relation to liability for AI systems. Though there are also some pragmatic issues affecting possible policy choices, some echo the preference for negligence by arguing that, if AI systems generally have better outcomes than humans, then negligence is the standard that will encourage their deployment for the greater good.[108] On the other hand, Pasquale notes that in the medical context the position is complicated by the likely greater ongoing guidance of healthcare providers in managing the deployment of AI.[109] Moreover, there are practical problems with assessing negligence in the context of an AI system. Although all humans are different, we feel confident in determining an objective standard against which to judge them. By contrast, it has been argued that AI is heterogeneous by nature with the variety of different techniques for creating AI only likely to increase.[110] There are other practical difficulties with enforcing negligence laws given the problems of attributing liability between healthcare professionals, hospitals, AI vendors and others, such as those who stream or process data.[111] In truth, this is more about potentially needing to adopt some form of network liability, and similar problems might arise under strict liability systems depending on how it is framed. Strict liability might also assist in providing compensation when there is automation bias, that is, over-reliance by professionals who place too much faith in the judgements of machines.[112] It can also be a means of ensuring that those groups who tend to be underrepresented in the data sets used to create algorithms (women and ethnic minorities) at least obtain compensation if the AI system does not take their needs sufficiently into account.[113] However, perhaps the strongest arguments for strict

106 T Honoré, 'Responsibility and luck: the moral basis of strict liability' (1988) 104 Law Quarterly Review 530–553.

107 G Calabresi, 'Some thoughts on risk distribution and the law of torts' (1961) 70 Yale Law Journal 499–553.

108 R Abbott, 'The reasonable computer: disrupting the paradigm of tort liability (2017) 86(1) George Washington Law Review 1–45.

109 Pasquale (n 16 above) 209.

110 J Turner, *Robot Rules: Regulating Artificial Intelligence* (Palgrave Macmillan 2019).

111 Pasquale (n 16 above) 208.

112 E Parasidis, 'Clinical decision support: elements of a sensible legal framework' (2018) 20 Journal of Health Care Law and Policy 183.

113 A Adamson and A Smith, 'Machine learning and health care disparities in dermatology' (2018) 11 JAMA Dermatology 1247–1248; and C Perez, *Invisible Women: Data Bias in a World Designed for Men* (Abrams Press 2019).

liability of AI systems remain that the costs associated with their use should be internalised and borne by those who seek to make profit. This is strengthened by the knowledge that rules can be built into AI systems to prevent them from causing deliberate harm.[114]

The EU seems to favour keeping the strictest form of liability for high-risk AI. However, the Product Liability Directive now clearly brings software and AI systems into its fold. It is true that it is arguable that the Directive does not provide a very strict form of liability. One might foresee negligence and strict product liability under the Directive applying across the board with the strictest form of liability retained for high-risk AI systems. Arguably, such a system amounts to no-fault liability that is more demanding than the strict liability found in the Product Liability Directive that can be justified to promote the use of such high-risk AI systems. However, in the current climate such a move is not imminent.

Network liability?

Traditional liability rules required there to be either a contractual nexus or negligence. Although the previous Product Liability Directive broke the mould, it did not specifically address the problem of allocating liability when several actors may potentially have caused the harm.[115] AI systems may involve various actors: a system might, for example, have hardware (developed by A) powered by background software (developed by B) which runs different programs based on algorithms (developed by C and D) and relying on data inputs (by E) and interaction with other devices as part of the internet of things. If something goes wrong and harm occurs, this might be due to one of several products, the programs they run, the algorithms or the quality of the data received. Indeed, the harm may lie in how they interreact or perhaps fail to interreact. Disentangling this network of relationships to allocate responsibility may be complex and often impossible, especially for the injured party. If one party controls the whole network then liability may be easier to establish, but this is often not the case. That is why it has been argued that there should be a form of network liability under which the injured party could sue an entire network or just one party within the network, leaving members of the network to fight over the allocation of liability.[116]

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114 Pasquale (n 16 above) 211 quoting Asimov's Laws of Robotics.

115 Art 5 of the Directive merely provided: 'Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.'

116 Howells and Twigg-Flesner (n 11 above).

A medical sector solution?

