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Operationalising ‘publicness’ in data-intensive health research regulation: An examination of the public interest as a regulatory device

Annie Sorbie

PhD in Law

**University of Edinburgh, School of Law
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Declaration

I declare that this thesis was composed by myself, that the work contained herein is my own except where explicitly stated otherwise, and that this work has not been submitted for any other degree or professional qualification.

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Abstract

This thesis is fundamentally concerned with revealing the complex and nuanced interrelationship between collective and individual interests in health research, and the implications of this for optimising contemporary health research regulation (HRR). This task of optimisation can be characterised as a persistent preoccupation in the health research arena, in that consideration of these interests can be located both in foundational international instruments that have shaped the course of modern health research regulation, as well as in contemporary instruments and guidelines. Nonetheless, the nature of human health research has been transformed since the post-World War II era, which has impacted both on how health research is conducted, as well as debates about what the regulation of this endeavour ought to look like. In this way, contemporary health research constantly challenges traditional regulatory structures that are underpinned by an increasingly outdated approach to individual and collective interests that are at stake. The regulatory system struggles to keep pace and this is particularly evident in relation to data-intensive health research.

This thesis tackles these tensions head on. I propose that a new approach to HRR is required that is capable of engaging with the multiplicity of ways in which decisions about the conduct of health research might impact on our lives. More particularly, I argue that there is something about the quality of human health research that is focused on realising and promoting collective interests that builds on, but also goes beyond, the protection of individuals who contribute to that research, and that this must be reflected in the way that it is regulated. The solution I offer is the concept of 'publicness', as introduced and explored in this thesis. More specifically, publicness reflects the interrelationship between collective and individual interests, thereby drawing attention to the context in which this interplay takes place, as well as the implications of this relationship for HRR, both now and in the future. I identify three interlinked and overlapping facets of publicness: relationality, temporality and accountability.

The analysis in this thesis deploys the tripartite framework provided by publicness in order to scrutinise several aspects of HRR. This serves to (i) reveal new insights in relation to existing concepts in HRR, namely the public interest, social value and social licence; (ii) identify how HRR can better account for the full range of interests in play throughout the research and data lifecycle, with a focus on temporal aspects of the research endeavour and the mutability and diversity of and within publics in HRR; and (iii) offer a reconceptualisation of the public interest that is better equipped to meet the realities and challenges of the contemporary health research environment. A case study, in relation to a high-profile and disputed transfer of identifiable NHS patient data from The Royal Free NHS Foundation Trust to Google DeepMind, reintegrates the preceding analysis to the contemporary data use landscape. This

illustrates how publicness helps to optimise HRR by both elucidating 'lessons learned', and through the identification of positive steps that can support future data-sharing initiatives to better account for publicness. In these various ways the diagnostic and normative value of publicness helps to provide a new understanding of what is at stake in health research and its regulation, and to provide a basis to move beyond what already exists in the sub-optimal HRR ecosystem.

Lay Abstract

Since the foundations for modern health research regulation were laid, in the period following World War II, careful consideration has been given to how health research can be regulated in such a way that protects the individuals involved in this endeavour, but also realises its potential societal benefits. However, the way in which health research is conducted has changed. While this may once have mainly involved ‘hands-on’ clinical research, where participants and researchers were in close contact, now this is just as likely to be carried out using large quantities of data, that were not originally collected for research purposes, with little contact between those using and those providing this data. Health research regulation (HRR) therefore needs to respond to these changes and better account for the individual and collective interests that are at stake when research takes place on a much larger scale.

In this thesis I argue that there is something about the quality of human health research that is focused on realising and promoting collective interests that builds on, but also goes beyond, the protection of individuals who contribute to that that research, and that this must be reflected in the way that health research is regulated. I argue that existing terminology does not adequately reflect the complex and nuanced relationship between the interests that are at stake, and therefore introduce the new concept of ‘publicness’. More specifically, I propose that publicness reflects the interrelationship between collective and individual interests, thereby drawing attention to the context in which this interplay takes place, as well as the implications of this relationship for HRR, both now and in the future.

I use publicness as the foundation for a framework to help examine both how health research regulation works at the moment, and also to identify ways that this could be improved going forward. By interrogating a case study, in relation to a high-profile and disputed transfer of patients’ identifiable health data from a public healthcare body to a private technology company, I show how publicness, as a new concept, can help to improve HRR by both identifying ‘lessons learned’, and by pointing to positive steps that can support future data-sharing initiatives.

**Operationalising ‘publicness’ in data-intensive health research regulation:
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Part I

Chapter 1: Introduction

Overview and summary of original contributions

This thesis is fundamentally concerned with revealing the interrelationship between collective and individual interests in health research, and the implications of this for optimising contemporary health research regulation (HRR). HRR is understood as encompassing ‘...the general ecosystem of activities, laws and regulations that seek to shape the conduct of any and all types of research involving human participants, or materials, data or tissues donated by them. This involves a complex morass of regulations and actors.’¹ As such, in this thesis I consider the ‘HRR ecosystem’ in this broad sense. In particular, this ecosystem comprises modes of health research that take place within and beyond the clinic, and it is not constrained to consideration of formal laws of regulations. Rather, the idea of an ecosystem points to the wide range of actors, activities and instruments that may be engaged in contemporary HRR, as well as the multi-directional ways that these may interact with one another over time. In this way health research and its regulation is conceived of as being cyclical and dynamic, rather than linear and static- in other words as a ‘research lifecycle’.

The task of HRR optimisation can be characterised as a persistent preoccupation in the health research arena, in that consideration of individual and collective interests can be located both in foundational international instruments that have shaped the course of modern health research governance, as well as in contemporary instruments and guidelines. Nonetheless, the nature of human health research has been transformed since the post-World War II era, which has impacted both on how health research is conducted, as well as debates about what the regulation of this endeavour ought to look like. In this way, contemporary health research constantly challenges traditional regulatory and governance structures that are underpinned by an increasingly outdated approach to individual and collective interests. The regulatory system struggles to keep pace and this is particularly evident in relation to data-intensive health research, for reasons I will come to shortly. This thesis tackles these tensions head on. I propose that a new approach to HRR is required that is capable of moving beyond the ‘individual interests *versus* collective interests’ binary and which can engage with the multiplicity of ways in which decisions about the conduct of health research might impact on our lives over time. More particularly, I argue that there is something about the quality of

¹ Isabel Fletcher and others, ‘Co-Production and Managing Uncertainty in Health Research Regulation: A Delphi Study’ (2020) 28 Health Care Anal 99, 100.

human health research that is focused on realising and promoting collective interests that builds on, but also goes beyond, the protection of individuals who contribute to that research, and that this must be reflected in the way that it is regulated. The solution I offer is the concept of 'publicness', as fully explored as this thesis unfolds.

Given the novelty of the term 'publicness' in HRR, I pause here to set out more thoroughly how this will be understood in this thesis, which will address both what publicness 'is' and what it 'does'. In the first respect the thrust of my argument is that publicness is a concept that draws our attention to the interrelationship between collective and individual interests. As such, it requires us to avert to the context in which this interplay takes place, as well as the implications of this relationship for HRR, both now and in the future. By naming and foregrounding this interrelationship, publicness provides a novel way to understand and navigate this relationship which, as will be shown as this thesis progress, is a feature thus far that has been missing from the relevant literatures. Moreover, as a deeply relational concept, the full meaning of publicness is also revealed by what it does – this is crucial to how publicness is operationalised, as referred to in the title to this thesis. In this respect, I demonstrate that publicness provides a tripartite framework of analysis, which pays specific attention to relationality, temporality and accountability. These features of publicness mean that it has inherent flexibility in how it is used. For example, it can be understood as a concept at an abstract level, but also as a basis for building a framework for normative action. And, while the full implications of this flexibility cannot be explored entirely in this thesis, I argue overall that publicness, whether deployed as a concept, as the foundation for a framework for analysis, or otherwise, better elucidates the relationship between the individual and the collective in HRR in various respects. A working definition for publicness, which I go on to develop throughout this thesis, is set out in Table 1. In the Chapters that follow I advance four

original and interrelated claims, across Part I and Part II, which respond to four broad research questions that drive the research in this thesis.

Table 1: A working definition of publicness in HRR

Publicness is a concept used to describe the interrelationship between collective and individual interests. This draws attention to the context in which this interplay takes place, as well as the implications of the interrelationship between collective and individual interests for HRR, both now and in the future.

Publicness also provides the foundation for a framework of analysis which directs attention to:

- **Relationality:** the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness, therefore moving away from oppositional ways of thinking about the interests at stake;
- **Temporality:** temporal aspects of these interests in health research, including how these may change over time;
- **Accountability:** how these interests can be accounted for when decisions are made about what, whether, how and with whom health research is conducted.

Part I

How is the interrelationship between individual and collective interests understood in HRR at present?

- First, my analysis will demonstrate that contemporary health research and its regulation have an inherent quality of 'publicness'. However, I will argue that the complex and nuanced relationship between the interests that are at stake in HRR is not, at present, adequately captured by the either/or terminology of 'individual or collective' and 'private or public' interests. Publicness, as constructed in this thesis, is a new concept that provides a novel way of engaging with the interrelationship between collective and individual interests and draws attention to the context in which this interplay takes place, as well as the implications of this relationship for HRR. Over the course of this thesis I engage with three facets of this new concept that draw attention to *inter alia* relationality, temporality and accountability. Publicness in this context is framed as a 'threshold concept', which opens up a new and transformative way of thinking about the interests that are at stake in health research and its regulation.² This sheds light on particular features of the interrelationship between individual and

² Jan Meyer and Ray Land, 'Threshold Concepts and Troublesome Knowledge: An Introduction' in Jan Meyer and Ray Land (eds), *Overcoming Barriers to Student Understanding: Threshold Concepts and Troublesome Knowledge* (Routledge 2006).

collective interests and therefore reveals a fresh perspective on HRR. I argue that this new understanding is required both to elucidate the complexities of this relationship, and to support the optimal operation of HRR, now and for the future.

To what extent is publicness currently operationalised in the HRR ecosystem? What does this tell us, both about existing concepts in HRR, and about publicness itself?

- Second, I deploy the tripartite framework of analysis that operationalises publicness in order to evaluate three existing concepts in HRR, with the aim of identifying areas whether they may manifest certain features of publicness. In doing so I show that elements of publicness can already be found in the HRR ecosystem, and that these are present in different approaches in several ways. In particular, I consider the *ethical objective of realising social value* in research, *notions of social licence for research*, and, crucially for this thesis, the use by the *law of the public interest as a regulatory device*. However, I argue that these existing approaches are not - either alone, or in combination - sufficient to fully enact publicness in HRR; rather each captures aspects of this concept. Thus, the claim is made that a robust conceptualisation of publicness is necessary to provide a common means to facilitate meaningful interdisciplinary conversations about what is at stake in HRR. Publicness here serves two purposes: it helps us to understand better what is the nature and role of existing mechanisms within HRR, and secondly, it provides a solid theoretical and practical basis to move beyond what already exists in the sub-optimal ecosystem. In this thesis I consider the HRR ecosystem to be sub-optimal – in other words, to be of less than the highest standard or quality - when it fails adequately to reflect the complexities of the interrelationship between individual and collective interest that are in play, and how these may change over time. As I will go on to argue as this thesis unfolds, to fail to do so has conceptual implications, for example in circumstances where a binary or oppositional understanding of this interrelationship fails to capture the full range and depth of interests that are at stake, and therefore should be accounted for by HRR. Further, this also has practical implications where the lack of a robust conceptualisation of these interests flattens notions of ‘publics’ (a term I come to next) in HRR, or results in a temporally limited view of the research lifecycle (as defined above), which may impact on the social and regulatory legitimacy of the HRR endeavour, particularly when these pull apart from one another. As I argue later, there are good reasons to believe that further refinements and changes to the HRR environment are required, and that my concept of publicness provides a strong basis with potential normative force on which to build such changes.

Part II

In what ways can publicness help us to better understand and to enrich aspects of the HRR ecosystem?

- Third, I outline concrete ways in which publicness delivers a concept that can flesh out and enrich the HRR ecosystem through consideration of (1) the temporal aspects of regulating individual and collective interests over time and (2) the mutability and diversity of and within ‘publics’ in HRR. As explored further in Chapter 4, the term ‘publics’ is used to indicate that there is no single, homogenous ‘public’, and to prompt further consideration of how such publics may be constituted. The analysis in Part I, which uses publicness as the foundation for a tripartite framework for analysis, as introduced above, highlights both ‘temporality’ and ‘the mutability and diversity of and within publics’ as areas where the optimisation of HRR is stymied in circumstances where the full range of interests in play, and how these are brought to bear throughout the research lifecycle, are overlooked. Here I use publicness to deepen and extend my analysis of the relationship between individual and collective interests in the health research endeavour and how these may change over time.

How can publicness facilitate an examination of the public interest as a regulatory device in HRR?

- Fourth, and with a focus on how publicness is expressed legally, a new account of the public interest as a regulatory device is developed. I use the term ‘regulatory device’ simply to denote that appeals to ‘the public interest’ are made here in respect of its use for a particular purpose by regulatory agents or authorities in the discharge of their functions – in this case these regulatory functions are in the context of health research, as set out in further detail in Chapter 5. Other examples of regulatory devices used in a similar sense are the need for consent (to assure regulators that research participants are willingly taking part in health research and are not being coerced) and anonymisation of data (to seek to assure regulators, to the extent that this is possible, that patient and participant data are secure and that potential harms are minimised). In particular, I focus on the much-vexed intersection between the public interest and extra-legal insights provided by empirical evidence. Here I operationalise publicness by deploying this as the foundation for a framework of analysis - comprising relationality, accountability, temporality - as a way of facilitating a cross-disciplinary examination of this neglected issue. On the basis of this analysis, I offer a reconceptualisation of the public interest through the lens of publicness. The approach I suggest: (i) explores the notion of ‘the public’ in the public interest and how

context can shape these interests; (ii) points to the ways in which the research path and the public interest overlap and intersect each other throughout the entire life cycle; and (iii) emphasises the nuanced role of transparency in multi-factorial decision making, yet underlines that mere transparency is in no way a synonym for accountability.

As I will go on to show, these four contributions are established conceptually through argumentation, but also illustrated by the use of a number of examples, including an extended case study that analyses a contemporary data-intensive innovation.

In what follows in this Chapter, I outline the nature of the entire context for this research – i.e. the health research ecosystem - and then, more specifically, why data-intensive health research provides a site of study where these opportunities and challenges are thrown into particularly sharp relief. Finally, I set out why a socio-legal approach is suited to the task of exploring publicness and provide an overview of the thesis structure.

Contemporary health research and its regulation

Since the foundations of modern HRR were established in the post-World War II period, there have been significant changes in how health research is conducted. In Chapter 2 I focus specifically on how the regulation of health research has engaged with the individual and collective interests at stake in this endeavour and show that this has been a persistent and evolving concern. I argue that while a more nuanced understanding of the interconnectedness of these dual considerations has developed over time, a more radical paradigm shift is required in order to reflect fully the complexities of the interrelationship between collective and individual interests. However, first I consider the broader technoscientific, socio-cultural and institutional context of this evolution in health research. This discussion highlights fundamental changes in each of these domains which have significant implications for how the co-construction of biomedical science with society is understood and enacted in health research and its regulation. This exercise points to at least three reasons why a new understanding of what is at stake is required in order to understand the complexities of the relationship between individual and collective interests, and to support the optimal operation of HRR, as I come to shortly.

Technoscientific processes of change, which have gained momentum in biomedicine from the mid-1980s onwards, have been described by Clarke et al as 'biomedicalization'.³ This term is used to capture:

'...the increasingly complex, multi-sited, multidirectional processes of medicalization that today are being both extended and reconstituted through the emergent social forms and practices of a highly and increasingly technoscientific biomedicine.'⁴

The authors identify five key processes of biomedicalization, one of which is the impact on medicine of innovations, such as computer and information technologies and the integration of these to biomedical activities.⁵ An example of this is 'data banking' where the move from paper to electronic health records has vastly increased the capacity for data to be integrated and analysed. These changes have the potential to 'cut both ways', in that they may drive advances in human health, but also create new vulnerabilities (for example, due to easier access to health records), with the impact on individuals and society being both major and uneven.⁶

Socio-cultural understandings of this unevenness of impact have also developed over a similar period of time. In particular, intersectionality is a way of thinking that draws attention to identities and power,⁷ sameness and difference.⁸ While this idea is often traced to when it was named in the late 1980s, in Crenshaw's examination of the intersection of race and gender,⁹ the core ideas of intersectionality were developed over the preceding decades through the intellectual work and social activism of women of colour.¹⁰ Hill Collins and Bilge highlight the work of Frances Beal during this period, whose essay entitled 'Double Jeopardy: To be Black and Female'¹¹ provides an intersectional critique of the impact of sexism, racism and capitalism on Black women's lives. A further example of how social movements have shaped intersectionality can be found in the Combahee River Collective's publication of 'A

³ Adele E Clarke and others, 'Biomedicalization: Technoscientific Transformations of Health, Illness, and U.S. Biomedicine' (2003) 68(2) *American Sociological Review* 161.

⁴ *ibid* 162.

⁵ *ibid* 173.

⁶ *ibid* 175.

⁷ Jasmine A Abrams and others, 'Considerations for Employing Intersectionality in Qualitative Health Research' (2020) 258 *Soc Sci Med* 113138.

⁸ Sumi Cho and others, 'Toward a Field of Intersectionality Studies: Theory, Applications, and Praxis' (2013) 38 *Signs* 785.

⁹ Patricia Hill Collins and Sirma Bilge, *Intersectionality* (2nd edn, Polity Press 2020) 73.

¹⁰ *ibid* 74.

¹¹ Frances M Beal, 'Double Jeopardy: To Be Black and Female' (2008) 8(2) *Meridians* 166.

Black Feminist Statement',¹² which also incorporates heterosexism into their analysis of '...the manifold and simultaneous oppressions that all women of color face'.¹³ Crenshaw's Black feminist critique of antidiscrimination doctrine, feminist theory and antiracist politics examines various US courts' approaches to cases brought by Black women plaintiffs.¹⁴ She exposes the law's tendency to use a frame of analysis which thinks about discrimination as occurring in terms of single categories – for example of sex or race – and therefore distorts Black women's experiences. Crenshaw describes how 'single-axis thinking' focuses on the 'most otherwise privileged' within single category groups, and marginalises those who are multiply burdened, thereby obscuring claims that arise as a result of multiple sources of discrimination.¹⁵ Crenshaw's contribution is part of a rich body of scholarly work, rooted in Black feminist theory, which has explored the use of intersectionality as a frame of analysis across disciplines,¹⁶ and in multiple contexts relating to the simultaneous and interrelated effects of factors including gender, race, class, disability, sexual orientation, age, religion and national identity.¹⁷ Over time common elements of intersectionality have emerged, namely:

'1) the assumption that all individuals have multiple identities that converge; 2) within each identity is a dimension of power or oppression; and 3) identities, though possessed by individuals, are also created by socio-cultural context and are thus, mutable.'¹⁸

A more recent body of literature has specifically considered how intersectionality can be employed in the context of health research, given the potential for this approach to better engage with health inequalities, to generate holistic understandings of health and therefore to deliver more comprehensive solutions.¹⁹ For example, Abrams et al indicate multiple ways

¹² 'The Combahee River Collective Statement (1977)' (*BlackPast*, 16 November 2012) <www.blackpast.org/african-american-history/combahee-river-collective-statement-1977/> accessed 12 March 2022.