The medical sector is well known for pioneering no-fault solutions.[117] In relation to AI in the medical sector there is a justification for such a no-fault solution to promote the development of AI which may have great societal benefits.[118] In order to encourage acceptance of AI medical systems and to mitigate the impact on public confidence of the, hopefully, rare instances when things go wrong, no-fault liability could play a role. Borrowing from the UK approach to automated vehicles, one party could be selected and their insurer required to pay for harm caused by AI. Although the parties might want to argue over allocation of liability, in practice this will most likely be sorted out on a practical basis. The injured party need not be involved. However, the problem, alluded to above, of linking causation to the AI system remains. This can be handled more pragmatically under no-fault insurance-backed regimes than under traditional tort law causation rules. However, as the experience under the Vaccine Damage Payments Act 1979 demonstrates, this can still be problematic.[119] Future research is needed into how causation can be fairly applied so that compensation goes to parties whose harm can reasonably be attributed to AI-systems. Scandinavia may provide some useful evidence of good practice.

CONCLUSION

As AI becomes more pervasive, there is a need to tackle important liability questions. Is it enough to adapt existing negligence and strict liability rules by procedural tools such as disclosure requirements and presumptions of negligence, defect or causation? Or does the interconnection between actors require new approaches to liability, such as network liability or the even more radical solutions we have already seen for autonomous cars. Indeed, does the medical context raise its own set of issues surrounding the interaction between medical practitioner and devices that may demand novel no compensation solutions? A lesson from the autonomous car context is that strong liability regimes can serve to bolster confidence in AI innovation. However, the history of attempts to introduce no-fault regimes in the health sector does not provide grounds of optimism

117 Compare also Holm et al (n 17 above).

118 On justifications for no-fault schemes, see G Howells, 'Justifications for preferential adoption of no-fault accident compensation schemes' (2019) Otago Law Review 127–155.

119 D Fairgrieve et al, 'Comparing no-fault compensation systems for vaccine injury' (2023) 31(1) Tulane Journal of International and Comparative Law 75–118.

as saving money seems to be the bottom line.[120] The EU is starting to grapple with how existing liability regimes can be adapted to AI. The UK is lagging behind. The consequence of Brexit so far seems to be that our legal regimes remain moribund, whilst the EU laws are reformed in response to innovation. Brexit does, it is often stated, give the UK the freedom to forge ahead and fashion its own novel solution, whether for AI generally or for the medical context in particular. To date, however, there are few signs of the groundwork for proposing any imaginative reforms.

120 See, for example, the proposal for a rapid resolution and redress scheme for birth injuries: J Cumberlege, *The National Maternity Review: Better Births* (NHS England 2016) Annex D.

Northern Ireland
Legal Quarterly
Spring Vol. 76 No. 1 (2025) 140–145
Book Reviews DOI: 10.53386/nilq.v76i1.1144

Justice in Global Health: New Perspectives and Current Issues edited by Himani Bhakuni and Lucas Miotto

Shirin Boroomand
University of Bristol
Correspondence email: yd23754@bristol.ac.uk.

Justice in Global Health: New Perspectives and Current Issues, Himani Bhakuni and Lucas Miotto (eds) (Routledge 2024) 326pp; paperback £35.99/hardback £135/ebook £32.39

In the wake of the Covid-19 experience, considered one of the most paralysing global threats to health and human social lives, this book aims to provide perspectives on various issues in global health justice. As explained by the editors, the book avoids proposing a single theoretical solution for all health inequalities worldwide. Therefore, the fundamental hypothesis of the book may be the necessity of a particularistic perspective on global health justice, in addition to the systemic and unified view. Accordingly, the book is divided into five parts, each section looks at one particular challenge of justice in global health.

The first part, focusing on citizenship, power, and relational justice, highlights the need to discuss duty distribution alongside resource distribution, a connection that is closely tied to discussions on institutional and structural reforms. Aligned with that theme, Xuanpu Zhuang, in the first chapter titled 'World citizenship and global health,' supports the idea of a weak version of world citizenship. To realise this, he prefers a relational egalitarian approach to cosmopolitan justice, asserting that justice is a situation where everyone is related to others 'as equal' (at 18). In securing the social and political status of

world citizens as equals, medical support plays a crucial role. Taking a capability approach, he argues how lacking medical support will undermine global equal citizenship and exacerbate the problematic social hierarchies in terms of esteem, treatments, attitudes, power and deliberation (at 21–25). In the next chapter, Nils Freyer and Hendrik Kempt consider the concept of artificial intelligence-based decision support systems (AI-DSS) and elucidate how the global explainability standards for these systems create a concern for justice. They elaborate that such standards are less prone to be met in underdeveloped areas; a situation that leads to domination for those countries who have the technology and have defined the standards (at 39). Having assessed the complex implications of lowering standards in health-insecure collectives, they finally propose the idea of a plural standard AI governance that also advocates for the self-sustaining development of healthcare infrastructure in these collectives (at 49).