¹³ *ibid.*

¹⁴ Kimberle Crenshaw, 'Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics' (1989) 1(8) *University of Chicago Legal Forum* 139.

¹⁵ *ibid* 160.

¹⁶ Cho and others (n 8).

¹⁷ Ange-Marie Hancock, 'When Multiplication Doesn't Equal Quick Addition: Examining Intersectionality as a Research Paradigm' (2007) 5 *Perspectives on Politics* 63.

¹⁸ Abrams and others (n 7) 2; Nicole M Else-Quest and Janet Shibley Hyde, 'Intersectionality in Quantitative Psychological Research: I. Theoretical and Epistemological Issues' (2016) 40(2) *Psychology of Women Quarterly* 155.

¹⁹ For example, see Olena Hankivsky and others, 'Exploring the Promises of Intersectionality for Advancing Women's Health Research' (2010) 9 *International Journal for Equity in Health* 5; Salla Sariola, 'Intersectionality and Community Engagement: Can Solidarity Alone Solve Power Differences in Global Health Research?' (2020) 20 *The American Journal of Bioethics* 57; Else-Quest and Hyde (n 18); Joshua K Dubrow and Corina Ilinca, 'Quantitative Approaches to Intersectionality: New Methodological Directions and Implications for Policy

that intersectionality may be brought to bear on qualitative health research on matters from study design, through to participant selection and analysis.²⁰ They point to the wider applicability of this framework to health research on the basis that:

‘...insofar as intersectionality contends that all people are members of multiple social categories or groups, which contain a dimension of power or inequality, this framework is applicable to all groups.’²¹

The literature on intersectionality emphasises the heterogeneity of publics, as well as the relationship between collective interests, and the individual interests which these comprise. As such, this literature is well suited to assist in the exploration of a central concern of this thesis, namely how we may better understand and engage with the interrelationship of individual and collective interests in HRR, and how this may change over time in a pluralistic society. As can be seen from the working definition of publicness delivered earlier in this Chapter, and as set out in Table 1, an intersectional understanding of relationality informs one limb of the tripartite framework that grounds publicness. As I will go on to describe and develop in more detail in Chapter 4, when relationality is grounded in this way – i.e. as a dynamic and multi-faceted consideration - it further contributes to an understanding of the ‘mutability and diversity’ of and within publics in HRR. In other words, this elucidates how publics may change over time, as well as the ‘sameness and differences’ of the individual interests that exist within publics that may be obscured by a homogenous conceptualisation of ‘the public’ that ignores inequalities and how these may intersect. Considerations of sameness and differences are also central to the literature on intersectionality. Accordingly, this provides further justification for anchoring this aspect of the thesis in that particular analytical frame. In this thesis, I make no claim to an original contribution to this growing and vibrant body of literature on intersectionality and HRR. However, I do wish to explicitly acknowledge that this scholarship has shaped both the wider social-cultural landscape in which HRR takes place – where the heterogeneity of publics demands attention - and my own reflections on how diversity may be flattened within the terminology of ‘the public’ in the context of HRR. This is particularly relevant to my discussion of the conceptualisation of publics in Chapter 4.

Analysis’ in Olena Hankivsky and Julia S Jordan-Zachery (eds), *The Palgrave Handbook of Intersectionality in Public Policy* (The Politics of Intersectionality, Springer International Publishing 2019); Hancock (n 17); Abrams and others (n 7) 2.

²⁰ Abrams and others (n 7) 2.

²¹ *ibid.*

Finally, from an institutional perspective, Raman and Mohr trace the trend in the UK and in Europe, since the late 1990s, towards ‘making research social’.²² This refers to the development of, and growing emphasis on, ‘...new forms of engagement between scientist and research funders on the one hand, and “society” or “the public” on the other’. This aligns with the position that research can be improved when it is done ‘...‘with’ or ‘by’ the public, not ‘to’, ‘about’ or ‘for’ them’.²³ Raman and Mohr trace symbolic changes in terminology as the ‘science *and* society’ agenda in the early 2000s, became branded as ‘science *in* society’ in the mid-2000s, and finally moved to the present day terminology of ‘responsible research and innovation’ (known as RRI).²⁴ In this sense RRI has a more expansive meaning and:

‘...implies that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.’²⁵

When understood in this way RRI demonstrates some features of what I have characterised above as an optimal approach to HRR, in that this expands the range of actors engaged and understands research as a process rather than an event. However, the precise relationship between the individual and collective interests at stake remains vague, as well as the full implications of this for HRR over time. It is this residual vagueness that this thesis aspires to dispel, at least in part.

These new accounts of science, biomedicine and health research, and the experiences of those engaged in, excluded from, and impacted by this endeavour, point to at least three reasons why contemporary health research demands a new approach to the complexities of the relationship between individual and collective interests. I identify these here and then expand on each below. The first is related to changes in the *type* of health research that is carried out. This is epitomised by the increase in health research using ‘big data’,²⁶ as characterised by the ‘three Vs’, namely: volume (to reflect the magnitude of data involved);

²² Sujatha Raman and Alison Mohr, ‘A Social Licence for Science: Capturing the Public or Co-Constructing Research?’ (2014) 28(3-4) *Social epistemology* 258, 259.

²³ Health Research Authority, ‘Public Involvement’ (2022) <www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/> accessed 12 March 2022.

²⁴ Raman and Mohr (n 22) 259.

²⁵ Horizon 2020, ‘Responsible Research & Innovation’ (*European Commission*, 1 April 2014) <<https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation>> accessed 2 December 2021.

²⁶ Council for International Organizations of Medical Sciences (CIOMS), ‘International Ethical Guidelines for Health-Related Research Involving Humans’ (CIOMS, 2016) ix <<https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf>> accessed 2 December 2021; see extensive discussion in Graeme Laurie and E Shyong Tai (eds), ‘An Ethics Framework for Big Data in Health and Research (Special Issue)’ (2019) 11(3) *ABR*.

variety (in terms of the heterogeneity of types of data assembled); and velocity (to reflect the speed at which datasets can be compiled, analysed and actioned).²⁷ As I elaborate further below, in the context of data-intensive health research, this poses a serious challenge to existing governance structures. A second consideration is *how and with whom* health research is conducted, for example in relation to the inclusion and exclusion of groups of people from research and its benefits.²⁸ Third, the preceding discussion calls attention to *what* counts as responsible and effective HRR.

Starting with the *type* of research carried out, the foundational texts in HRR, which emerged in post-World War II period (and which I consider in more detail in Chapter 2) begin from the basis of an individual participant / researcher relationship in a ‘hands-on’ clinical research setting.²⁹ However, contemporary health research is increasingly conducted by ‘...large international consortia of researchers that are reliant on large data sets and biobanks’, or indeed networks of biobanks.³⁰ Whereas health data may once have been collected for a specific research purpose, now data sets from seemingly disparate sources can be shared and linked.³¹ These new data assemblages, made possible by the advent of big data, ‘..are changing how individuals and collective divisions are conceptualised and framed in general and in the context of biomedicine and healthcare in particular.’³² Technological advances and widespread (though, as noted above, uneven) access to technology, have simultaneously created an environment in which some individuals and groups, with access to and knowledge of technology, may be empowered and included in participatory modes of health and health research, while others may be (further) marginalised and excluded, along existing (or new) socio-economic lines.³³ These developments blur the boundaries between patients, participants and consumers³⁴ and pose significant challenges for traditional governance structures.

Take, for example, the ‘one off’ model of informed consent, where a specific point in the data lifecycle is used to obtain individual consent that will determine future data uses – often when

²⁷ Amir Gandomi and Murtaza Haider, ‘Beyond the Hype: Big Data Concepts, Methods, and Analytics’ (2015) 35(2) International Journal of Information Management 137.

²⁸ Council for International Organizations of Medical Sciences (CIOMS) (n 26) ix.

²⁹ For example, the Nuremberg Code refers to ‘experiments’ and the first iteration of the Declaration of Helsinki is framed as ‘a guide to each doctor in clinical research’.

³⁰ Jane Kaye and others, ‘From Patients to Partners: Participant-Centric Initiatives in Biomedical Research’ (2012) 5(5) Nature Reviews Genetics 371.

³¹ *ibid.*

³² Sonja Erikainen and others, ‘Patienthood and Participation in the Digital Era’ (2019) 5 Digit Health 1, 4.

³³ Erikainen and others (n 32).

³⁴ *ibid.*

these are collected.³⁵ This approach may suffice in circumstances where future uses are linear, known and predictable, and restricted to a single institution. However, advances in health research, as outlined above, mean that governance models must now grapple with networked and multi-directional data uses, as these are shared and linked across national and international borders. Even if consent is obtained on a dynamic³⁶ or ongoing basis, this approach is put under strain in circumstances where the scale at which health research is conducted means that individual participants, and groups of participants, are no longer clearly delineated³⁷ nor easily categorised as citizen, or patient, or public or consumer. In these circumstances obtaining consent, either at the point of collection or at a later date is, at best, limited and in many cases inadequate to the task – at least in terms of delivering the best possible results from health research. This is reflected, in part, by the law, and in associated policy which strongly advises that: ‘For the purposes of the [General Data Protection Regulation], the legal basis for processing data for health and social care research should NOT be consent.’³⁸ Further considerations include the extent to which reliance on a consent model may skew research findings³⁹ and/or lead to the exclusion of relevant groups from the benefits of those findings.⁴⁰ In sum, in such circumstances consent may be impractical if not impossible, thus rendering governance structures that are underpinned by a narrow approach to the individual and collective interests at stake obsolete. This brief example illustrates some limitations that arise from an overreliance on consent as a governance mechanism, but also the mindset engendered by a narrow focus on individual interests – such as the protection of participants through an impoverished view of what respect for autonomy means – to the exclusion of other interests at stake. Such an approach, which neglects the social conditions and interpersonal context that people inhabit,⁴¹ risks overlooking other interests that the

³⁵ The British Academy for the Humanities and Social Sciences and The Royal Society, ‘Data Management and Use: Governance in the 21st Century’ (June 2017) <royalsociety.org/-/media/policy/projects/data-governance/data-management-governance.pdf> accessed 6 November 2020.

³⁶ Jane Kaye and Megan Pictor, ‘Consent’ in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021).

³⁷ Charles Auffray and others, ‘Making Sense of Big Data in Health Research: Towards an EU Action Plan’ (2016) 8(1) *Genome Medicine* 71.

³⁸ Health Research Authority, ‘Consent in Research’ (19 April 2018) <www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/consent-research/> accessed 12 March 2022.

³⁹ General Medical Council, ‘Using Patient Information for Research Purposes’ (30 November 2017) <<https://www.gmc-uk.org/ethical-guidance/learning-materials/using-patient-information-for-research-purposes>> accessed 7 March 2022.

⁴⁰ Wendy A Rogers, ‘Vulnerability’ in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021).

⁴¹ N Stoljar, ‘Informed Consent and Relational Conceptions of Autonomy’ (2011) 36(4) *Journal of Medicine and Philosophy* 375.

individual may have, for example in the responsible use of their data for health research purposes, as well as the broader societal interests that may be engaged.

In relation to *how and with whom* health research is conducted, this is an area where there has also been significant change from the 1980s onwards. In the context of the AIDS epidemic, Epstein outlines how this created a social movement that shifted the relationship between people with HIV/AIDS and the production of biomedical knowledge.⁴² Activists underwent a ‘process of “expertification”⁴³’ as they acquired knowledge and used this to influence medical science from the inside. This led to frustration from some activists that their right to actively participate in research was curtailed by what was seen as an unnecessarily paternalistic approach in traditional HRR.⁴⁴

Rid also charts a move in HRR away from an uncritical ‘protectionist approach’ towards individuals in HRR. She points to an evolving understanding of the negative impact that this may have on groups of people, such as pregnant women or children, who may suffer from ‘overprotection’.⁴⁵ However, while the (highly contested) designation of vulnerability may ensure that special protections are provided to identified individuals or groups, it may also have a detrimental effect, such as exclusion from health research, resulting in a weak or absent evidence base for effective treatments.⁴⁶ This is not to downplay the need to take into account the differential impacts that health research may have on individuals or groups of people.⁴⁷ Rather, it highlights the dangers of homogenising participants, and the necessity for new approaches that allow for dynamic and nuanced ways of thinking about the potential benefits and harms of contemporary health research (including those arising from being excluded from research), and also about the power dynamics that are inevitably in play.⁴⁸ It also directs attention to who is involved in or excluded from the health research endeavour, and the disruption of the traditional dynamic between those who ‘shape’ and ‘do’ research, and those who ‘have research done to them’ and may, or may not, receive the benefits.

Finally, the preceding discussion underlines the myriad ways in which the conduct of health research has fundamentally shifted, raising broader questions about *what* should legitimately

⁴² Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (University of California Press 1996).

⁴³ *ibid* 13.

⁴⁴ Simon Woods and Pauline McCormack, ‘Disputing the Ethics of Research: The Challenge from Bioethics and Patient Activism to the Interpretation of the Declaration of Helsinki in Clinical Trials’ (2013) 27(5) *Bioethics* 243.

⁴⁵ Annette Rid, ‘Judging the Social Value of Health-Related Research: Current Debate and Open Questions’ (2020) 63(2) *Perspect Biol Med* 293, 297.

⁴⁶ Rogers (n 40) 20; Rid (n 45) 297.

⁴⁷ Rogers (n 40).

⁴⁸ *ibid* 26.

be supported as responsible health research. The growing emphasis on the social aspect of health research requires a re-evaluation of the interests that are at stake and how these should be reflected in the HRR ecosystem more broadly. For example, and as discussed further in this thesis, if ‘public benefit’ is a key driver of the acceptability of data usages beyond direct care, then how should this ‘public’ and their ‘benefits’ be understood and addressed by regulation, in circumstances where, for reasons I come to next, there is a widening gap between ‘science’ and ‘society’? In sum, this changing technoscientific, socio-cultural and institutional context has significantly altered the health research landscape, both in terms of the interests that are at stake, and how these should be accounted for in decisions made about how, what, with and for whom health research should be conducted.

Data-intensive health research: challenges and opportunities

In this thesis I focus on data-intensive health research as an area where this call for a new approach to the interests at stake in HRR has particular resonance.⁴⁹ This is a broad category of research that resists description as a single approach or set of processes. However, for the purposes of my argument I will rely on the definition in **Table 2** that was recently agreed upon by an international group of stakeholders.⁵⁰

⁴⁹ This is not to say that this analysis would not also be beneficial when applied other areas of research, or to particular topics, such as the use of genetic data.

⁵⁰ Mhairi Aitken and others, ‘Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research’ (2019) 4(1) IJPD 1.

Table 2: Data-intensive health research

The term data-intensive health research refers to forms of health research which are conducted through the linkage and analysis of data. These data can take many forms and be derived from diverse sources.

Some examples of the types of data which are used in this research include:

- Data from patient records;
- Administrative data (e.g. from social care, housing or education);
- Data from registries;
- Genomic data (e.g. from biobanks);
- Data generated through use of apps;
- Social media data.

Research may use data from a single source or link data from multiple sources together. These data are de-identified.

This research is conducted for a range of purposes including:

- Clinical decision support;
- Monitoring drug safety;
- Developing predictive models;
- Examining connections between social or behavioural factors and health outcomes;
- Audit of services.

Data-intensive research is both a product of processes of ‘biomedicalization’ and also shapes these processes. Technoscientific developments, such as the roll out in healthcare of electronic health records,⁵¹ and new computational capacities, such as artificial intelligence, have enabled this as a new form of research. In turn this has implications for the individual and collective interests that are engaged, and how these interrelate. For example, one characteristic of this type of research is the scale at which research is conducted – often involving data from huge numbers of people, or at a population level. As a result, and in contrast to many types of clinical research, where there is a direct relationship between those conducting and participating in research, the scientists or clinicians involved in data-intensive research may have no contact whatsoever with those whose data are used.⁵² As Aitken et al

⁵¹ Angela Wood and others, ‘Linked Electronic Health Records for Research on a Nationwide Cohort of More than 54 Million People in England: Data Resource’ (2021) 373 *BMJ* n826.

⁵² Georgina Hobbs and Mary P Tully, ‘Realist Evaluation of Public Engagement and Involvement in Data-Intensive Health Research’ (2020) 6(1) *Res Involv Engagem* 1.

note, this can create a ‘distance between “science” and “society”’.⁵³ However, and despite this gap, people remain crucial to the research process both as the essential source of the data used, without which the research could not be undertaken, and the intended beneficiaries of the outputs of research conducted.⁵⁴

These changes in how research is conducted have direct implications for its regulation. While every project is different, the following features are typical.⁵⁵ For example, the types of data used tend not to have been originally obtained for research purposes. Rather these may be extracted from a wide range of routinely collected data sets, both within and beyond the health context (for example, from the housing or education sectors). This has the potential, therefore, to engage a range of regulatory systems. Further, rather than obtaining individual consent to take part in research, participation may often be managed via an opt-out system. The data extracted may then be de-identified by a computer, which removes information, such as names, addresses and NHS numbers. To facilitate future linkages between data sets this can be done in such a way as to allow for information be re-identified if required.⁵⁶ The Goldacre Review has very recently, in April 2022, highlighted in particular the technical and strategic barriers that can hinder the ‘better, broader, safer use of NHS data for analysis and research’.⁵⁷ However, even if these technical capacities are increased, the optimisation of health research still requires that each of these processes must be governed, legally and ethically, in such a way that accounts for the individual and collective interests at stake, and how these interrelate. These considerations are at the heart of this thesis, which scrutinises how the quality of ‘publicness’ in HRR should be understood and operationalised in a way that is legally, ethically and socially legitimate.⁵⁸

⁵³ Aitken and others, ‘Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research’ (n 50) 3.

⁵⁴ *ibid* 1.

⁵⁵ For example, some of the examples given in this paragraph draw on the Clinical Record Interactive Search (CRIS) system which has been developed for use within the NIHR Maudsley Biomedical Research Centre (BRC). ‘CRIS’ (*South London and Maudsley NHS Foundation Trust*, 2022) <<http://projects.slam.nhs.uk/research/cris>> accessed 12 March 2022.

⁵⁶ This may be authorised by the Health Research Authority under Section 251 of the NHS Act 2006, as I explore further in Chapter 3.