The second part of the book, 'Responsibility for justice: law, civil society, and the private sector' gathers discussions on how civil society, courts and the private sector can contribute to the development of global health justice. In the first chapter of this part, Luciano Bottini Filho argues that the structural litigation model can yield more satisfying results in transforming structural violence and addressing the root causes of inequalities in health services, compared to an individual litigations model. He further considers the factors required for constructing the pathway of structural litigations (at 64 and 65) and thoroughly compares this paradigm by studying cases, with the right-based judgments that seek to immediately eradicate the particular case of right infringement (at 66 and 67). Alternatively, the writer examines the cases of 'states of constitutional affairs', applied in the Colombian and Brazilian judicial systems, allowing the court to engage with systematic and structural injustice (at 69). Alice Trotter and Ioana Cismas consider Noma, a preventable but mortal disease. Defining 'framing' as a perspective on an issue that conveys a special understanding, they evaluate how framing Noma as an issue in human rights and also as a neglected tropical disease (NTD) will change the related international policies and the situation of patients and survivors. While medicalised and humanitarian framing, described as traditional framing, contributed to the 'locality and scope of intervention' (at 85), the writers provide reasons (including interviews) why it is time for new framings – namely, human rights and NTD – which will open a new path for advocacy and action on Noma (at 87–99). Alvaro Fernandez-Mora discusses the restrictive regulations of intellectual property rights due to public health concerns, including advertising bans, health warnings and plain packaging. He considers these restrictions on tobacco, alcohol and foods high in fat, sugar, and salt

(HFSS) and examines the relevant regulations and litigations across various jurisdictions. The struggle to maintain the balance between public health interests, and the stakeholders' rights and freedom of expression within tobacco, alcohol and HFSS industries falls under the responsibility of the courts, and Fernandez-Mora explains how each of these restrictions needs different justifications (at 124).

Part three contains discussions on sexual and reproductive justice and aims to highlight the challenges and complications faced by less-studied groups in the field of sexual and reproductive rights. Concerning children and adolescents, Gottfried Schweiger studies their sexual rights from the perspective of the capability approach, which Schweiger believes contributes to defining the well-being of these groups. He explains how the capability approach influences the rights of these two groups to enjoy sufficient well-being and to develop a personal conception of it (at 136). He then refers to the concept of 'sexual health' as a set of capabilities encompassing physical, mental, cognitive and social aspects (at 139). In the final section, the writer examines the concepts of vulnerability and autonomy concerning sexual rights and explores how these concepts vary between children and adolescents (at 140–142). In the last chapter of this part, Keerty Nakray focuses on people with serious intellectual disabilities living in assisted living facilities, with a special emphasis on India. Nakray considers the challenges of intellectually disabled people in fulfilling their sexual and reproductive rights and explains the common misunderstandings about them (at 155 and 156). Furthermore, she elaborates on the concept of 'network consent' as a process that assists mentally disabled people in enjoying their sexual and reproductive rights in long-term care homes. Delving deeply into the regulations in India, Nakray asserts that people with disabilities in this country encounter limitations on their reproductive rights. However, the laws related to the consent in these groups in India are not homogeneous (at 163).

The theme of part four is global health governance, security and transition. Aligned with this theme, Daniel Elliot Weissglass delves into the consideration of justice in global health governance and meticulously examines the role of enforcement. In this chapter, Weissglass focuses on the International Health Regulations (IHR) and the political consequences of noncompliance and how it reproduces itself in a cycle by eroding normativity (at 189). Following an examination of the fundamental obligations imposed by the IHR on countries, Weissglass elucidates how this noncompliance issue, among many others, erodes the legitimacy of the global health system and leads to the violation of global health justice, particularly during health urgencies (at 184–186). Ultimately, he proposes various strategies to