⁵⁷ Ben Goldacre and Jessica Morley, ‘Better, Broader, Safer: Using Health Data for Research and Analysis. A Review Commissioned by the Secretary of State for Health and Social Care.’ (April 2022) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1067053/goldacre-review-using-health-data-for-research-and-analysis.pdf> accessed 13 May 2022.

⁵⁸ Aitken and others, ‘Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research’ (n 50).

Socio-legal approach

I have taken a socio-legal approach to the desk-based research that underpins this thesis. This is understood in broad terms ‘...as a way of seeing, of recognising the mutually constitutive relationship between law and society’.⁵⁹ This acknowledges that law (and also, in the case of this thesis, regulation) is often:

‘...contingent, uncertain, and multidirectional, resulting in modes of action that are not always (or not only) those it claims to follow, and resting on socially and politically loaded assumptions, and histories, that it does not always make apparent’.⁶⁰

Socio-legal research does not prescribe a particular methodological approach, and may be carried out in a variety of ways, engaging with disciplines within and beyond the law. Further, while work that falls under this umbrella can involve empirical enquiries, a socio-legal approach can equally be brought to bear on conceptual work and the selection and reading of legal and non-legal texts, as is the case here.⁶¹

I have selected this approach because it aligns with a fundamental premise of this work, as described above, that health research itself involves ‘...complex, multi-sited, multidirectional processes’⁶² and that these processes are enacted and constituted through social practices and forms.⁶³ Further, the enterprise of conducting health research – which itself engages matters concerning science, society, ethics, law and regulation – is inherently interdisciplinary. This ‘outward looking’ orientation can be distinguished from a purely doctrinal legal approach, which involves an ‘internal approach’, that is restricted to the ‘...analysis of legal rules and principles taking the perspective of an insider in the system’.⁶⁴ In contrast, the work in this thesis must necessarily look outside of the system of law, because the role of law within the health research ecosystem is but one factor influencing how research is done, who is involved, and how benefits and risks are managed.

Therefore, to engage with both *content* and *context* in this thesis I will draw on a wide range of sources. These include academic peer-reviewed literature and grey literature from within the law (broadly understood) but also from related disciplines such as bioethics, science &

⁵⁹ Naomi Creutzfeldt and others, ‘Socio-Legal Theory and Methods: Introduction’ in Naomi Creutzfeldt and others (eds), *Routledge Handbook of Socio-Legal Theory and Methods* (1st edn, Routledge 2019) 4.

⁶⁰ Emilie Cloatre, ‘Law and Biomedicine and the Making of “Genuine” Traditional Medicines in Global Health’ (2019) 29 *Critical Public Health* 424, 427.

⁶¹ Creutzfeldt and others (n 59) 7.

⁶² Clarke and others (n 3) 162.

⁶³ *ibid.*

⁶⁴ Christopher McCrudden, ‘Legal Research and the Social Sciences’ (2006) 122 *LQR* 632, 633.

technology studies, and sociology. When considering the nature of law and regulation, I have focused not only on ‘the law in the books’, as ascertained through doctrinal legal methods⁶⁵ (using traditional legal sources such as legislation, case law and guidelines), but also on how this is understood and operationalised in practice (using academic literature and other grey material, such as policy publications and other publically available material relating to regulatory and decision making process). In this way my analysis of HRR is ‘outward looking’ and set in context, thereby providing a wider perspective. This approach, then, moves us from a baseline understanding of what *must* be done (under the law) to a much richer comprehension of what *can* be done (within the law) to promote a health research ecosystem that works best to deliver the range of objectives that drive the entire enterprise.

In line with the socio-legal methodological approach outlined above, I have principally used two methods in this thesis to answer my research questions. First I have synthesised a wide and novel body of literature, legal and extra-legal. This has allowed me both to situate my work in the wider HRR context, and also to delineate why publicness provides a new and novel approach. Second, I have used case studies to demonstrate how publicness may play out in practice. Throughout the thesis I use a number of brief case studies to bring to life examples of particular points, such as how the use of confidential patient data for health research can have implications both for individual and collective interests (Chapter 2). The purpose of using these more compact case studies is primarily illustrative. However, in Chapter 6 I have delivered an extended case study in relation to a collaboration between The Royal Free London NHS Foundation Trust and GoogleDeepmind. I have chosen this as a high profile and innovative example of the secondary use of health data. Here the extended case study format is used to illustrate how publicness represents a concept that can support the robust review and revision of data-intensive initiatives throughout the research lifecycle in circumstances where there are multiple and related interests at play.

Thesis structure

I have, so far, outlined the changing technoscientific, socio-cultural and institutional context of contemporary health research and its regulation, and introduced data-intensive health research as a focus in this thesis. I have argued that new modes of health research have disrupted the traditional relationship between researchers and participants, and between individual and collective interests, and that a new approach to HRR is required that can engage with the multiplicity of ways in which decisions about the conduct of health research

⁶⁵ Terry Hutchinson and Nigel Duncan, ‘Defining and Describing What We Do: Doctrinal Legal Research’ (2012) 17(1) Deakin Law Review 83.

might impact on our lives. I have proposed that a socio-legal approach is well suited to explore both how these interests in HRR are conceptualised, and how these are operationalised.

In Chapter 2 I will introduce more thoroughly the new concept of publicness. Here I explore the contours of publicness using the threshold concept framework, and explain why this has the potential to meet some of the challenges of contemporary HRR. I then use publicness as the foundation for a framework of analysis in order to evaluate three existing concepts in HRR, each of which is in some way concerned with the relationship between individual and collective interests, namely the public interest, social value and social licence (Chapter 3). This analysis demonstrates that while each of these concepts manifest certain features of publicness, they are limited and limiting in different ways. As a result they are neither individually, nor cumulatively, sufficient to enact publicness in HRR. I conclude Part I by revisiting publicness, in light of the preceding analysis, in relation to the work this concept can do and, crucially, what is missing from existing concepts in HRR. These missing elements are explored further in Part II.

Part II provides three examples of how publicness, as developed in Part I, may be operationalised, thus demonstrating different facets and uses of this concept. Having previously used publicness to identify what is missing from existing concepts in HRR in Part I, Chapter 4 illustrates how publicness can help to flesh out and enrich the HRR ecosystem. More specifically I use the 'normative force' of publicness (an aspect I address further in Chapter 2) to explore particular sub-optimal features of HRR and to identify how these can better account for the full range of interests in play throughout the research and data lifecycle. As such, I examine (1) the temporal aspects of regulating individual and collective interests over time and (2) the mutability and diversity of and within publics in HRR. In respect of the first point, I argue that while current understandings of HRR recognise the relevance of temporality to HRR in different ways, time is commonly characterised as part of the historical backdrop against which regulation takes place. In contrast, publicness demands further scrutiny of the *multi-directional interaction* of time and interests in HRR and reveals that not only can time and context shape regulation, but that law and regulation are also capable of shaping context and creating horizons of time. This will be explained fully in due course. On the second point, I suggest that greater attention should be paid to how the diversity of and within publics is understood in HRR. I outline how publicness pushes us further to consider the *mutability and diversity within different publics* in relation to the multiple perspectives that people may have on what socially legitimate research looks like. Here the use of an intersectional lens does not prescribe a 'one size fits all' regulatory approach – but rather requires that attention is paid to inequalities and how these might intersect.

In Chapter 5, I remain with the theme of the optimisation of the HRR ecosystem but narrow my focus to the public interest as a regulatory device in HRR. I focus in particular on the much-vexed intersection between the public interest as a regulatory device, and extra-legal insights provided by empirical evidence. My aim in this Chapter is determinedly not to provide a 'how to' guide on either *conducting* different modes of public engagement and involvement, nor on the *practicalities* of incorporating outputs from this into law and policy.⁶⁶ Rather, I use publicness and its facets - of relationality, accountability, temporality - as a way of facilitating a cross-disciplinary examination of the public interest as a regulatory device. On the basis of this analysis, I offer a reconceptualisation of the public interest through the lens of publicness. The approach I suggest: (i) explores the notion of 'the public' in the public interest and how context can shape these interests; (ii) points to the ways in which the research path and the public interest overlap and intersect each other throughout the entire life cycle; and (iii) emphasises the complex and nuanced role of transparency in multi-factorial decision making. This directs attention not only to 'the public interest' in terms of how this may be realised from the (expected) findings from research, but also to the ways in which this may be manifested in processes of research and regulation in relation to data use.

In order to integrate the preceding analysis, in Chapter 6 I bring this to bear on a high profile collaboration between The Royal Free London NHS Foundation Trust and Google DeepMind.⁶⁷ This was in relation to the creation of an application to help to detect and manage acute kidney injury, known as 'Streams'. Here concerns were raised about the large scale sharing and use of identifiable health data, and in particular, the use of around 1.6 million identifiable partial patient records in the testing phase of the Streams application, which resulted in the Information Commissioner finding that data protection legislation had been breached in a number of respects. This case study illustrates how publicness delivers a concept that can support the review and revision of data-intensive initiatives, where there are multiple and related interests at play, throughout the full research lifecycle.

In Chapter 7, I provide a summary of the key conclusions that I have drawn in Part I and Part II of this thesis, before recapping the original contributions that these contain. Finally, I consider a number of future directions for research that may follow on from these findings.

⁶⁶ For a discussion of how to do public engagement that is meaningful and effective see Kieran O'Doherty and Alice Hawkins, 'Structuring Public Engagement for Effective Input in Policy Development on Human Tissue Biobanking' (2010) 13(4) Public Health Genomics 197.

⁶⁷ Now Google Health UK.

Chapter 2: What is ‘publicness’, and how can it help to optimise HRR?

Introduction

So far in this thesis I have argued that technoscientific, socio-cultural and institutional changes have had significant implications for contemporary health research and its regulation. This has facilitated new types of research that harness the power of big data, and have transformed how and with whom health research is conducted. Together this has disrupted the traditional researcher/participant relationship and blurred the lines between patients, participants and publics. As a result, it is posited that a new understanding of what is at stake is required in order to understand the complexities of the relationship between individual and collective interests engaged by contemporary health research and its regulation.

In this Chapter I consider how health research regulation has engaged with these individual and collective interests, and show that this has been a persistent and evolving concern since the post-World War II period. While there has been a growing recognition of the interconnectedness of these dual considerations, I propose that a more radical paradigm shift is required in order to reflect fully the complexities of this interrelationship. My argument unfolds as follows. First, I identify the persistent tension in health research between collective and individual interests. This is located both in foundational international instruments that have shaped modern HRR, such as the Nuremberg Code and the first and subsequent iterations of the Declaration of Helsinki, as well as in contemporary instruments and guidelines. My analysis highlights that while there are collective interests in the goal of advancing knowledge through responsible health research, it is axiomatic that health research also relies on the participation of individuals *qua* individual persons whose rights and interests must be protected. Although this insight in itself is hardly novel, I argue that the new concept of ‘publicness’ helps to elucidate the full complexities of this relationship, and its implications for health research regulation. I frame this as a threshold concept⁶⁸ that can drive a fundamental shift in perspective⁶⁹ by engaging with the interrelationship between collective and individual interests, as well as with the multiple ways that health research may bear on our lives. Further, I distinguish between publicness’s function as a threshold concept in HRR, and the different

⁶⁸ Meyer and Land (n 2).

⁶⁹ *ibid.*

ways in which certain features of this may be found in existing concepts, namely the public interest, social value and social licence (to which I return in more detail in Chapter 3).

In summary, this Chapter both delineates how publicness is understood in this thesis, and its transformative capacity to take our understanding beyond that which is routinely accepted in order to help to optimise the regulation of contemporary health research.

Individual and collective interests in health research and its regulation

The foundations of modern health research ethics and governance can be traced back to events following Nazi atrocities perpetrated during World War II. More specifically, the Nuremberg Code 1947 ('the Code')⁷⁰ was formulated following the trial of doctors accused of murder and torture in the course of what they claimed to be medical experimentation.⁷¹ The Code, as set out in **Table 3**, consists of ten principles, which apply to 'experimentation' (to use the terminology of the Code) on human subjects.

⁷⁰ 'The Nuremberg Code' (1947) <fhi360.org/sites/all/libraries/webpages/fhi-retc2/Resources/nuremburg_code.pdf>.

⁷¹ Evelyne Shuster, 'Fifty Years Later: The Significance of the Nuremberg Code' (1997) 337(20) *New England Journal of Medicine* 1436.

Table 3: Nuremberg Code: Principles

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

As called for by the context, the Code focuses on the rights of human subjects in the context of clinical research, and emphasises, in particular, the need for voluntary and informed consent to be obtained from health research subjects, describing this as ‘absolutely essential’.⁷² Although the Code has no legal standing, it contains tenets of modern HRR, such as the need for research to be directed towards yielding ‘...fruitful results for the good of society’,⁷³ and for the risks of research to be proportionate to its aims.⁷⁴ While the (potential)

⁷² ‘The Nuremberg Code’ (n 70) Principle 1.

⁷³ *ibid* Principle 2.

⁷⁴ *ibid* Principle 6.

benefits of experimentation are recognised in the Code, the protection of individual rights is paramount.

Condemnation of Nazi war crimes underpinned continued debate on the ethics of health research by the World Medical Association (WMA).⁷⁵ This resulted first in the Declaration of Geneva in 1948, which provided a general statement of doctors' responsibilities to put the health of their patient first.⁷⁶ Subsequently the Declaration of Helsinki in 1964 more specifically addressed 'Ethical Principles for Medical Research Involving Human Subjects'.⁷⁷ The influence of the Code's ten principles is evident in the original iteration of the Declaration of Helsinki, which contains similar provisions on, amongst other matters, the moral and scientific justification for medical research⁷⁸ and proportionality.⁷⁹ However, the introduction to the first edition of the Declaration of Helsinki presents the rationale for the drafting of this document as follows: 'Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity...'.⁸⁰ This can be compared to the wording used in the Nuremberg Code, where consent is presented as 'absolutely essential'.⁸¹ The Declaration represents, to some extent, a rolling back from this position, as it requires that freely given consent should be obtained 'if at all possible'.⁸² Unlike the Code, the Declaration has been updated on numerous occasions since its inception, and most recently in 2013.⁸³ The text has expanded and the terminology has been updated, to address matters such as the participation of underrepresented groups⁸⁴ and the availability of

⁷⁵ Bernard A Fischer, 'A Summary of Important Documents in the Field of Research Ethics' (2006) 32(1) *Schizophr Bull* 69.

⁷⁶ 'WMA Declaration of Geneva (Adopted by the 2nd General Assembly of the World Medical Association, Geneva, Switzerland)' (September 1948) <<https://www.wma.net/policies-post/wma-declaration-of-geneva/>> accessed 13 March 2022.

⁷⁷ 'WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (Adopted by the 18th WMA General Assembly, Helsinki, Finland)' (June 1964) <<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>> accessed 13 March 2022.

⁷⁸ 'The Nuremberg Code' (n 70) Principle 1.

⁷⁹ *ibid* Principle 3.

⁸⁰ 'WMA Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects (adopted by the 18th WMA General Assembly, Helsinki, Finland)' (n 77) 1.

⁸¹ 'The Nuremberg Code' (n 70) Principle 1.

⁸² Section II Clinical research combined with professional care, in 'WMA Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects (adopted by the 18th WMA General Assembly, Helsinki, Finland)' (n 77) 2.

⁸³ 'WMA Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects (adopted by the 18th WMA General Assembly, Helsinki, Finland)' (n 77).

⁸⁴ 'WMA Declaration of Helsinki (Amended by the 64th WMA General Assembly, Fortaleza, Brazil)' (October 2013) Paragraph 13 <<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>> accessed 13 March 2022.

compensation in the case of harm.⁸⁵ The changing nature and scope of the research endeavour, as reviewed in Chapter 1, is reflected in the wording introduced at the 52nd WMA General Assembly in 2000, which notes that: ‘Medical research involving human subjects includes research on identifiable human material or identifiable data’.⁸⁶ However, the 2013 publication retains the Code’s message that:

‘While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects’,⁸⁷ often referred to as the ‘primacy principle’.⁸⁸

This tension between, on the one hand, the individual rights of participants and, on the other, the collective benefits of health research, can also be traced through numerous other international texts, which aim to set universal standards. The Council of Europe Convention on Human Rights and Biomedicine,⁸⁹ known as the Oviedo Convention, similarly states that: ‘The interests and welfare of the human being shall prevail over the sole interest of society or science’,⁹⁰ while providing for biomedical research to be carried out freely subject to appropriate protections.⁹¹ The subsequent UNESCO Universal Declaration on Bioethics and Human Rights⁹² (‘the Universal Declaration’) refers back to the Declaration of Helsinki and Oviedo Convention (amongst other documents), and sets out ‘universal standards’ in the context of a human rights framework.⁹³ This explicitly addresses the ethical issues that are presented by advancements in health research, recognising that ‘..scientific and technological developments have been, and can be, of great benefit to humankind ...and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole...’.⁹⁴ Article 3.2, reiterates the primacy principle

⁸⁵ ‘WMA Declaration of Helsinki (amended by the 64th WMA General Assembly, Fortaleza, Brazil)’ (n 84) Paragraph 16.

⁸⁶ ‘WMA Declaration of Helsinki (Amended by the 52nd WMA General Assembly, Edinburgh, Scotland)’ (October 2000) Introduction, Paragraph 1 <<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>> accessed 13 March 2022.

⁸⁷ ‘WMA Declaration of Helsinki (amended by the 64th WMA General Assembly, Fortaleza, Brazil)’ (n 84) General Principles, Paragraph 8.

⁸⁸ Joanna Różyńska, ‘Taking the Principle of the Primacy of the Human Being Seriously’ (2021) 24 *Medicine, health care, and philosophy* 547.

⁸⁹ Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, Spain, 4. IV.1997.

⁹⁰ *ibid* Article 2.

⁹¹ *ibid* Article 15.

⁹² ‘Universal Declaration on Bioethics and Human Rights’ (*UNESCO*, 19 October 2005) <http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html> accessed 13 March 2022.

⁹³ R Andorno, ‘Global Bioethics at UNESCO: In Defence of the Universal Declaration on Bioethics and Human Rights’ (2007) 33(3) *J Med Ethics* 150.

⁹⁴ Universal Declaration on Bioethics and Human Rights (n 92) Preamble.

that ‘the interests and welfare of the individual should have priority over the sole interest of science or society’. A feature of the UNESCO Universal Declaration is the attention it pays to the multiple stakeholders in the health and health research endeavour, noting that ‘... decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole’.⁹⁵ This underlines the manifold ways that health research may bear on our lives. Such impacts may not be linear or distinct, and we may be affected in different ways in our multiple and overlapping roles: as patient; as participant; as citizen; and as part of wider society.

The UNESCO Universal Declaration also refers to prior versions of the ‘International Ethical Guidelines for Health-Related Research Involving Humans’, as prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO).⁹⁶ The current iteration of this CIOMS document provides 25 expansive guidelines.⁹⁷ In line with more recent iterations of the Declaration of Helsinki, CIOMS expressly expands the reach of these guidelines ‘from “biomedical research” to “health-related research”’⁹⁸ in order to clearly bring research with health-related data within its parameters. The Guidelines also address specific contemporary issues, such as research in low-income settings,⁹⁹ benefit sharing,¹⁰⁰ and community engagement.¹⁰¹ Guideline 1, ‘Scientific Social Value and Respect for Rights’ considers the central issue of the relationship between the value of responsible health research and the protection of individual interests. Scientific and social value is positioned as a ‘fundamental justification’ for health research, but one that comes with a moral obligation that rests on those who conduct research to ensure that the rights of individual and communities are protected and respected.¹⁰² It is made explicit that scientific and social value cannot justify ‘mistreatment or injustice’.¹⁰³ Taken together, this suggests a turn towards a more nuanced understanding of the relationship between collective and individual interests, where neither broader social value (or indeed ‘fruitful results for the good of society’, to use the terminology of the Nuremberg Code), nor respect for individual rights alone, can justify responsible health research. As I come to in more detail in Chapter 3,

⁹⁵ *ibid* General Principles.

⁹⁶ Council for International Organizations of Medical Sciences (CIOMS), ‘Working Groups: Bioethics’ (CIOMS, 2022) <https://cioms.ch/working_groups/bioethics/> accessed 13 March 2022.

⁹⁷ CIOMS (n 26).

⁹⁸ *ibid* ix.

⁹⁹ *ibid* Guideline 2.

¹⁰⁰ *ibid* Guideline 3.

¹⁰¹ *ibid* Guideline 7.

¹⁰² *ibid* Guideline 1.

¹⁰³ *ibid*.

the use of a social value requirement in health research is itself a contested concept.¹⁰⁴ Nonetheless, what can be said for now, is that that this notion of societal good is a reoccurring theme in HRR, and seeks to capture something about the wider benefits that can come from research. That is, there must be something about the quality of human health research that is focused on realising and promoting collective interests that builds on, but also goes beyond, the protection of individuals who contribute that that research. This idea is not, at present, adequately captured by the either/or terminology of ‘individual or collective’ and ‘private or public’ interests. This brings us, therefore, to the concept of publicness.

Publicness in HRR: a threshold concept

The preceding analysis of international instruments is by no means exhaustive – there are many other declarations, statements and standards, both general and on specific issues, that bear on the conduct of health research and the interests identified.¹⁰⁵ However, this limited exercise serves to illustrate both that the interplay between individual and collective interests has been a persistent concern in international health research regulation, and that the emphasis on each has changed, from the post-World War II era onwards. This has taken place against the backdrop of transformational change in health research, as explored in Chapter 1, which has disrupted how we understand both the range and (overlapping) roles of stakeholders whose interests are engaged by new modes of contemporary health research. The tracing exercise above also demonstrates a shift over time away from an antagonistic understanding of these dual considerations, and towards a more nuanced understanding of how these may be interconnected. Nonetheless, the exact nature of this relationship remains far from clear. While the ‘public/private trope’ in HRR has been challenged in different ways, including in relation to the range and scope of interests that this can accommodate, this distinction, and the vocabulary it provides, remains ‘...largely intact as a framing device’.¹⁰⁶ This may be useful as a starting point, in order to stimulate debate about the interests that are at stake. However, the binary nature of this terminology also serves as a barrier to more open thinking; accordingly, this thesis seeks to move beyond an oppositional relationship between

¹⁰⁴ Johannes JM van Delden and Rieke van der Graaf, ‘Social Value’ in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021).

¹⁰⁵ There are multiple other instruments, both general and on specific issues, that continue in the same vein, for example, the Universal Declaration of Human Rights of the United Nations (1948); the Belmont Report (1979); and more documents addressing specific issues such as UNAIDS/WHO Ethical Considerations in Biomedical HIV Prevention Trials (2007/2012) and the work of the Human Genome Organization (HUGO). The Council of Europe have produced multiple topic-specific instruments that reflect the Oviedo Convention. These demonstrate how the reach of ‘research’ has broadened in the last 75 years.

¹⁰⁶ Graeme Laurie, ‘Private and Public Dimensions of Health Research Regulation’ in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021) 228.

the interests in play, and to engage with the multiplicity of ways in which decisions about the conduct of health research might impact on our lives. To do so requires a way of talking about the interconnectedness of these interests that recognises, and draws out, the complexities of this interrelationship. I propose therefore that a more radical paradigm shift is required. In this respect I offer the new concept of publicness as a means to better elucidate this fundamental concern, and therefore to facilitate the interdisciplinary discussions that are required about how this is operationalised in order to optimise HRR. The concept of publicness is introduced here, and then further examined and refined in subsequent Chapters.

In essence, publicness, in its simplest terms, is a new concept that reflects the interrelationship between individual and collective interests. As I will explore in this and in subsequent Chapters, publicness can help to optimise HRR by naming and foregrounding this relationship, and by providing the foundation for a framework for analysis in relation to each of its three facets: relationality, temporality and accountability. As such, it provides a novel way to navigate the interrelationship between individual and collective interests that pays attention to the context in which this interplay takes place, as well as the implications of this relationship for HRR, both now and for the future. As understood in this thesis, publicness is a broad concept, which may be present, to a greater or lesser extent, in different scenarios related to health research and its regulation. Further, as a deeply relational and contextual concept its full meaning unfolds through consideration not only of what it 'is', but also of what it 'does'.

Take, for example, the interest a patient has in the confidentiality of their health data being respected when information from their electronic health record is subsequently used for health research. One consideration here is the protection of the participant's informational privacy by the researchers who are using their data in order to prevent harms that could be caused by unauthorised disclosure. Yet this is not the *only* interest that is in play – an individual might also conceivably have an interest in the use of their data, with adequate safeguards, for responsible health research.¹⁰⁷ Further, a failure to respect that person's informational privacy could also impact on a group or societal level in various ways. For example, where it is possible to do so, the person may exercise their right to opt out of or withdraw from research. This could limit the coverage of a research resource, or the validity of findings that rely upon this data, and therefore impact negatively on the collective benefits that can be realised from this. As I will come to in more detail later in this thesis, trust in the research context cannot be assumed and may easily be broken.¹⁰⁸ Therefore wider publics or other stakeholders (such as

¹⁰⁷ Kerina H Jones and others, 'The Other Side of the Coin: Harm Due to the Non-Use of Health-Related Data' (2017) 97 *Int J Med Inform* 43.

¹⁰⁸ Michael McDonald and others, 'Trust in Health Research Relationships: Accounts of Human Subjects' (2008) 3(4) *J Empir Res Hum Res Ethics* 35.

clinicians) may lose trust in research that is conducted by researchers who do not protect individual participant's data. Furthermore, those who might otherwise be minded to take part in future research could be deterred from doing so. This could limit or even halt the research that can take place, which itself may impede advances in human health. By acknowledging the quality of publicness that is engaged by this simple scenario our attention is drawn to the co-existence of individual and collective interests and their interconnectedness, which must be accounted for when decisions are made about whether and how health research is conducted. This more accurately reflects the realities of the health research endeavour, where interests can, yet rarely, fall neatly into either/or categories of 'individual' or 'collective'.

Consideration of publicness also raises questions around how these interrelated interests may change over time. While in clinical research samples collected may deplete as they are used, the position is reversed in respect of data, in circumstances where:

'the use and value of ...data ... proliferates over time and might be used for a multitude of research projects by a range of stakeholders in the public and commercial sectors.'¹⁰⁹

As I explore further in Chapter 4, this proliferation of data can create a temporal disconnect between people, who are the source of data, and the subsequent use and reuse of that data in the future. This may impact on HRR, both in terms of the limitations of the information that can be provided prospectively about future (and yet unknown) uses of data for research, and the extent to which it is possible or practical to go back to those whose data is being used in order to provide further information at a later date.¹¹⁰ As set out in Chapter 1, in the context of data-intensive research, and explored later in this thesis, this requires that regulatory frameworks and mechanisms are able to adapt over time in order to meet the full range of interests at stake.

The example above (in relation to the interests engaged by the use (or non-use) of confidential health data) also illustrates a normative function of publicness, which directs attention to how the implications of this interrelationship between individual and collective interests can be accounted for by regulation when decisions are made about how health research should be conducted. In other words, if there is a degree of publicness to our own health data – because of its potential to benefit not just ourselves, but also others, such as our families, or disease groups, or communities, both now and in the future - then this has obvious implications for

¹⁰⁹ Annie Sorbie, 'Medical Data Donation, Consent and the Public Interest After Death: A Gateway to Posthumous Data Use' in Jenny Krutzinna and Luciano Floridi (eds), *The Ethics of Medical Data Donation* (Springer International Publishing 2019) 123.

¹¹⁰ Sorbie, 'Medical Data Donation, Consent and the Public Interest After Death' (n 109).

HRR, in that this suggests that informational privacy is not the sole consideration for the use of this data for research purposes. There may also be individual and collective interests in the proactive use of data for responsible health research, which makes an overly cautious approach equally problematic¹¹¹ where there are potential harms that arise from the non-use of data.¹¹² Indeed it has been suggested that: ‘...the problem of data non-use is much greater than it appears, and is arguably more dangerous to individuals and society than any privacy risks in sharing clinical data’.¹¹³ Recognition of publicness in this scenario has the potential to impact on decisions around how best to govern the use of data in the research context – for example whether to rely on consent alone and/or other regulatory devices, such as authorisation in the public interest¹¹⁴ - in order to account for the multiple interests engaged. As I come to further below, and explore in later Chapters of this thesis, this raises questions not only about publicness itself, as a broad concept that reaches across disciplinary boundaries, but also in relation to the distinctive ways that this is operationalised by existing conceptual approaches.

The discussion above provides a starting point from which to interrogate notions of publicness. However, it also raises questions in relation to the role of this concept within the health research landscape, and the work that it will do in this thesis in order to help to elucidate what is at stake in a different way.¹¹⁵ In this respect Land and Mayer’s work on ‘threshold concepts’ provides some assistance. In the context of higher education they describe a threshold concept as a portal that opens up a new and transformative way of thinking about a phenomenon or discipline.¹¹⁶ This is distinct from a core concept, which needs to be understood, but ‘...does not necessarily lead to a qualitatively different view of the subject matter’.¹¹⁷ Over the last two decades Land and Meyer’s work has been drawn on by a range

¹¹¹ *ibid.*

¹¹² Graeme Laurie and others, ‘A Review of Evidence Relating to Harm Resulting from Uses of Health and Biomedical Data’ (Prepared for the Nuffield Council on Bioethics Working Party on Biological and Health Data and the Wellcome Trust’s Expert Advisory Group on Data Access) (30 June 2014) <<https://www.nuffieldbioethics.org/wp-content/uploads/FINAL-Report-on-Harms-Arising-from-Use-of-Health-and-Biomedical-Data-30-JUNE-2014.pdf>>; see also ‘The Caldicott Principles’ (*National Data Guardian*, 2022) <<https://www.gov.uk/government/publications/the-caldicott-principles>> accessed 13 December 2021, Principle 7: ‘The duty to share information for individual care is as important as the duty to protect patient confidentiality’.

¹¹³ Laurie and others (n 112) 136.

¹¹⁴ Graeme Laurie and others, ‘On Moving Targets and Magic Bullets: Can the UK Lead the Way with Responsible Data Linkage for Health Research?’ (2015) 84(11) *International Journal of Medical Informatics* 933.

¹¹⁵ Holly Hassel and Christie Launius, ‘Crossing the Threshold in Introductory Women’s and Gender Studies Courses: An Assessment of Student Learning’ (2017) 5(2) *TLI* 30, 30.

¹¹⁶ Meyer and Land (n 2) 3.

¹¹⁷ Jan HF Meyer and Ray Land, ‘Threshold Concepts and Troublesome Knowledge (2): Epistemological Considerations and a Conceptual Framework for Teaching and Learning’ (2005) 49 *Higher Education* 373.

of disciplines, from economics¹¹⁸ to medical education,¹¹⁹ in order to better understand what and how students learn.¹²⁰ Here I use this idea to reveal and make explicit the contours of publicness, and the work that this concept can do to drive a perspective shift in HRR.

The example that Land and Meyer offer to illustrate a threshold concept is the application of the concept of heat transfer to the act of cooking.¹²¹ They pose the question: if the aim is to expediently cool down two cups of hot liquid by adding a quantity of cold liquid, should this be added immediately or after a few minutes? In other words, which liquid will be cooler at the point that the temperature is measured after the addition of the cool liquid to the second cup? The answer is that the cool liquid should be added after a few minutes. This is because the hotter initial temperature of the liquid in that cup means that there is a steeper temperature gradient and so it loses more heat. Once a chef understands the threshold concept of heat transfer (which is grounded in physics and is expressed as a mathematical equation), it has implications for how they perceive this aspect of their work. This shifts their attention away from a sole focus on the ingredients that they use, towards a new awareness of how pans are selected to apply heat to these ingredients in the optimum way. In other words, the chef's understanding of heat transfer leads to a fundamental change in how they think about cooking.¹²² In this example the effect of the threshold concept relates to a small but specific part of the culinary process, indicating that its impact need not be all-encompassing. However, a threshold concept will have the power to re-frame something that was previously familiar, and therefore to tease out significant aspects of this that might not otherwise be apparent.

Looking across disciplines, Hassel and Launius provide an account of their work in identifying four threshold concepts in women's and gender studies. They too note the value of a threshold concept as an analytical lens¹²³ which enables the user to 'look at the world differently'¹²⁴ or see things in a new light. The authors set out how they conferred with colleagues, before narrowing down the threshold concepts in their discipline to:

¹¹⁸ Martin Shanahan and Jan HF Meyer, 'The Troublesome Nature of a Threshold Concept in Economics' in Jan HF Meyer and Ray Land (eds), *Overcoming Barriers to Student Understanding: Threshold Concepts and Troublesome Knowledge* (Routledge 2006).

¹¹⁹ Virginia Randall and others, 'Threshold Concepts in Medical Education' (2018) 7(3) *MedEdPublish* 176.

¹²⁰ Hassel and Launius (n 115).

¹²¹ Meyer and Land (n 2).

¹²² *ibid* 3–4.

¹²³ Hassel and Launius (n 115).

¹²⁴ *ibid* 35.

'the social construction of gender, privilege and oppression, intersectionality, and feminist praxis, recognizing their interconnectedness as well as the ways that related ideas could lay equal claim to their prominence in the field...'.¹²⁵

This list is neither exhaustive nor final, and Hassel and Launius call for wider discussion of their approach within the field.¹²⁶ They also note that different disciplines have taken a more expansive approach to identifying threshold concepts, with 37 such concepts¹²⁷ being identified in the context of writing studies.¹²⁸

Returning to the implications of this discussion for the development of publicness as a threshold concept in health research and its regulation, there are a number of parallels with each of the examples given above, albeit that HRR provides a novel disciplinary setting. More specifically, as set out in the survey of international instruments at the start of this Chapter, the presence of individual and collective interests in the health research endeavour is well established. However, publicness provides a novel way of engaging with these interests that transcends the binary terminology of 'individual or collective' and 'private or public' interests. Rather, by providing a way to foreground and discuss the *interrelationship* between collective and individual interests this reveals a new perspective on the co-existence of these interests and their interconnectedness that otherwise risks being overlooked. More particularly, publicness does so by providing a means of seeing and framing interests in ways that do not necessarily pit one set of interests against another. To fail to engage with publicness is therefore to the detriment of attempts to govern health research in such a way that recognises the full extent of the interests at stake and how these interrelate.

Publicness can be further delineated with reference to the five characteristics of a threshold concept that have been identified by Land and Meyer. These are: that these tend to be (i) transformative; (ii) 'probably' irreversible; and (iii) integrative; and may potentially be (iv) bounded; and (v) troublesome.¹²⁹ I turn to each of these features below, but first pause to consider a key objection to the threshold concept framework. While there is a significant body

¹²⁵ *ibid* 31.

¹²⁶ *ibid* 33.

¹²⁷ As the prevalence of threshold concepts in this example indicates, the positioning of publicness in this way is not to the exclusion of the possibility that there may be other potential threshold concepts in HRR. Though I do not identify these in this thesis, this discussion of publicness may provide the basis for a wider conversation within the field on this topic.

¹²⁸ Linda Adler-Kassner and Elizabeth Wardle, *Naming What We Know: Threshold Concepts of Writing Studies* (University Press of Colorado 2015).

¹²⁹ Meyer and Land (n 2) 6–8.

of research that has used this framework,¹³⁰ and the detailed criticism of this approach is relatively sparse, this has tended to coalesce around the issue of definitional weakness. As Salwén asserts:

‘Definitions are used for clarificatory purposes. With reference to definitions, scientists can clarify what they are talking or thinking about and thereby make it possible for themselves or others to investigate whether or not there are objects or phenomena of the sort the definitions specify. Then, hopefully, the scientists are able to formulate empirical generalizations connecting objects or phenomena that satisfy the definition with other interesting properties.’

He goes on to dismiss Meyer and Land’s ‘portal’ definition, noting that it is ‘...far too metaphorical to serve scientific purposes’.¹³¹ He concurs with arguments by Rowbottom¹³² and O’Donnell¹³³ who find that the vagueness of the terminology used to describe the five characteristics of a threshold concept (for example, ‘tends to be’; ‘probably’; ‘potentially’) make these ‘...unidentifiable in principle’.¹³⁴ Given these objections, Salwén does not critique the detail of specific uses of the idea in the literature.

In this way Salwén and others rightly point to the flexibility that is inherent to the definition of the threshold concept. However, this overlooks the ability of this approach to adapt and respond to the demands of different disciplines, which has likely contributed to its uptake in multiple contexts over a sustained period of time. Accounts in the literature also recognise that threshold concepts are not absolute nor fixed – rather they are a site for discussion.¹³⁵ In the context of higher education, users of the framework have outlined how: ‘...the threshold concepts approach foregrounds the process of learning and ... lays bare and articulates ... how the concepts as lenses can illuminate content’.¹³⁶ Therefore, the value added by the threshold concept framework to this thesis is not its ability to provide scientific certainty about what is (or indeed is not) a threshold concept. Rather, value is found in the framework’s capacity to explore the contours of publicness, and the insights that this can elucidate in the

¹³⁰ Jan Meyer and Ray Land, *Overcoming Barriers to Student Understanding : Threshold Concepts and Troublesome Knowledge* (Routledge 2006); Ray Land and others, *Threshold Concepts in Practice* (Educational Futures, Springer 2016).

¹³¹ Håkan Salwén, ‘Threshold Concepts, Obstacles or Scientific Dead Ends?’ (2021) 26(1) *Teaching in Higher Education* 36, 40.

¹³² Darrell Patrick Rowbottom, ‘Demystifying Threshold Concepts’ (2007) 41(2) *Journal of Philosophy of Education* 263.

¹³³ Roderick O’Donnell, ‘Threshold Concepts and Their Relevance to Economics’ (14th Annual Australasian Teaching Economics Conference, Brisbane, Queensland, 1 January 2009).

¹³⁴ Salwén (n 131) 41.