reform the enforcement issue, ranging from tactics like naming and shaming and halting conditional supports, to implementing more severe sanctions (at 195). Ryoa Chung and Joanne Liu refer to the context of health securitisation where health issues are construed as high-level national security issues (at 206). Their research centres on the ethical ramifications, specifically what they term the 'subordination of basic human rights' and, in particular, the right to health (at 208). By referencing illustrations of this process, the authors argue for the unconditional protection of human rights to health and the promotion of international solidarity and cooperation (at 211 and 212). In the final chapter of part four, Himani Bhakuni and Lucas Miotto deal with the concept of transitional health justice (THJ), defined as rules and mechanisms applied by states in their efforts to reform their health systems after emergencies (at 217). Clarifying the identification criteria of circumstances for THJ, Bhakuni and Miotto point to pervasive structural inequality and normalised individual or collective wrongdoing, as well as serious existential and fundamental uncertainty about authority as the defining circumstances of THJ (at 220 and 221). Following a thorough examination of the relationship between transitional justice and THJ, along with the mechanisms and demands associated with THJ, the authors endorse the idea that THJ can be considered as a facilitator of transitional justice (at 231).

Part five stands as the book's most theoretical segment, containing papers on novel frames and approaches to global health justice. In her chapter, Erika Blacksher explores Nancy Fraser's normative framework and her categorisation of two processes of subordination: maldistribution and misrecognition (at 243). Blacksher tries to evaluate the suitability of Fraser's framework to be applied to health justice issues. Elaborating on the concept of 'participatory parity' in Fraser's framework, Blacksher scrutinises how we can justify the significance of health for justice, determine health inequalities and establish priorities for health resources according to Fraser's theory (at 246–254). She subsequently examines how applicable Fraser's theory is in addressing current health justice problems globally, with a focus on population health studies (at 255). Running parallel to the conceptual and normative benefits of Fraser's framework in discussions of health justice, Blacksher emphasises that applying Fraser's theory to health justice problems lacks clarity regarding issues related to individuals who are not yet adults (at 260) In the subsequent chapter, Man-to Tang sheds light on the Confucian approach to global health, where sufficiency for all is the central rule (at 275). Explaining the fundamentals of justice in the Confucian approach, Tang clarifies the standards of such an account for global health. This entails individuals with health resources providing assistance to the less advantaged

and requires states to prevent stockpiling and scarcity of health resources (at 280). Tang proceeds to assert that sufficiency, fairness, and responsibility are the three main principles of the Confucian approach to health justice (at 281). Regarded as a non-egalitarian perspective, the writer illustrates how the Confucian approach can contribute to advancing global health justice. Finally, in the book's final chapter, which is particularly intriguing, Sridhar Venkatapuram provides answers to what we seek in a theory of global health justice. Differentiating between a theory of global health justice and a theory of global justice with health concerns, Venkatapuram puts the focus of his discussion on the necessity of determining the criteria of global health justice first (at 291). He briefly explains opposing approaches to global justice and highlights the health concerns of various ranges of these theories. Venkatapuram argues that, to decide on the best option for global health justice, it needs to meet some standards (at 298). He claims that relevancy and responsiveness to real-world health problems, perseverance and stability over time, and intertheoretical harmony are the satisfactory requirements of a theory of health justice (at 299). According to these criteria, he favours the idea that a capabilities approach is the best option among rival approaches to global health justice (at 301).

All five sections of the book have offered valuable insights, and, in certain instances, shed light on overlooked prospects for global health justice. This book does not encompass nearly all of the challenges related to global health justice. Nevertheless, the book has successfully attained a commendable balance, particularly in three dimensions. Firstly, the book engages in discussions on both theoretical issues and abstract concepts, offering fresh perspectives on practical challenges in health justice. This array of approaches to field problems aligns with the editors' perspective that the endeavour to create an extensive and purely theoretical account of global health justice, while beneficial, may not suffice to address inequalities. Thus, the highlighted balance aids the reader in perceiving the book's subjects in harmony with one another. As an illustration, consider the link between the suggested framing of Noma as an NTD and misrecognition as an injustice under the theoretical framework of Nancy Fraser's account.

Another notable balance achieved by this collection lies in navigating various realms of justice. The book does not confine itself to distributive justice or any specific subcategory of justice. Instead, readers can explore discussions on restorative, distributive and even transitional justice in global health. This is a significant accomplishment, especially considering the potential limitation of global health justice to a single type. Nevertheless, this book does draw readers' attention to other often

neglected areas of global health justice and illustrates the diversity inherent in this field of discussion.