¹³⁵ Hassel and Launius (n 115).

¹³⁶ *ibid* 37.

context of this thesis, and in HRR more widely. In this way the use of the threshold concept framework helps to articulate more clearly something that is implicit in the HRR literature – that the binary expression of the interests engaged in health research is too crude – and to express the nuance of how these interrelate more explicitly and in ways that are more sophisticated as compared to what we currently understand. Timmermans and Meyer have argued that ‘...there is a need to shift conversations away from unproductive debates regarding the precise definition of the term ‘concept’ and instead honour the range of meanings this term may hold across disciplines’.¹³⁷ It is in this spirit that I return to Land and Meyer’s five characteristics.

The most distinctive and non-negotiable¹³⁸ characteristic is that a threshold concept should be *transformational*. This may be specific to part of a defined area, but should deliver ‘a significant shift in the perception of a subject, or part thereof’.¹³⁹ This shift is illustrated in the context of HRR in relation to conceptions of individual and collective interests, which are often siloed and polarised. This can be seen in relation to the primacy principle in HRR, as discussed above, where the protection of individual interests effectively ‘trumps’ collective interests. Similarly, the public and private dimensions of HRR are ‘...too often...presented as being in tension with each other, sometimes irreconcilable so’.¹⁴⁰ As I explore further in Chapter 3, this oppositional approach is also evident in the law that bears on the conduct of (legally) legitimate health research, as illustrated by the operation of Article 8 of the European Convention on Human Rights.¹⁴¹ Here the individual is provided with the right to respect for private and family life,¹⁴² *except* for where interference with this is legal and necessary in a democratic society (for example, to further societal interests, such as public safety or the protection of health or morals).¹⁴³ The use of publicness, both linguistically as a way of naming the interrelationship between individual and collective interests, and also as the foundation for a framework for analysis, drives a move away from this orthodoxy in two key ways. First, this rejects the ‘individual interests *versus* collective interests’ binary in HRR. Rather, when contemplating decisions about the regulation of health research, publicness provides a means of engaging (conceptually and linguistically) with the way in which the interests of ‘publics’ writ large, and the interests of individuals within these collectives, may reflect, capture and build upon one

¹³⁷ Julie A Timmermans and Jan HF Meyer, ‘A Framework for Working with University Teachers to Create and Embed “Integrated Threshold Concept Knowledge” (ITCK) in Their Practice’ (2019) 24(4) *International Journal for Academic Development* 354, 357.

¹³⁸ Timmermans and Meyer (n 137).

¹³⁹ Meyer and Land (n 2) 7.

¹⁴⁰ Laurie (n 106) 227.

¹⁴¹ As enacted into UK law by the Human Rights Act 1998.

¹⁴² Human Rights Act 1998 Article 8(1).

¹⁴³ *ibid* at Article 8(2).

another. Second, publicness elucidates the multiplicity of ways in which decisions about the conduct of health research might impact on our lives. This requires a deeper understanding of how actors may simultaneously inhabit multiple roles and move between these: as an individual patient and/or participant, and/or a member of wider publics. In Chapter 1 I have outlined how these distinctions have become fluid in the context of data-driven research, and I use publicness to develop my analysis of 'publics' further, in Chapters 3 and 4 in particular.

Second, Meyer and Land describe a threshold concept as being something that is unlikely to be forgotten or easily unlearned, and so is 'probably' *irreversible*.¹⁴⁴ In the case of publicness this is driven by the change of perspective this concept requires. For example, the lens of publicness re-frames established tenets of HRR, such as the protection of participants and the promotion of responsible research, in order to illuminate the interconnectedness of these fundamental considerations. This provides a new way of thinking about how these should be accounted for in HRR that is holistic rather than antagonistic. As outlined in Chapter 1, the need to engage with publicness has been accelerated by significant changes in how and with whom health research is conducted. This, in turn, has eroded traditional distinctions between patients, participants, patient groups and publics, and exposed the nuance that exists within these categorisations. In this way publicness also responds to Land and Meyer's third criteria, in that it is *integrative*,¹⁴⁵ both in terms of the illumination of the interests that are at stake in HRR, but also the multiple and overlapping roles that are inhabited by stakeholders.

Land and Meyer caveat their fourth and fifth criteria noting that these may apply to threshold concepts, but that this is not necessarily or always the case. Nonetheless these also resonate, in different ways, in the context of publicness. The *bounded*¹⁴⁶ nature of a threshold concept is described by Land as Meyer as potentially '[serving] to constitute the demarcation between disciplinary areas'.¹⁴⁷ Elsewhere in the literature this is described as a: '...contextualising function; it helps to define what the discipline is and what it is not, what is critical and what is peripheral'.¹⁴⁸ An example from gender studies is the concept of intersectionality – this is central to the field but, as demonstrated from the discussion in relation to the growing use of intersectional approaches in the health research context at the start of this thesis, not exclusive to it. Whereas boundedness could be seen as restrictive and a barrier to interdisciplinary, Barradell and Fortune suggest that '...thinking about margins helps to identify both the uniqueness of a discipline and what may be required to work in or with

¹⁴⁴ Meyer and Land (n 2) 7.

¹⁴⁵ *ibid* 7–8.

¹⁴⁶ *ibid*.

¹⁴⁷ *ibid*.

¹⁴⁸ Sarah Barradell and Tracy Fortune, 'Bounded – The Neglected Threshold Concept Characteristic' (2020) 57(3) *Innovations in Education and Teaching International* 296, 297.

other disciplinary spaces.¹⁴⁹ In this thesis I draw a distinction between publicness, as a threshold concept in HRR, and the ways in which this is operationalised through different approaches, for example through the use of the public interest (in law), social value (in ethics), or the grant of a social licence by stakeholders to those that conduct health research (in the sociology of the occupations). As I will come to Chapter 3, these existing approaches each animate aspects of publicness, yet are not synonyms and operate within different disciplinary norms and contexts. Here I diverge from the use of a threshold concept *within* a disciplinary boundary, as I argue that publicness *per se* is not tied to a particular disciplinary approach or perspective. Rather this helps to explore a phenomena in HRR, and provides a common language to talk about the multi-layered set of interests in play that transcends disciplinary boundaries. The value of this contribution is illustrated by Hewer et al's discussion of the use of interdisciplinarity as method in the context of biomedicine, which coalesces around three key terms – personhood, public interest and property.¹⁵⁰ The authors reflect on these categories and note that the way that terms for discussion are defined are often more intelligible to one discipline than another, thereby closing down some conversations, while opening up others.¹⁵¹ Alternatively, a term might resonate strongly with a range of disciplines or approaches, but be used in quite different ways, with each ascribing to it their own norms, meanings and values. Both scenarios can hamper productive interdisciplinary dialogue. In Chapter 3 I will show how engaging with publicness can open up interdisciplinary conversations in order to provide a foundation from which to analyse the strengths and limitations of existing concepts that, in different ways, capture elements of the social side of research, as well as how these may (or may not) interrelate. This provides an opportunity to co-create meaning, without one discipline dominating the narrative.

Finally, a threshold concept may be seen as troublesome. This could be because it '...appears counter-intuitive, alien ... or incoherent'.¹⁵² Meyer and Land outline that there may be varied and multiple reasons for this troublesomeness. These could relate to the integrative nature of a threshold concept, which means that it requires an understanding of each of its constituent parts and how these fit together, or the subtleties of the distinctions that the concept seeks to draw out.¹⁵³ These are both features of publicness, as outlined above, which directs a move away from the clear, albeit unrealistic, division of interests into separate 'individual' or 'collective' silos, and towards engagement with shades of grade and nuance, where features

¹⁴⁹ Barradell and Fortune (n 148).

¹⁵⁰ Rebecca Hewer and others, 'Understanding the Role of Law in Biomedicine – Reflections on Interdisciplinarity as Method' [2022] SSRN (forthcoming).

¹⁵¹ *ibid* at footnote 3.

¹⁵² Meyer and Land (n 2) 8.

¹⁵³ *ibid* 12.

of health research and its regulation may have more or less degrees of publicness. The potential divisiveness of this move is rooted in the historical tension between the goal of knowledge generation and the rights and interests of individual participants in HRR. For example, in the context of the UNESCO Universal Declaration, Andorno expresses surprise at criticism of the reiteration of the primacy principle – that ‘...the interests and welfare of the individual should have priority over the sole interest of science or society’.¹⁵⁴ He notes its inclusion in numerous international texts (such as the Declaration of Helsinki)¹⁵⁵ and opines that this is a fundamental bioethical principle directed to preserving human dignity.¹⁵⁶ However, Landman and Schuklenk suggest that this proposal of absolute primacy is untenable and disconnected from the academic discipline of bioethics (which in turn contains different fields – consider, for example, the difference between medical ethics, public health ethics, and research ethics). To demonstrate the fallacy of the Declaration’s position, Landman and Schuklenk give the example of an intervention required on grounds of public health where societal interests may prevail (steps taken in response to the recent Covid-19 pandemic provide a case in point here) and argue that UNESCO have simply got this wrong.¹⁵⁷ This dispute illustrates, albeit in a limited way, the potential for a new conception of publicness – which focuses on the interrelationship between individual and collective interests - to disrupt the *status quo*, where these interests are routinely pitted against one another. However, as discussed in Chapter 1, while this step change may be troublesome, it is also vital in the context of contemporary health research.

Conclusion

New environments for and modes of health research present great opportunities for the advancement of human health, but also significant challenges to HRR.¹⁵⁸ In this respect commentators have called for ‘new social, ethical and legal frameworks and solutions’ which engage ‘..across disciplines, contexts and sectors’.¹⁵⁹ In this Chapter I have considered how health research regulation has engaged thus far with the individual and collective interests at stake in health research. While a more nuanced understanding of their interconnectedness has developed over time, I have argued that a new approach is required. The preceding

¹⁵⁴ Andorno (n 93) 151.

¹⁵⁵ *ibid* 153.

¹⁵⁶ *ibid*.

¹⁵⁷ Willem Landman and Udo Schüklenk, ‘UNESCO “declares” Universals on Bioethics and Human Rights - Many Unexpected Universal Truths Unearthed by UN Body’ (2005) 5(3) *Dev World Bioeth* iii.

¹⁵⁸ Kaye and others (n 30); Effy Vayena and Alessandro Blasimme, ‘Health Research with Big Data: Time for Systemic Oversight’ (03 2018) (1) *J Law Med Ethics* 119.

¹⁵⁹ Erikainen and others (n 32).

discussion has illustrated the potential for the concept of publicness to recognise and elucidate the complexities of the interrelationship between individual and collective interests, and therefore to facilitate interdisciplinary discussions about how this is operationalised in order to optimise HRR. I have drawn on key texts in HRR, an interdisciplinary body of academic literature, and the use of examples, to develop a more detailed working definition of publicness, as set out in **Table 4**.

Table 4: A working definition of publicness in HRR

Publicness is a concept that is used to describe the interrelationship between collective and individual interests. This draws attention to the context in which this interplay takes place, as well as the (potential) positive and negative consequences that might result – both now and in the future.

Publicness also provides the foundation for a framework of analysis which directs attention to:

- **Relationality**: the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness, therefore moving away from oppositional ways of thinking about the interests at stake;
- **Temporality**: temporal aspects of these interests in health research, including how these may change over time;
- **Accountability**: how these interests can be accounted for when decisions are made about what, whether, how and with whom health research is conducted.

This working definition draws out key aspects of publicness that drive a shift away from oppositional ways of thinking about the interests that are at stake, and pays attention to how these may change over time. These three facets of publicness can be summarised as relationality, temporality and accountability, which form the foundation for the analytical framework that I deploy in subsequent Chapters. These socially embedded descriptors provide stability in that they are not tied to a particular discipline, yet are sufficiently flexible to be able to adapt to changes over time and across contexts. My analysis so far also begins to suggest that publicness also has a normative dimension that directs us to consider how the interrelationship between collective and individual interests can be accounted for when decisions are made about what, whether, how and with whom health research is conducted.

While I have identified the shortcomings of the present terminology in HRR – where individual and collective, or private and public interests are siloed and/or pitted against one another – I have approached the introduction of publicness, as a new concept, with caution. To justify the use of what might be considered to be ‘yet another neologism’, I have used the threshold concept framework to further delineate the contours of publicness, as well as the insights that

this can elucidate in the context of this thesis, and in HRR more widely. In particular, I have shown how publicness can be transformative, ‘probably’ irreversible, and integrative, and may potentially be bounded and troublesome. Nonetheless, whether or not the reader accepts this categorisation of ‘threshold concept’, this discussion has highlighted, amongst other matters, the distinction between publicness as a broad concept, and the different ways in which this may be manifested in existing concepts.

The preceding consideration of what publicness ‘is’, has pointed to various ways in which this may be used. To recap key points from this Chapter, I have presented publicness as a novel way of approaching and understanding the interrelationship between collective and individual interests. It can be understood as a concept (indeed, I have also argued that this is a threshold concept) that is in itself inherently relational. However, my analysis has also engaged with how publicness may be used in particular contexts. For example, it can be deployed:

- as a lens, that concentrates our attention on this new way of looking at the familiar HRR landscape;
- more significantly, as the foundation for a tripartite framework of analysis, as set out in Table 4.

This analysis is not intended, however, to limit the ways in which publicness may be deployed. Indeed, as this thesis unfolds, I will further propose, in Chapter 4, that publicness can also be understood as an attribute of a group. In this thesis I have therefore embraced, rather than resisted, the different ways in which publicness may be deployed. Future research will be able to unpack more fully these different facets of publicness. In this thesis, I concentrate on the conceptual and operational features of publicness. While the analysis so far may have clarified publicness and its uses, it also raises questions about whether, and to what extent, publicness is currently operationalised in HRR. The next Chapter takes this question as its focus, and analyses three different ways that that publicness could be seen to be expressed in HRR through existing concepts, namely the use by the law of the public interest as a regulatory device, the ethical objective of realising social value in research, and the role that notions of social licence play in regulation.

Chapter 3: Operationalising publicness in HRR

Introduction

In Chapter 2 I argued that a robust notion of publicness is required in order to facilitate HRR that recognises the full extent of the relationship between individual and collective interests. In this Chapter, I build on this position to show how publicness can provide a new perspective on familiar concepts in order to shed light on their function, strengths and limitations. This opens up discussions across disciplinary boundaries about how existing concepts may be reimagined; it also reveals how publicness can be used in its own right to add value across the HRR ecosystem more broadly, as explored further in Part II of this thesis.

In this Chapter I draw on the conceptualisation of publicness developed in Chapter 2 and deploy the tripartite framework of analysis that operationalises publicness in order to evaluate three existing concepts in HRR, with the aim of identifying areas whether they may manifest certain features of publicness. In particular, I consider the use by the law of the public interest as a regulatory device, the ethical objective of realising social value in research, and the role that notions of social licence play in regulation. I illustrate how each of these approaches captures elements of the social aspect of health research and its regulation. However, while they are often used interchangeably, or in close proximity, public interest, social value and social licence are not synonyms for each other, and each is grounded in different disciplinary norms. My analysis therefore uses the *diagnostic* value of publicness to reveal the work that existing concepts already do in health research regulation, individually and in relation to one another. In addition, however, I also appeal to publicness in health research in a *normative* sense in order to help to form new ideas about how HRR should be conducted.

I begin with a brief overview of the rationale for the selection of the public interest, social value and social licence for examination, and demonstrate how each of these approaches are grounded in the literature and in the context of HRR. These are then considered in turn, in order to identify the extent to which each existing concept may manifest certain features of publicness. As expanded on below, this analysis uses three facets of publicness (relationality, temporality and accountability) as a framework to analyse the public interest, social licence and social value. This reveals the strengths and limitations of these individual approaches, and helps to delineate their respective functions, in circumstances where there are too often collapsed together. It establishes ways in which each of these concepts engage with the social aspect of health research, but also why they cannot alone, nor in combination, enact publicness fully in HRR. This in turn has implications for the conceptualisation of publicness

itself, with regard to the work that this does to facilitate interdisciplinary conversations, and its potential to add value to existing concepts and enrich the HRR ecosystem, as explored in Part II of this thesis.

Publicness (a recap) and existing concepts in HRR

In this thesis, publicness has been framed as a threshold concept that helps to reimagine what is at stake in health research and its regulation. As set out in Chapter 2, publicness reflects the interrelationship between collective and individual interests and illuminates the context in which this interplay takes place, recognising that this has implications for HRR, now and in the future. In sum, publicness directs our attention to relationality, temporality and accountability, as expanded upon in **Table 5**.

Table 5: A working definition of publicness in HRR (a recap)

Publicness is a concept used to describe the interrelationship between collective and individual interests, thereby drawing attention to the context in which this interplay takes place, as well as the implications of the relationship between collective and individual interests for HRR, both now and in the future.

Publicness also provides the foundation for a framework of analysis which directs attention to:

- **Relationality**: the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness, therefore moving away from oppositional ways of thinking about the interests at stake;
- **Temporality**: temporal aspects of these interests in health research, including how these may change over time;
- **Accountability**: how these interests can be accounted for when decisions are made about what, whether, how and with whom health research is conducted.

In the preceding Chapter, a further distinction was drawn as between publicness *per se* and the various ways that certain facets of this might manifest through different and existing approaches. Crucially, I have posited that publicness is not tied to a particular disciplinary approach, nor is it framed by any given disciplinary perspective; this is part of its appeal and strength. Instead, this concept helps to navigate a phenomenon in HRR – namely the tension between collective and individual interests – in a way that transcends disciplinary boundaries and provides a common language to talk about the multi-layered interests in play. This claim is explored further in this Chapter.

It has been established so far that the need to engage with publicness has been driven by technoscientific, socio-cultural and institutional changes, which have significantly altered the health research landscape.¹⁶⁰ For example, the impact of developments in technoscience mean that data have become 'bigger', thereby creating the potential for distance between the source of this data - which may be large groups of people, and perhaps even populations, as opposed to a small group of clearly defined participants – and its use.¹⁶¹ Publicness provides a way of recognising and grappling with this shift by naming, framing and valuing the interrelationship between individual and collective interests. However, its use is not intended to replace or exclude *existing* concepts that have, in different ways, also sought to engage with the social side of research. Three potential candidates for examination here include the use of the public interest as a regulatory device in law, the ethical social value requirement for health research, and the need for research to be carried out within the parameters of a social licence, which is rooted both in occupational sociology and literature around corporate social responsibility. Notwithstanding the different contexts in which these ideas have developed, these concepts have often been used interchangeably in the HRR literature, or in close proximity to one another. For example, in her work on the need for social value in health-related research, Rid explicitly does not distinguish between social value and '...and related concepts, such as social benefit, public benefit and public interest.'¹⁶² Similarly, in Schaefer et al's consideration of the use of public interest waivers for health data and tissue research they '...remain neutral on whether social value is essentially the same concept as public interest, or a distinct notion.'¹⁶³ Likewise, when analysing the need for a social licence for the use of personal data for health research purposes, Carter et al find that a condition of this is that the use of personal data is 'in the public interest'¹⁶⁴ and 'in service of the public good'.¹⁶⁵ When exploring the role of data custodians in establishing and maintaining social licence, Allen et al also consider the role of the public good, and positions the public interest as a central consideration, noting that this reflects requirements set out in the law.¹⁶⁶ The proximity of these concepts to each other in these examples can perhaps be explained, in circumstances where

¹⁶⁰ Clarke and others (n 3).

¹⁶¹ Aitken and others, 'Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research' (n 50).

¹⁶² Rid (n 45) 294.

¹⁶³ G Owen Schaefer and others, 'Clarifying How to Deploy the Public Interest Criterion in Consent Waivers for Health Data and Tissue Research' (2020) 21 BMC Medical Ethics. For an argument that the public interest and social value are distinct see Angela Ballantyne and G Owen Schaefer, 'Public Interest in Health Data Research: Laying out the Conceptual Groundwork' (2020) 46 Journal of Medical Ethics 610.

¹⁶⁴ Pam Carter and others, 'The Social Licence for Research: Why Care.Data Ran into Trouble' (2015) 41(5) Journal of Medical Ethics 404, 408.

¹⁶⁵ *ibid.*

¹⁶⁶ Judy Allen and others, 'The Role of Data Custodians in Establishing and Maintaining Social Licence for Health Research' (2019) 33(4) Bioethics 502, 508.

each seeks to capture something about the relationship between individuals, society and health research, and therefore necessarily engages with elements of publicness, as understood in this thesis. However, collapsing these together obscures the current and potential functions of these existing concepts and fails to reveal the ways in which they are both similar and different. As I will show in more detail below, these terms are not synonyms nor are their respective functions entirely equivalent. The sections that follow introduce and interrogate the public interest, social value and social licence, and then use the diagnostic force of publicness in order to start to identify areas of overlap and divergence.

However, before moving on to engage in more detail with each existing concept, I first address the implications of choosing these particular examples for further scrutiny in this thesis. I have suggested so far that publicness can provide a new and fruitful way of framing the relationship between individual and collective interests in health research, both in its own right, and as a way of reimagining existing concepts in the field. Therefore, as set out above, the intertwined concepts of the public interest, social value and social licence provide a promising site in which to explore this proposition. However, there are also other concepts that might also benefit from similar attention and that have also attained prominence in the field. Here the selection of one concept over another is inevitably more marginal and subjective, though a choice has to be made, and made carefully. For example, the examples above have already shown that, alongside references to the public interest, terms are often used such as the public good¹⁶⁷ and public benefit.¹⁶⁸ However, as I come to further below, the terminology of the public interest is deeply embedded in the law, particularly in relation to the use of confidential data for health research purposes. I have therefore chosen this for examination as an archetypal legal attempt to engage with the relationship between individual and broader societal interests.

Another important idea is that of a social contract¹⁶⁹ for health research, which Lucassen et al note is sometimes used interchangeably with the term social licence. Indeed, Horn and Karasidou suggest that the terms social licence and social contract both ‘...describe a set¹⁷⁰ of values and norms defining responsibilities and rights that are im-/explicitly ‘agreed upon’ in

¹⁶⁷ Carter and others (n 164); Allen and others (n 166).

¹⁶⁸ Mhairi Aitken and others, ‘Who Benefits and How? Public Expectations of Public Benefits from Data-Intensive Health Research’ (2018) 5(2) *Big Data & Society* 1.

¹⁶⁹ The Academy of Medical Sciences, ‘Exploring a New Social Contract for Medical Innovation’ (3 June 2015) <<https://acmedsci.ac.uk/policy/policy-projects/exploring-a-new-social-contract-for-medical-innovation>> accessed 13 March 2022.

¹⁷⁰ Anneke Lucassen and others, ‘Ethics and the Social Contract for Genomics in the NHS’ in *Annual Report of the Chief Medical Officer 2016* (Department of Health 2017); A further example of these terms being used interchangeably can be found in Sujatha Raman and Alison Mohr, ‘A Social Licence for Science: Capturing the Public or Co-Constructing Research?’ (2014) 28(3-4) *Social epistemology* 258, 267 who describe social contract as a ‘parallel device’ to social licence; and Sam HA Muller and others, ‘The Social Licence for Data-Intensive Health Research: Towards Co-Creation, Public Value and Trust’ (2021) 22(1) *BMC Medical Ethics* 110, 111.

a society'.¹⁷¹ Lucassen et al prefer the term social contract '...because of its helpful implication of the location of healthcare and medical research in a broader context of social arrangements, practices and institutions'.¹⁷² However, the idea of a 'licence' is also attractive, because of the implication this invokes (for lawyers, at least) of the fragility of this putative and tacit agreement, and the ease with which this may be revoked in circumstances where societal norms are transgressed. A further consideration that has influenced my decision to focus on social licence is the recent attention that this has received in the specific context of data driven research,¹⁷³ including a prominent position in a recent international consensus statement on public involvement and engagement with data-intensive health research.¹⁷⁴ None of this is to say that the concept of a social contract is less worthy of scrutiny in terms of its operationalisation of publicness. Rather, the position is that, for the purposes of this exercise, it is not necessary to consider both social licence and social contract, and the former has been selected here.¹⁷⁵

Finally, a further prominent pro-social concept in health research regulation is that of solidarity. The meaning of solidarity has been extensively developed by Prainsack and Buyx¹⁷⁶ and was recently summarised by Kieslich and Prainsack as '...a practice that reflects a person's – or persons' – commitment to support others with whom the person(s) recognise(s) similarity in a relevant respect'.¹⁷⁷ Solidaristic practice may take place at different levels, namely tier 1 (between individuals), tier 2 (group level) and tier 3 (as reflected in legal, administrative or bureaucratic norms).¹⁷⁸ Here a particularly fine judgment has been made to focus on social value rather than solidarity for two key reasons. The first is its emergence, and recent scrutiny,

¹⁷¹ Ruth Horn and Angeliki Kerasidou, 'Sharing Whilst Caring: Solidarity and Public Trust in a Data-Driven Healthcare System' (2020) 21(1) BMC Medical Ethics 110, 114.

¹⁷² Lucassen and others (n 170) 16.

¹⁷³ P Alison Paprica and others, 'Social Licence and the General Public's Attitudes toward Research Based on Linked Administrative Health Data: A Qualitative Study' (2019) 7 Canadian Medical Association Open Access Journal 40; Mhairi Aitken and others, 'Establishing a Social Licence for Financial Technology: Reflections on the Role of the Private Sector in Pursuing Ethical Data Practices' (2020) 7(1) Big Data & Society; Muller and others (n 170).

¹⁷⁴ Aitken and others, 'Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research' (n 50).

¹⁷⁵ Future research can, indeed, apply the analytical approach adopted here to social contract with precisely the same objective of showing its similarities and differences to other concepts in the field.

¹⁷⁶ Barbara Prainsack and Alena Buyx, 'Solidarity: Reflections on an Emerging Concept in Bioethics' (Nuffield Council on Bioethics, 2011); Barbara Prainsack, *Solidarity in Biomedicine and Beyond* (Cambridge University Press 2017); Katharina Kieslich and Barbara Prainsack, 'Solidarity in Health Research Regulation' in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021).

¹⁷⁷ Kieslich and Prainsack (n 176) 57.

¹⁷⁸ *ibid* 58.

in the context of 'biomedicalization',¹⁷⁹ which views science as a matter of co-creation between science and society.¹⁸⁰ The second is because of the use of social value as a key principle by the most recent version of the CIOMS International Ethical Guidelines for Health Related Research.¹⁸¹ There are, undoubtedly, other concepts that could also be considered in depth in this thesis, but I do not have space to do so here, nor is this necessary for the purposes of the current exercise.

Public interest

Give the focus of this legal thesis, I will start by introducing the public interest as a regulatory device. I follow a uniform format in this section, and in the following two sections of this Chapter, in that first I delineate the concept under consideration with regard to how it seeks to capture elements of the social aspect of health research and its regulation, and trace its disciplinary roots. Next, I consider each concept, using publicness as the foundation for a framework for analysis, in order, to reveal its strengths and limitations. In particular, this analysis pays attention to three facets of publicness (as developed in Chapter 2, and recapped in **Table 5** above), which can be summarised as relationality, temporality and accountability. Reflexive observations about what the totality of this exercise reveals, both about these existing concepts, and about the concept of publicness itself, are considered in the penultimate section of this Chapter, after each existing concept has been addressed individually.

While the public interest provides a logical starting point for the purposes of this analysis, it is not necessarily one that is straightforward. This notion has been debated across disciplines by political scientists, philosophers and lawyers (amongst others), and well beyond the confines of health research and its regulation.¹⁸² It has been variously held up as a concept that is central to the 'civilised polity',¹⁸³ and dismissed as a rhetorical device that is vague and ambiguous.¹⁸⁴ The views of the political scientist Sorauf, during a resurgence of interest in this concept in the post-World War II period in America, provide a snapshot of this ambivalence. In his earlier work he initially concedes what he describes as a 'modest conception' of the public interest as 'our interest in the democratic method and its settlement of conflict by orderly

¹⁷⁹ This term has been introduced and developed by Clarke et al, as described in Chapter 1. See Clarke and others (n 3).

¹⁸⁰ van Delden and van der Graaf (n 104).

¹⁸¹ CIOMS (n 26); van Delden and van der Graaf (n 104) 46. Solidarity is mentioned once in the CIOMS document, while social value is mentioned 53 times.

¹⁸² Stephen K Bailey, 'The Public Interest: Some Operational Dilemmas' in Carl J Friedrich (ed), *Nomos V: The Public Interest* (1st ed, Atherton Press 1962).

¹⁸³ *ibid.*

¹⁸⁴ Glendon A Schubert, *The Public Interest: A Critique of the Theory of a Political Concept* (Free Press 1961).

rules and procedures'.¹⁸⁵ This account recognises the potential of the public interest to act as a 'hair shirt', in that this may serve as an uncomfortable but ever present reminder of the broader interests that are at stake, and in particular those that might be '...unorganised and unrepresented (or underrepresented)'.¹⁸⁶ However, in Sorauf's later work he retreats from this position, and finds instead that the public interest is more likely an instrument of oversimplification which is used, ineffectively, to 'solve' the problems of pluralism.¹⁸⁷ In law, similar concerns have been raised by Feintuck in relation to the malleability of the public interest as a concept which '...will vary according to time, place and the specific values held by a particular society'.¹⁸⁸ He depicts this as an 'empty vessel' which is best substantiated by the '... fundamental value laden, democratic imperatives that underlie society: human dignity, parity of esteem, and the ability to participate actively in society'.¹⁸⁹ Taken together these accounts of the public interest from outside of the HRR context indicate little consensus, other than that the public interest is a contested concept that is 'much used but ill defined'.¹⁹⁰ Nonetheless, and in different ways, each approach grapples with the connection between individuals, society and participation in public life.

Turning to HRR more specifically, the public interest is a key feature of the legal and policy landscape. As discussed in Chapter 2, the idea that health research should advance collective interests, while also protecting participants, is not new and is reflected in the Nuremberg Code, which requires that research must '...yield fruitful results for the good of society',¹⁹¹ and in the Declaration of Helsinki.¹⁹² Appeal to the public interest can also be seen in the legal mandate for the Health Research Authority (HRA), the organisation that oversees the ethical approval and review of relevant health and social care research in England (amongst other matters, as I come to further below). The Care Act 2014 sets out twin objectives for the HRA, to both 'protect and promote' the interests of participants, potential participants and the general public by encouraging safe and ethical health research.¹⁹³ As the HRA explains:

¹⁸⁵ Frank J Sorauf, 'The Public Interest Reconsidered' (1957) 19(4) *The Journal of Politics* 616, 633.

¹⁸⁶ *ibid* 639.

¹⁸⁷ Frank J Sorauf, 'The Conceptual Muddle' in Carl J Friedrich (ed), *Nomos V: The Public Interest* (1st ed, Atherton Press 1962).

¹⁸⁸ Mike Feintuck, *The Public Interest in Regulation* (OUP 2004).

¹⁸⁹ *ibid*.

¹⁹⁰ John Bell, 'Public Interest: Policy or Principle?' in *Law and the public interest: proceedings of the 1992 ALSF Conference* (Stuttgart, Association for Legal and Social Philosophy (Great Britain) 1993).

¹⁹¹ The Nuremberg Code (n 70).

¹⁹² WMA Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects (adopted by the 18th WMA General Assembly, Helsinki, Finland) (n 77).

¹⁹³ Care Act 2014 s110(2). 'The main objective of the HRA in exercising its functions is— (a) to protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical, and (b) to promote the interests of those participants and potential

‘Our vision is for high-quality health and social care research that improves people’s health and wellbeing, and our core purpose is to protect and promote the interests of patients and the public in health and social care research.’¹⁹⁴

To narrow the focus further, the role of the public interest in law is particularly relevant in relation to the use of confidential patient data in health research. Here appeals to the public interest can be found in statute (i.e. law that has been passed by Parliament) and in case law (i.e. precedents set on the basis of previous judicial decisions in accordance with the hierarchy of the court structure). Before considering publicness more directly, I will analyse how the public interest is deployed by the law in four key areas that impact on the regulation of data-intensive health research. These are: (i) the Human Rights Act 1998 (HRA 1998); (ii) the data protection regime provided for by the General Data Protection Regulation (GDPR)¹⁹⁵ and the UK Data Protection Act 2018 (DPA 2018); (iii) the common law duty of confidentiality (CDC); and (iv) the establishment of the HRA’s Confidentiality Advisory Group (CAG), which allows for the CDC to be set aside in certain circumstances. I therefore start broadly, by considering law that has a direct bearing on health research using data but is not tailored to this context, and end by considering the work of the CAG, which specifically considers applications for support for the use of confidential data for health research (and other purposes) without consent.

Starting with statute, the HRA 1998 enacts into domestic law the rights and freedoms that are set out in the European Convention on Human Rights (ECHR), thereby enabling citizens to challenge public bodies that do not act in accordance with these rights.¹⁹⁶ Although these provisions are not specific to health or data use, it was clear at the time that the HRA 1998 was incorporated into UK law¹⁹⁷ that this would have implications for health research.¹⁹⁸

Of particular relevance to research using health data is Article 8 of the HRA 1998 (**Table 6**) which provides individuals with the right to respect for their private and family life. This covers

participants and the general public by facilitating the conduct of research that is safe and ethical (including by promoting transparency in research).’

¹⁹⁴ Health Research Authority, ‘What We Do’ (2022) <www.hra.nhs.uk/about-us/what-we-do/> accessed 13 March 2022.

¹⁹⁵ Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data [2016] OJ L119/1 (‘GDPR’) (UK).

¹⁹⁶ Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as Amended) (ECHR) (1953).

¹⁹⁷ In October 2000.

¹⁹⁸ Richard Horton, ‘Health and the UK Human Rights Act 1998’ (2000) 356(9236) *The Lancet* 1186.

matters such as the protection of a person's confidential health information, or their administrative data relating to their housing or the benefits they claim. This right may only be infringed in circumstances where this is justified by a legitimate aim (as set out in Article 8, paragraph 2). Although the phrase, 'the public interest' is not explicitly used in paragraph 2, the legitimate aims this sets out have been summarised in cases involving disclosure of information about a person's HIV status as being where this is: '...justified by an overriding requirement in the public interest..., in the interest of the applicant himself or in the interest of the safety of hospital staff...'.¹⁹⁹ While Article 8 is primarily concerned with the negative obligation to protect against arbitrary interference by a public authority (for example, the disclosure of citizens' confidential data without justification), there may also be positive obligations on the state to ensure that these rights are upheld.²⁰⁰ In both cases the approach of the court is similar in that: '[r]egard must be had to the fair balance that has to be struck between the *competing interests* of the individual and of the community as a whole...'²⁰¹ [*emphasis added*], thereby creating a space in which individual and collective interests are set up in opposition with one another.

This approach is further illustrated by guidance issued by the European Court of Human Rights on Article 8, specifically in relation to the use of health information. This expands on the reasons why respect for the confidentiality of health data is important for individuals:

'It is crucial not only to respect the privacy of a patient, but also to preserve his or her confidence in the medical profession and in the health services in general. Without such protection, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance. They may thereby endanger their own health and, in the case of communicable diseases, that of the community. The domestic law must therefore afford appropriate safeguards to prevent any such communication or disclosure of personal health data as may be inconsistent with the guarantees in Article 8 of the Convention.'²⁰²

Although this guidance provides an account of how *individual* interests are engaged in this scenario, it does not extend to the ways in which collective interests may be impacted (beyond mention of communicable diseases affecting the wider community), nor to how the individual

¹⁹⁹ European Court of Human Rights, 'Guide on Article 8 of the Convention – Right to Respect for Private and Family Life' (31 December 2020) 49 <https://www.echr.coe.int/documents/guide_art_8_eng.pdf> accessed 13 March 2022.

²⁰⁰ European Court of Human Rights (n 199).

²⁰¹ *ibid.*

²⁰² *ibid.*

and collective interests at stake might interrelate. The oppositional framing of individual and public interests within the ECHR regime is also seen in its due process. A claimant alleging a breach of their human rights must first show that a relevant right is 'engaged'. Only thereafter can the state argue that the interference was necessary, proportionate and in accordance with the law. In other words, the individual's life has been impinged upon but the ECHR ecosystem deems this infringement justified. There is a public gain at the expense of a private loss.

Turning next to a second omnibus statute, this time with a focus on data, the GDPR, which is tailored to the UK by the DPA 2018, applies when businesses and organisations process personal data²⁰³ – that is information that relates to an identified or identifiable individual. Again, this legislation is not specific to health research which uses data, but the legislation has obvious application in circumstances where identifiable confidential data is used for research purposes. The GDPR and DPA 2018 provide a number of lawful bases for processing personal data, including that this is a 'task in the public interest'.²⁰⁴ As touched upon in Chapter 1, HRA Guidance indicates that when a public authority, such as a university or NHS body, processes data for health and social care research, the appropriate legal basis is the 'public interest' ground,²⁰⁵ and not consent.²⁰⁶ Where special category data is processed (i.e. data that is sensitive because it relates to defined matters including health) a 'special category condition' to process the data will also need to be identified;²⁰⁷ these include that the processing is necessary for research related purposes.²⁰⁸ However, in order to rely on this condition, there are also additional requirements that must be met, including that the processing must be 'in the public interest'.²⁰⁹

Neither the GDPR, nor the DPA 2018, provide a definition of 'the public interest', though a late addition to the Explanatory Note²¹⁰ to the DPA 2018 makes it clear that universities should be

²⁰³ ICO guidance provides that: 'Information which has had identifiers removed or replaced in order to pseudonymise the data is still personal data for the purposes of UK GDPR. Information which is truly anonymous is not covered by the UK GDPR.' Information Commissioner's Office, 'What is Personal Data?' (2022) <<https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/key-definitions/what-is-personal-data/>> accessed 13 December 2021.