Lastly, the book achieves a balance between two distinct perspectives on health justice problems. At times, the focus may shift to fundamental problems that are acknowledged and discussed as critical challenges to global health, along with the corresponding explanations and proposed solutions. Topics such as vaccine distribution, governance and enforcement (as discussed in Nakray's chapter 'Justice in global health governance' in this book) within the global health system, securitisation of health and so on constitute these discussions. Yet, this is not the sole perspective on the challenges of health justice at the global level. Alternatively, one can also address a problem with more localised dimensions that can have global implications; like an illness which is more common in some parts of the world (Filho's, 'Framing Noma'), or a type of litigation in some specific jurisdictions that can also be followed in some other jurisdictions (Freyer and Kempt's 'Everything is unconstitutional'). Additionally, and notably, this book delves into the global impact of a school of thought with parochial roots in the realm of global health justice (Blacksher's, 'Beyond egalitarianism').

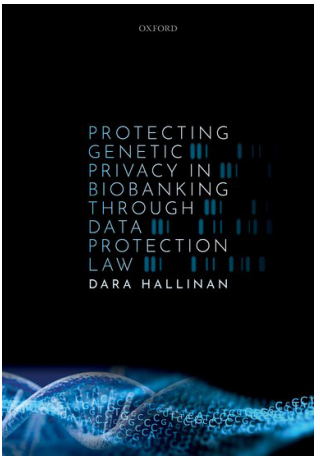
The editors intriguingly explain the distinction between international and global perspectives on health justice. According to them, the former delves into the concept of justice within and between nations, while the latter extends justice beyond borders (at 2). The global understanding of justice transcends national and international boundaries, considering a complex network of actors, systems and notions, and appears less organised than under the international paradigm. Accordingly, while states remain crucial for evaluating justice/injustice, they are not the sole units in this intricate framework. From my perspective, the book could enhance its consideration of the global aspect over the international one. Most of the chapters present analyses based on the states and the relations between them. Therefore, despite the explanation that the editors provide in the introduction about the new paradigm of studying health justice at the global level, the reader is left with the question of examples of this new perspective across the discussions in the book.

There are numerous books addressing inequalities in global health, but this particular one challenges our conventional understanding of what should be included in discussions of global health justice. It successfully gathers a broad range of perspectives on existing problems while introducing new considerations that merit attention. It is undoubtedly worth reading and serves as a valuable reference for those conducting research in the field of global health justice.

Northern Ireland
Legal Quarterly
Spring Vol. 76 No. 1 (2025) 146–149
Book Review DOI: 10.53386/nilq.v76i1.1187

Protecting Genetic Privacy in Biobanking through Data Protection Law by Dara Hallinan

Başak Bak*
University of Reading
Correspondence email: b.bak2@reading.ac.uk.



Protecting Genetic Privacy in Biobanking through Data Protection Law by Dara Hallinan (Oxford University Press 2021) 304pp; hardback £110

With biobanking becoming the cornerstone of medical research and personalised healthcare, protecting genetic privacy has emerged as a critical issue. DNA, which carries sensitive personal information, is uniquely individual and functions as an ultimate identifier. Moreover, if compromised, it cannot be replaced. Collecting, storing and using genetic data in biobanks for scientific research, therefore, requires robust safeguards that protect individuals' rights and prevent misuse. In an era where biobanks serve as essential infrastructure for medical research that increasingly relies on genetic data, Dara Hallinan's *Protecting Genetic Privacy in Biobanking through Data Protection Law* is a timely and insightful exploration of how genetic privacy in biobanks is protected across Europe. The book comprehensively analyses the European Union (EU) General Data Protection Regulation (GDPR), arguing that 'the substantive

* Dr Bak is a lecturer in law at the University of Reading, specialising in genetic privacy and European data protection law. She is also a Certified Information Privacy Manager (CIPM) and a Certified Information Privacy Professional/Europe (CIPP/E).

framework presented by the GDPR already offers an admirable baseline level of protection for genetic privacy' (at 3). Although the book identifies numerous issues – specifically, 'twenty-three different problems, of eight distinct types' (at 258) – with the GDPR, Hallinan also argues that the GDPR provides the flexibility to enable solutions and procedural mechanisms to address those challenges (at 259).

Hallinan's book is divided into 11 chapters, including the introduction (chapter 1) and conclusion (chapter 11).

Chapters 2 and 3 provide background information about the concept of genetic data and the European biobanking landscape, respectively. Chapter 2 explains what information genetic analyses can reveal and situates such analyses within their social context. Chapter 3 offers an overview of the origins of European biobanking, as well as the approaches and operations shaping it.