²⁰⁴ GDPR (n 195) Article 6(1)(e).

²⁰⁵ Sometimes called the 'public task' ground for short.

²⁰⁶ This is for a number of reasons, not least because for valid consent in GDPR terms, the person providing the consent must be able to withdraw it at any time. There is no exemption to this for research.

²⁰⁷ GDPR (n 195) Article 9.

²⁰⁸ Ibid. Article 9(2)(j).

²⁰⁹ See DPA 2018, Schedule 1, paragraph 4 for the precise details, but, in summary, these additional requirements include that the processing: is necessary for that purpose, subject to appropriated safeguards, not likely to cause substantial damage or distress to an individual, and not used for measures or decisions in relation to particular individuals.

²¹⁰ An Explanatory Note does not form part of a statute, but provides an influential source of information about how this should be interpreted.

able to rely on this ground when processing data for medical research that is in the public interest. Despite the circularity of this advice it does at least provides some context in relation to how the public interest may be deployed, though it does little to elucidate the content of this concept.

In addition to these legislative regimes, those wishing to use confidential data for health research must also consider the CDC.²¹¹ In short, the CDC provides that where confidential information, such as information about a person's health or treatment,²¹² is imparted to another person, in circumstances giving rise to an obligation of confidentiality, this must not be disclosed without consent or some other justification.²¹³ One such justification is that the disclosure is 'in the public interest'. Here the law is not made and developed by Parliament, but by judicial decisions taken on the facts of each case that comes before the court. The hierarchy of the civil court system means that decisions of the lower courts (for example, the Divisional Court of the High Court of Justice) will be bound by decisions of the higher courts (for example, the Court of Appeal or, higher still, the Supreme Court), but not *vice versa*.²¹⁴ Precedents in the common law have established that there is not only a personal interest in maintaining confidentiality, but also a wider public interest in doing so in order that patients (in general) are not discouraged from consulting with healthcare practitioners.²¹⁵ Further, case law in relation to whether the disclosure of deceased patients' records to a public inquiry was 'in the public interest' has also indicated that the public interest (which is different from 'what the public found interesting') is multifaceted and may encompass interests in: disclosure, maintaining confidentiality and maintaining confidence in the institutions under investigation.²¹⁶

In sum, when it comes to data protection legislation the oppositional framing (as observed above in relation to the ECHR) can also be seen here, in that breach of an individual right can be justified by (amongst other matters) an appeal to the public interest. In contrast, the case law has found that when considering a breach of confidence the balance to be struck is between two competing public interests (for example, those in maintaining confidence and the

²¹¹ For an illuminating account of the interaction between data protection law and the CDC in relation to valid consent see Edward S Dove and Mark J Taylor, 'Signalling Standards for Progress: Bridging the Divide Between a Valid Consent to Use Patient Data Under Data Protection Law and the Common Law Duty of Confidentiality' (2021) 29(3) *Med Law Rev* 411.

²¹² 'It has always been accepted that information about a person's health and treatment for ill-health is both private and confidential. This stems not only from the confidentiality of the doctor-patient relationship but from the nature of the information itself.' *Campbell v MGN Ltd* [2004] UKHL 22; [2004] 2 AC 457 at [145]

²¹³ *Coco v A N Clark Ltd* (1969) 86 RPC; See also *Campbell v MGN Ltd* (n 212), which cites to *Coco* and was decided after the HRA 1998.

²¹⁴ Courts and Tribunals Judiciary, 'Structure of the Courts and Tribunal System' (2022) <www.judiciary.uk/about-the-judiciary/the-justice-system/court-structure> accessed 13 December 2021.

²¹⁵ *W v Egdell* [1989] EWCA Civ 13

²¹⁶ *Lewis v Secretary of State for Health* [2008] EWHC 2196.

prevention of harm). In this way, the court has reconceptualised what is at stake, to facilitate a more commensurate comparison, though the oppositional framing remains.

The law as outlined above applies to health research as well as to circumstances in which direct medical care is provided and has infused policy. For example, in December 2020 the then National Data Guardian,²¹⁷ Dame Fiona Caldicott, introduced a new Caldicott Principle²¹⁸ in relation to ensuring that people have clear expectations about how their data will be used, as set out in **Table 7**.

Table 7: Caldicott Principle 8

Inform patients and service users about how their confidential information is used

A range of steps should be taken to ensure no surprises for patients and service users, so they can have clear expectations about how and why their confidential information is used, and what choices they have about this. These steps will vary depending on the use: as a minimum, this should include providing accessible, relevant and appropriate information - in some cases, greater engagement will be required.

This sentiment was echoed in 2021, by the current National Data Guardian, who emphasised the potential impact on current and future patients:

‘If people feel that their information may be used in unexpected ways, for purposes they may not support, this greatly undermines the fundamental relationship of trust. The effect may be to deter patients from seeking treatment, or, when seeking treatment, to only disclose partial or false details, thereby denying clinicians the information they need to deliver safe and effective care. Incomplete and inadequate health and care records are to the detriment of both the safe care of individuals now, and of system wide planning, research, and innovation for the future.’²¹⁹

²¹⁷ The National Data Guardian is an independent champion for patients and the public in relation to the use of confidential health and care information. The Health and Social Care (National Data Guardian) Act 2018 provides a statutory basis for this role and the power to issue official guidance about the processing of health and adult social care data in England. For more information on the role of the NDG see ‘About Us’ (GOV.UK, 2022) <www.gov.uk/government/organisations/national-data-guardian/about> accessed 13 December 2021.

²¹⁸ The Caldicott Principles ‘...apply to the use of confidential information within health and social care organisations and when such information is shared with other organisations and between individuals, both for individual care and for other purposes’. For further information see ‘The Caldicott Principles’ (n 112).

²¹⁹ National Data Guardian, ‘Data-Driven Innovation: Why Confidentiality and Transparency Must Underpin the Nation’s Bright Vision for the Future of Health and Care’ (4 October 2021) <www.gov.uk/government/news/data-driven-innovation-why-confidentiality-and-transparency-must-underpin-the-nations-bright-vision-for-the-future-of-health-and-care> accessed 13 December 2021.

As can be seen from this brief summary, guidance and judicial decisions provide a legal framework within which case-by-case judgments can be made both by the court and by those making decisions in relation to the use of confidential data in the public interest on a day to day basis, such as clinicians or researchers. However, there is no fixed definition of what the public interest 'is' and, if challenged, this will ultimately be decided by the courts or other elite decision makers on the facts of each case. This approach has the advantage of flexibility, but has also been criticised for a lack of certainty, which was felt particularly keenly by the medical community in the early 2000s when this was highlighted in relation to concerns over whether clinicians could lawfully pass data to registries (which collect and analyse data on particular diseases) without specific patient consent.²²⁰ This led to intervention by Parliament and the enactment of legislation to establish a further and important part of the health data landscape, namely the predecessor to what is now the HRA's CAG. This legislation, which can now be found at Section 251 of the NHS Act 2006 (as enabled by The Health Service (Control of Patient Information) Regulations 2002), provides the Secretary of State with the power to make regulations to 'set aside' the common law duty of confidentiality for defined 'medical purposes' (which includes health research) when this is either in the interests of improving patient care, or in the public interest.²²¹ Again, the legislation does not elaborate on *how* the public interest should be interpreted, though HRA guidance states that, amongst other matters, the CAG's considerations will include whether '...the public interest in the disclosure and potential benefits, on balance, outweigh the breach of confidentiality.'²²² What this means in practice for those conducting health research is that an application may be made to the HRA's CAG to obtain what is colloquially known as 'Section 251' support. If Section 251 support is recommended by CAG, and granted by the HRA, then the CDC is modified, in that anything done by the researcher that is necessary for the purpose of processing confidential patient information will be lawful despite any obligation of confidence owed to third parties.²²³ In other words, in the unlikely event of a legal challenge, the researcher need not worry about whether the court would, on the facts of their case, agree that the use of data without consent was indeed in the public interest, as the HRA's decision to grant Section 251 support would have already set aside the CDC (though it should be noted that the provisions of the GDPR and DPA 2018 still apply, in terms of how the data should be processed, stored and used).

²²⁰ Michel P Coleman and others, 'Confidentiality and the Public Interest in Medical Research – Will We Ever Get It Right?' (2003) 3 *Clinical Medicine* 219.

²²¹ National Health Service Act 2006 s251.

²²² Health Research Authority, 'Guidance for CAG Applicants: Recommendations and Approval Decisions' (26 April 2021) <www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants> accessed 13 December 2021.

²²³ The Health Service (Control of Patient Information) Regulations (UK 2002), Regulation 4.

The CAG maintains a register of all approved applications²²⁴ and publishes the minutes of its meetings²²⁵ which provides some evidence of how decisions are made in relation to the public interest across time and in diverse contexts. In 2020, in the first study of its type, researchers conducted a thematic analysis of feedback from a selection of Section 251 applications considered by CAG in order to create a repository of knowledge for future applicants.²²⁶ The findings of the study recognises that applicants must establish a rationale for their application, which includes showing that ‘...the purpose of the project is for medical research and in the public interest’.²²⁷ However, establishing this rationale is then equated by the authors with compliance with the DPA 2018 (or, in the case of earlier applications, the data protection legislation that preceded this). The study also suggests that there is a lack of detail provided by CAG in respect of the required rationale for applications, for example in relation to ‘...what may be considered reasonable or indeed appropriate and proportionate use of data beyond minimizing the identifiers requested for linkage’.²²⁸ This suggests that while, in practical terms, meaning is made for the public interest through these processes, this may be limited in respect of the role of the public interest specifically, in circumstances where this is viewed in narrow legalistic terms.

This whistle stop tour of the HRR landscape, with a focus on the use of health data without consent, illustrates that the public interest is both deeply embedded as a regulatory device in this context, but also somewhat elusive. So how might publicness, which foregrounds the relationship between individual and collective interests, be deployed here as the foundation for an analytical framework in order to enhance our understanding of this ‘notoriously uncertain idea’²²⁹ and provide a new perspective? To answer this, I return to the three facets of publicness.

First, publicness directs attention to *relationality*, including the identification and recognition of the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness. The preceding discussion has underlined how in some contexts – such

²²⁴ Health Research Authority, ‘Confidentiality Advisory Group Registers’ (4 March 2022)

<www.hra.nhs.uk/planning-and-improving-research/application-summaries/confidentiality-advisory-group-registers/> accessed 10 January 2022.

²²⁵ Health Research Authority, ‘CAG Meetings Dates and Minutes’ (25 October 2021) <www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/cag-group-meetings-and-minutes/> accessed 13 December 2021.

²²⁶ Lauren Cross and others, ‘Guidance for Researchers Wanting to Link NHS Data Using Non-Consent Approaches: A Thematic Analysis of Feedback from the Health Research Authority Confidentiality Advisory Group’ (2020) 5(1) IJPS 1.

²²⁷ *ibid* 4.

²²⁸ *ibid* 6.

²²⁹ Mark Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection* (Cambridge Bioethics and Law, Cambridge University Press 2012).

as when making decisions about whether or not to share confidential patient information for research purposes – the law recognises that this can engage a range of individual and collective interests. However, there is less clarity on if and how these interrelate, and which publics are invoked. For example, the human rights framework provided by the HRA 1998 offers a stark example of the law’s tendency to polarise individual and collective interests, and conceptualise these as competing with and encroaching upon one another. This antagonistic approach has also been identified in data protection legislation and, to a lesser extent, in relation to the CDC and associated case law. As has been demonstrated by the preceding discussion of the law, the position advanced in this thesis recognises that, while individual and collective interests are relational, this does not preclude the very real possibility that they may also, at times, come into conflict. Indeed, the examples in this Chapter relating to legislation and case law demonstrate this point amply. The very existence of courts is predicated on conflict and its resolution. Nonetheless, the concept of publicness assists here in a number of ways. First, using a publicness-informed approach helps to elucidate the contours of conflict in a richer sense than has been done to date. For example, by drawing attention to all kinds of sameness and difference it can assist considerably in finding common ground, even when conflict exists. The reach and impact of conflict can be reduced as a result. Second, publicness shifts the focus to the interrelationship between these interests and therefore provides a new starting point when questions arise as to how trade-offs between what may appear to be polarised interests should be resolved. This goes beyond seeing ‘conflict’ merely in oppositional terms and as a matter of winners and losers; a tendency that can too often prevail in legal conflict, at least when pursued through the courts. And third, and perhaps most crucially, this reframing exercise elucidates that what is at stake is broader than mere conflict resolution. Indeed, as I go on to argue in more detail in the paragraphs that follow, this brings us to the understanding that collective interests are as complex as the individuals whose interests these comprise, and temporally widens our gaze beyond the point of dispute resolution, in order to consider how publicness can be embedded not just during a moment of conflict but also beyond as various interests, collective and individual, play out. To return to the HRR context, this would mean that considerations of publicness would permeate the entire research lifecycle, including before, during and after any conflict.

A further point that emerges from this analysis is the apparent reluctance of the law or its institutions to engage more deeply with the views of diverse publics. By way of example, case law provides that there is not only an individual interest in maintaining the confidence of health information, but also a public interest in doing so (with the effect that, when contemplating disclosure, the court must balance the competing public interests in maintaining confidence

and in disclosure).²³⁰ However, in order to sustain this position the law does not require that empirical evidence of what actual members of the public think about the use of their health information is provided to the court – rather it is a matter of judicial opinion on how the relevant legal test should be applied. From an ‘insider’ perspective of the law, this explanation of the operation of legal precedent may be trite. However, the position remains worth stating explicitly, given that such an approach may jar with other disciplinary perspectives. Nonetheless, this inward-looking legal construction of the public interest, as outlined above, is consistent with an ‘intellectual tradition’²³¹ within the law of invoking fictional persons to provide a barometer of what ‘reasonable’ members of the public would expect in different circumstances. This can be traced back to idea of the *bonus paterfamilias* – good family father - in Roman law, and is reflected in English law in the notion of the ‘man on the top of the Clapham Omnibus’.²³² Both of these devices are used to invoke the hypothetical ordinary and reasonable person, for example to help decide if an action should be regarded as negligent in relation to what a reasonable person might expect given the circumstances and foreseeable consequences.²³³ The Supreme Court confirms this approach:

‘The spokesman of the fair and reasonable man, who represents after all no more than the anthropomorphic conception of justice, is and must be the court itself.’²³⁴

I argue in this thesis that, in order to appreciate the relationality between individual and collective interests in HRR, we require a more developed conceptual understanding of the relationship between the interests at stake. However, the analysis above goes one step further and implies that while these discussions remain wholly in the conceptual (or indeed legal) domain, and are developed in a vacuum, they will not necessarily attract social legitimacy. This cannot, of course, ever be guaranteed but a rich tradition of engagement with publics has shown that much can be learned (and gained) from doing so. Thus, while the public interest reaches for elements of publicness in terms of ‘the promotion of objectives valued by society’,²³⁵ the analysis above suggest that it falls short of fully animating this concept, both in terms of deep engagement with the interrelationship of individual and collective interests, and the views of actual publics when applying what is an ‘impersonal

²³⁰ *W v Egdell* (n 215); *Lewis v Secretary of State for Health* (n 216)

²³¹ *Healthcare at Home Limited v The Common Services Agency* (Scotland) [2014] UKSC 49 at [2]

²³² ‘reasonable person (reasonable man)’ in Jonathan Law (ed), *A Dictionary of Law* (Oxford University Press 2018).

²³³ *ibid.*

²³⁴ *Healthcare at Home Limited* (n 231) referring to Lord Radcliffe in *Davis Contractors Ltd v Fareham Urban District Council* [1956] AC 696, 728.

²³⁵ University of Edinburgh and others, ‘Public Interest in Health Research’ (March 2021)

<<https://www.law.ed.ac.uk/sites/default/files/2021-03/Public%20interest%20concept%20note.pdf>> accessed 14 March 2022.

standard'.²³⁶ While this may not be problematic in order to attain legal permissibility, this does not guard against the undesirable situation envisaged by the National Data Guardian, as outlined above, whereby public trust may be undermined where information is used in unexpected ways, or for purposes that people may not support. In other words, as far as law is concerned, it is sufficient for something to be labelled as 'in the public interest' in order to render a given action lawful, and this is not dependent on evidence of how affected citizens may feel about the matter. The relationship between legal compliance and public acceptability is explored further below, in relation to the need for a social licence for health research.

I now turn to the second facet of publicness, which is *temporality*, and the ability of the public interest to engage with interests in health research over time. In this respect, the analysis above points to the interpretive flexibility of the public interest, which resists definition and therefore has the potential to evolve over time in order to respond to different contexts and reflect changes in broader society. However, the apparent disconnect between the public interest and actual publics' views may hamper this responsiveness.

On a separate but related temporal point, the examples given above also illustrate how both *prospective* and *retrospective* decisions made in relation to the public interest, at fixed points in time, can impact negatively on its 'knowability'. On the one hand, the vast majority of decisions about whether research activities are 'in the public interest' are taken prospectively, and therefore rely on the 'hoped for' benefits that are expected to materialise. This is in sharp contrast to the dynamic nature of health research itself, where expected outcomes may not come to fruition, or unintended findings may be made. On the other hand, there are also circumstances when decisions in relation to the public interest are (albeit relatively rarely) *retrospectively* challenged - perhaps through referral to an oversight body, such as the Information Commissioner's Office,²³⁷ or, even more unusually, to a court. These challenges also bring their own limitations, in that the research in question, or data processing, may have already taken place, with the result that mitigating actions are limited to damage control or compensation. By way of illustration, in Chapter 6 I examine a case study where the transfer from an NHS Trust to Google Deepmind of 1.6 million partial patient records was later found to be unlawful.

The operation of the HRA's CAG stands, to some extent, in contrast to circumstances where a public interest decision is only reviewed in the event of a specific challenge to the legitimacy of that decision. The statute that established this body includes a safeguard, to the effect that

²³⁶ *Healthcare at Home Limited* (n 243).

²³⁷ The ICO is: 'The UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.' 'Information Commissioner's Office' (ICO 31 March 2022) <<https://ico.org.uk/>> accessed 1 April 2022.

there must be an annual review of the Regulations that govern this body, as well as requiring audit information from those granted Section 251 support.²³⁸ As such, the standard conditions attached to Section 251 support for the processing of confidential patient information without consent require not only that the HRA are notified of any significant change in circumstances²³⁹ or breach of confidentiality,²⁴⁰ but also that in *all cases* a review report is submitted every twelve months while support is in place.²⁴¹ While this regime is restricted to those cases that fall within the domain of the CAG, this provides an example of a more responsive approach in HRR. However, even here understandings of the public interest are unlikely to be enhanced if these reviews are considered at the level of the individual research project, rather than more systematically, and if the public interest is viewed in narrow legalistic terms as compliance with the relevant data protection legislation (as discussed above).