Chapter 4 details the theoretical foundation for the types of genetic privacy rights research subjects, genetic relatives and genetic groups have in biobanking. An essential, though not standalone, component of the book's overall narrative, this chapter depicts the conflict between different rightsholders. Notably, the chapter addresses the conflicts and confluences between genetic privacy rights and the legitimate interests of researchers, society and other stakeholders, including those without research interests, such as insurers.

Chapters 5 and 6 explore the protection of genetic privacy in biobanking at the international and European level, respectively. In examining international law, the book highlights its shortcomings, demonstrating that international protection provides a mere baseline rather than a definitive standard. It maps common and emerging international principles using tables. In my view, such mapping proves especially useful in highlighting that, unlike the rights of research subjects, the rights of genetic relatives and groups are not afforded international protection (at 85–88). Chapter 6 presents an engaging 'thought experiment' (at 91) and examines genetic privacy in biobanking in Europe by focusing on three chosen countries – Estonia, Germany and the United Kingdom (UK) – while excluding their respective data protection laws. It examines the Estonian Human Genes Research Act 2000, the German Civil Code and the Human Tissue Act 2004 of the UK. By comparing these three countries' approaches in tables, it also highlights gaps in the protection offered by national laws and demonstrates that the GDPR's broad, directly applicable and robust data protection framework serves as a viable alternative to national regulations (at 126–127). This analysis underscores the need for comprehensive data protection in biobanking, setting the stage for the book's subsequent chapters, which evaluate the effectiveness of the GDPR's protection.

Accordingly, the next three chapters (7, 8 and 9) examine the GDPR provisions in the context of biobanking. Chapter 7 addresses the subject matter, including whether biological samples qualify as personal data. Chapter 8 focuses on the GDPR's classification of biobanking, specifically the categorisation of both actors and personal data. Chapter 9 provides a compact exploration of key legal aspects of the GDPR's provisions, including the data protection impact assessment required before processing genetic data, consent requirements, data subject rights, data protection principles and cross-border transfers. Hallinan's concise summary of the GDPR in chapter 9 effectively identifies the relevant issues and laws related to genetic privacy. I find this chapter particularly engaging and highly referenceable, as it encapsulates all the key points about genetic data protection under the GDPR and can be read on its own.

Chapter 10 critically assesses the adequacy of the GDPR as an overarching framework for data protection in depth. This detailed chapter, more than double the length of others, identifies eight categories of issues within the GDPR system: its structural design; the level of protection it offers to research subjects, genetic relatives, and groups; the substantive protection it ensures; its technical applicability; its disproportionate impact on research; its practical application to biobanking; and the degree of harmonisation across Europe. I think two aspects of this analysis make this chapter unique. First, the chapter not only identifies the problems but also ranks the severity of their negative consequences for biobanking. Moreover, it proposes potential solutions for them. Second, Hallinan schematises 'the gaps in member states' approaches without data protection' and the degree of necessity for a solution for each gap (necessary, strictly necessary, or not necessary) in a table (at 252–253). The table indicates whether the GDPR's internal mechanisms can address the problems or if parallel national legislation is required to facilitate solutions. This unique schematisation effectively makes a technical topic more accessible and comprehensible. Hallinan concludes the overall analysis by asserting that none of the problems he identifies in the GDPR's approach fundamentally undermine its utility as a framework for protecting genetic privacy in biobanking, as most issues are 'amenable to resolution' (at 254).

Protecting Genetic Privacy in Biobanking through Data Protection Law offers a well-structured exploration of a critically important topic, identifies challenges and provides strategies and policy recommendations for mitigating those challenges. In my view, the book's thorough examination of the GDPR's provisions makes it an essential reference for understanding genetic privacy in biobanking

and European data protection law, especially for policy-makers and stakeholders in the biobanking field.

Researchers' growing reliance on biobanks makes addressing privacy concerns unquestionably urgent, but the extent to which the book's proposed solutions will be embraced, particularly given genomic technologies' rapid pace of change, remains uncertain. Hallinan acknowledges that uncertainty and, in the conclusion, writes of biobanking's future outlook (at 259):

> The biobanking community have choices as to how they perceive, and operationalise, the GDPR. They may choose to embrace the GDPR, and establish a healthy culture of compliance in which the potential of the law may best be realised, or they may choose to oppose the GDPR, and establish a culture of resistance in which realisation of potential is impossible. Time will tell.