Finally, I consider a third facet of publicness, namely *accountability*, and how the interrelationship between collective and individual interests over time can be accommodated when decisions are made about how health research is conducted. This highlights a strength of the law, in that this provides an enforceable framework for the resolution of matters where the public interest is at stake, albeit that the preceding discussion highlights ways that this structure may be overly rigid and temporally limited. Decisions taken in the courtroom, or through the opinions of the CAG, have the potential to influence wider decision-making about how research is conducted, whether by setting legal precedent in case law, or the establishment of 'precedent set categories' for consideration by the CAG (being matters which are often discussed at meetings and therefore can be dealt with through an expedited process).²⁴² In this way the public interest in HRR may be understood as a device that functions to carve out a legally legitimate space within which research activities that infringe on individual interests but have potential public benefits can be carried out, which would otherwise not be permitted. In this respect, decisions about sharing confidential health information for research purposes without consent provides the paradigm example.

This brief analysis, through the lens of publicness, suggests that the use of the public interest in law has the *potential* to facilitate scrutiny of the relationship between individual and collective

²³⁸ National Health Service Act (n 221) s60(4); The Health Service (Control of Patient Information) Regulations (n 223) s2(5).

²³⁹ Health Research Authority, 'Standard Conditions of Support' (17 August 2018) Condition 9 <www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/standard-conditions-support> accessed 13 December 2021.

²⁴⁰ *ibid* Condition 11.

²⁴¹ *ibid* Condition 10.

²⁴² Health Research Authority, 'The CAG Precedent Set Review Pathway' (20 October 2020) <www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/cag-precedent-set-review-pathway> accessed 13 December 2021.

interests so that this not overlooked, in the manner of Sorauf's hair shirt. However, publicness also highlights the oppositional framing of these interests, the temporal limitations of this concept, and its self-referential approach to the views of diverse publics, when these are reduced to the judicial construction of a fictional 'reasonable man' or a 'reasonable public'.

Social value

An example of how publicness can be expressed in the context of an ethical framework is provided by the CIOMS 2016 Guidelines, which require that there must be social value in health research in order for this to be ethically permissible.²⁴³ This is described as '...the prospect of generating the knowledge and the means necessary to protect and promote people's health'.²⁴⁴ In common with the public interest, the notion of social value is not new in health research regulation and is seeded in foundational documents, such as the Nuremberg Code.²⁴⁵ The idea that research should have value – be this social, scientific and/or clinical - features as one of the seven requirements for ethical research as proposed by Emanuel et al in their 'discipline-defining'²⁴⁶ paper published over twenty years ago.²⁴⁷ Here this is understood in largely scientific terms as follows:

'To be ethical, clinical research must be valuable, meaning that it evaluates a diagnostic or therapeutic intervention that could lead to improvements in health or well-being; is a preliminary etiological, pathophysiological, or epidemiological study to develop such an intervention; or tests a hypothesis that can generate important knowledge about structure or function of human biological systems, even if that knowledge does not have immediate practical ramifications.'²⁴⁸

This is justified on that basis that:

'[t]here are 2 fundamental reasons why social, scientific, or clinical value should be an ethical requirement: responsible use of finite resources and avoidance of exploitation.'²⁴⁹

²⁴³ CIOMS (n 26).

²⁴⁴ *ibid* 1.

²⁴⁵ The Nuremberg Code (n 70) Principle 2.

²⁴⁶ Danielle M Wenner, 'The Social Value Requirement in Research: From the Transactional to the Basic Structure Model of Stakeholder Obligations' (2018) 48(6) *Hastings Center Report* 25, 25.

²⁴⁷ EJ Emanuel and others, 'What Makes Clinical Research Ethical?' (2000) 283(20) *JAMA* 2701, 2703.

²⁴⁸ *ibid*.

²⁴⁹ Emanuel and others (n 247).

However, perhaps due to its rhetorical appeal (another quality that is shared with the public interest) social value has, until recently, escaped extensive interrogation.²⁵⁰ Rid further suggests that the ‘protectionism paradigm’ in health research - that is a focus on participant protection in ethical debate - may explain why this concept has been under examined.²⁵¹ Nonetheless, she points to how contemporary concerns in health research regulation – in relation to matters such as global health disparities - have brought social value to the fore.²⁵² Further, an increasing focus on population level health research has widened the lens from the traditional participant / researcher relationship, to more closely scrutinise ‘...the broader institutional, social, and political contexts that shape these relationships’.²⁵³ Van Delden and van der Graf characterise the growing interest in social value as a response to the turn away from a ‘science-internal’ approach to the legitimacy of research activities, and towards the recognition of science as a matter of co-creation between science and society.²⁵⁴ On both accounts broad elements of publicness, in relation to the interplay between individual and collective interests, are reflected in the need to engage with the (expected) social benefits of health research, and to whom these may accrue.

As academic debate in relation to social value has matured, this has moved on from a largely uncritical acceptance of social value as a ‘good thing’, and towards greater scrutiny of its ethical foundations.²⁵⁵ In contrast to the general acceptance that research ought to be socially valuable, two influential critics of this concept have spurred further discussion about whether this can be justified as a requirement for *all* health research. Wertheimer argues against Emanuel et al’s two-pronged justification (that is, responsible use of finite resources and avoidance of exploitation) for the social value requirement, which he characterises as the ‘allocation’ argument and the ‘exploitation avoidance’ argument.²⁵⁶ On the first point he argues that the social value requirement does not apply to privately-funded research and notes that ‘...there is surely something in the view that the way in which people spend their resources is up to them’.²⁵⁷ While Wertheimer accepts that it may be better that commercial organisations do not pursue research without social value, he finds that this is not unethical or impermissible. On the ‘exploitation avoidance’ point, he suggests that social value is not required in order to avoid exploitation in circumstances where participants have consented and are not at ‘net risk’

²⁵⁰ Agomoni Ganguli-Mitra and others, ‘Reconfiguring Social Value in Health Research Through the Lens of Liminality’ (2017) 31 *Bioethics* 87, 87.

²⁵¹ Rid (n 45) 297.

²⁵² *ibid* 298.

²⁵³ *ibid* 299.

²⁵⁴ van Delden and van der Graaf (n 104) 46.

²⁵⁵ Wenner (n 246) 25–26.

²⁵⁶ Alan Wertheimer, ‘The Social Value Requirement Reconsidered’ (2015) 29(5) *Bioethics* 301, 302.

²⁵⁷ *ibid* 303.

(i.e. those risks which are not offset by benefits).²⁵⁸ Resnik pursues a similar line of argument, though he distinguishes between a strong version of social value (where research is *only* ethical where it can reasonably be expected that it will substantially benefit the public) and a weak version (where the expectation of substantial benefit to the public is *one consideration amongst others*, and therefore not required for research to be ethical).²⁵⁹ In his view, social value is ethically desirable, but it is only necessary when research ‘...imposes more than minimal risks on non-consenting subjects; or...is supported by public resources’.²⁶⁰ In response, Wendler and Rid have argued that, all studies must have ‘sufficient’ (as opposed to ‘strong’) social value. On their account all studies must have *some* social value in order to be ethical, but the level of social value will depend on the circumstances of each study, taking into account matters such as the resources invested and the net risks to participants (i.e. those risks which are not offset by benefits). In this regard they advance eight ethical and policy arguments to support their points, in relation to (i) protecting participants who cannot consent; (ii) ensuring the acceptability of high risk research with competent adults; (iii) maintaining researcher integrity; (iv) avoiding participant deception; (v) safeguarding against exploitation; (vi) stewardship of public resources; (vii) promoting public trust; and (viii) the recognition that there may be some studies that fall outside of these arguments, though these are likely to be rare and therefore do not undermine the claim that social value should be required for all studies. The thrust of Wendler and Rid’s argument is that the reality of how research is conducted means that social value is a requirement for ethical research, and should be incorporated in guidelines and policy. As noted at the start of this section, this can be seen in the incorporation of social value as a key principle in the most recent CIOMS Guidelines, as applicable to *all* health research involving human subjects.²⁶¹ This requirement explicitly includes research that is data driven – which is notable as much of the literature in this area focuses on ‘hands on’ clinical research.

A further perspective on social value in research is provided by Wenner, who responds to the ‘attack’ on social value by proposing a more fundamental shift in how social value is understood.²⁶² This is particularly pertinent for the purposes of this discussion in that it speaks to the range of interests that are engaged by the health research endeavour. She suggests that traditionally discussions, both for and against a strong social value requirement, have

²⁵⁸ David Wendler and Annette Rid, ‘In Defense of a Social Value Requirement for Clinical Research’ (2017) 31(2) *Bioethics* 77.

²⁵⁹ David B Resnik, ‘Difficulties with Applying a Strong Social Value Requirement to Clinical Research’ (2018) 48 *Hastings Cent Rep* 35, 70.

²⁶⁰ *ibid* 66.

²⁶¹ van Delden and van der Graaf (n 104) 46.

²⁶² Wenner (n 246).

been based on a 'transactional model of stakeholder obligations'.²⁶³ In this context the relevant considerations focus on the immediate stakeholders to that transaction and matters such as consent given and benefit received.²⁶⁴ She proposes that this is inadequate to capture the full range of ethical considerations in play, and instead prefers a 'basic structure model of stakeholder obligations'. This account is:

'... grounded in a claim that clinical research plays a direct role in establishing the justice or injustice of our social organization and should therefore be governed more explicitly by justice-based considerations. As such, the model explicitly accounts for the fundamentally social nature of the research enterprise itself.'²⁶⁵

The preceding discussion underlines that there is support in the literature, and also in policy, for a robust social value requirement in health research regulation,²⁶⁶ but that views on its meaning, justification, value and application are far from unanimous. Here again I use the lens of publicness in order to provide a new perspective on this familiar concept.

Following the framework approach taken in relation to the public interest above, first publicness draws attention to *relationality*, and therefore illuminates how each of the preceding viewpoints on social value are fundamentally concerned with the interests engaged in the health research endeavour, regardless of whether they argue for or against a social value requirement. Those who argue against a universal social value requirement for health research tend to focus more narrowly on individual interests and the need to respect the autonomy of participants to decide for themselves how they wish to trade off the risks and benefits of health research. As Wertheimer asserts:

'It might be objected that people – and especially poor people – don't have good judgment about the relative value of the risks of participation and the benefits of payment, and that we can be confident that they are not being exploited only by excluding the value of payment from our assessment. I see no reason to accept the premise of this argument, but even if this is so, it remains the case that if a *reasonable* assessment of the value of payment in the subject's *objective position* adequately compensates a subject for the risks and burdens of participation, then she is not at net risk and social value is not necessary to avoid exploitation.'²⁶⁷

²⁶³ *ibid.*

²⁶⁴ *ibid* 26.

²⁶⁵ *ibid.*

²⁶⁶ Rid (n 45) 300.

²⁶⁷ Wertheimer (n 256) 305.

However, those who are in favour of a universal social value requirement instead present a more holistic view of the health research endeavour, and the interconnectedness of the interests that are engaged.²⁶⁸ In this wider context the potential for exploitation is not restricted to individual participants but should also be viewed in relation to the benefits and burdens of the research enterprise overall. Wenner's account of social value explicitly moves away from a model based on 'free and fair transactions' between researchers and participants, and towards considerations of justice and how this should guide biomedical progress.²⁶⁹ More specifically, she argues that the impacts of research on health systems are not merely 'externalities' (i.e. a cost or benefit to a third party who has no say in this), but rather '...intended consequences of the research enterprise'.²⁷⁰ For example, outputs from health research can drive prescribing practices, or guide which interventions are available to patients, and these in turn are funded by the taxpayer, in public health systems, or passed onto the patient, in private health systems.²⁷¹ The result is that:

'The patients who are affected by the influence of the clinical research enterprise on medical practice are like those who are affected by externalities: they cannot be properly construed as parties to the research transaction. Patients cannot choose to "opt out" of the effects of health research on their local health system. But equally importantly, those consequences for health care systems cannot be construed as externalities: they are not accidental, or "foreseen but unintended consequences." Instead, changing medical practice is the basic motivation behind the vast majority of both publicly and privately funded research.'²⁷²

The use of publicness as a framework for analysis highlights the contrast between, on the one hand, this broader account of those who are impacted by the research enterprise, beyond the individual participant and researcher, and, on the other, Wertheimer's position, based on the 'objective subject'. This provides an example of how social value has the *potential* to accommodate a broader range of interests, though this is dependent on how the interrelationship of individual and collective interests is itself conceptualised.

Publicness also draws our attention to the *temporality* of regulation, such as the downstream impacts of health research activities. A further consideration that this highlights is the framing of social value (like the public interest, to some extent) as a prospective requirement. Returning to Emanuel et al's definition, this provides that there is value in an intervention that

²⁶⁸ Wendler and Rid (n 258) 82.

²⁶⁹ Wenner (n 246) 29.

²⁷⁰ *ibid* 28.

²⁷¹ Wenner (n 246).

²⁷² *ibid* 29.

'could lead to improvements in health or well-being' [*emphasis added*]. The authors acknowledge that:

'Assessment of the value of research is made prospectively before any data are collected. Consequently, determinations of social value are uncertain and probabilistic, entailing judgments about the usefulness of a sequence of research and chances of implementing the results.'²⁷³

Wenner's definition similarly only requires that research 'holds out *the prospect* of producing socially valuable knowledge.'²⁷⁴ Wendler and Rid also explicitly address this point and acknowledge that, while studies must have the *potential* to improve health, the reality is that not all will do so, providing the following example of where this may be the case:

'...some clinical trials end up recruiting so few participants that they yield no useful information. These trials do not violate the [*social value requirement*], provided there is sufficient reason to believe *ex ante* – at the time the trials are initiated – that they will yield data which can be used to improve health.'²⁷⁵

This points to a limitation in the use of social value, in that even if this requirement is accepted and put into practice, it does not necessarily follow that the research produced will have actual social value. A new perspective on this is provided by Ganguli-Mitra et al, who argue that social value should not be approached as a static requirement, but rather as a dynamic concept that matters at all stages of the research process.²⁷⁶ The authors find that social value 'must be revisited and re-created iteratively throughout the research lifecycle and by all relevant stakeholders'²⁷⁷ if the full potential of social value is to be realised, and have greater impact throughout the research cycle. As I will come to in Chapter 4, when temporality and relationality are considered together, publicness urges us to further consider the multi-directional impact of time and interests in HRR.

The issues raised above point to different ways in which the interrelationship between collective and individual interests may be *accounted for* when decisions are made about the conduct and regulation of health research. The examination of contemporary debates in relation to the social value requirement in research illustrates how, when viewed through the lens of publicness, accounts of the relationship between individual and collective interests can significantly alter how this concept is understood. In particular, publicness highlights the

²⁷³ Emanuel and others (n 247).

²⁷⁴ Wenner (n 246) 25.

²⁷⁵ Wendler and Rid (n 258) 78.

²⁷⁶ Ganguli-Mitra and others (n 250).

²⁷⁷ *ibid* 96.

contrast between a narrow view of the individual interests that are at stake in health research and its regulation, and a broader conception of these interests that accommodates the ways in which individual and collective interests may build upon one another. Further, a focus on the temporal aspects of social value indicates that, in common with the use of the public interest, this requirement tends to be applied prospectively to research (though, in the case of social value, there is even less prospect of review). Given that, as argued above, health research may yield unexpected (positive and/or negative) results, this limits the extent to which social value can be brought to bear throughout the research lifecycle, in order to release its full potential, leading to calls for new forms of governance that incorporate feedback loops and collaborative regulatory practices.²⁷⁸

In contrast to the role of the public interest which, as argued above, carves out a *legally legitimate* space in which health research activities can take place, the preceding analysis, though the lens of publicness, frames the principal function of social value as an *ethical* promise of the societal good that health research is expected to deliver. A further contrast between public interest and social value is that while the former can legitimate an encroachment on individual interests (at least in the eyes of the law), the latter is not presented as a trump card in what counts as ethical research, i.e. social value alone is not enough to produce ethically sound research. Nonetheless, if science is truly a matter of co-creation, and so social value should not be left to science alone to evaluate, questions remain in relation to how the ‘social’ aspect of social value is legitimised. Van Delden and van der Graaf suggest that public and patient involvement in health research may have a role to play here,²⁷⁹ though, as discussed further below, in relation to social licence, this also raises issues of inclusion and legitimacy.

Social licence

The term social licence can be understood as ‘...an informal agreement that is granted by communities and relevant stakeholders to an organisation to do certain work’.²⁸⁰ This concept is rooted in two distinctive bodies of literature, though in both a social licence is ‘intangible and unwritten’²⁸¹ and ‘goes well beyond a legal permission’.²⁸² A social licence is not formally

²⁷⁸ Ganguli-Mitra and others (n 250).

²⁷⁹ van Delden and van der Graaf (n 104) 46.

²⁸⁰ Paprica and others (n 173); David Rooney and others, ‘Doing the Social in Social License’ (2014) 28 *Social Epistemology* 209.

²⁸¹ Aitken and others, ‘Establishing a social licence for Financial Technology: Reflections on the role of the private sector in pursuing ethical data practices’ (n 173) 2.

²⁸² Mary Dixon-Woods and Richard E Ashcroft, ‘Regulation and the Social Licence for Medical Research’ (2008) 11(4) *Med Health Care Philos* 381.

granted by governments or institutions, but rather by 'communities of stakeholders'.²⁸³ Discussions of social licence can first be located in relation to the extractive industries, such as mining and forestry, where industrial activities impact on individuals, communities and wider publics.²⁸⁴ These impacts, be they environmental and/or social, may be felt at a local and/or at a national level, and result in scrutiny of the legitimacy of these activities.²⁸⁵ It has been claimed that the need for a social licence was originally used as a metaphor in the mining industry to underline the equal importance of (and potential threat to operations posed by) formal regulatory risks, and risks relating to the social legitimacy of the activities in question.²⁸⁶ In this way, the use of social licence has been employed as a dimension of corporate social responsibility²⁸⁷ since the 1990s, as a way of improving relations between those engaged in industries, such as mining, and affected stakeholders.²⁸⁸ References to 'data mining' have been used in the context of health, which may invite similarities to be drawn between the need for a social licence for data-intensive research, in the same way as one is required by these extractive industries.²⁸⁹ For example, the use of data has the potential to both deliver benefit and harm to affected stakeholders. However, there are important differences too, in that it has been argued that data does not pre-exist in the world as a natural resource.²⁹⁰ Further, the 'affected stakeholders' in relation to data-intensive health research, which may be carried out at a large-scale or population level, are also unlikely to be identifiable in the same way as in an industry, such as mining and forestry, which takes place in a particular geographical location.²⁹¹

A second use of social licence, which is more often drawn upon in the context of health research, is rooted in the sociology of occupation. Here a body of literature has developed with a focus on health research and, more specifically, innovative uses of health data. The work of the Chicago School sociologist, Everett Hughes, addresses the relationship between

²⁸³ Aitken and others, 'Establishing a social licence for Financial Technology: Reflections on the role of the private sector in pursuing ethical data practices' (n 173) 2.

²⁸⁴ Pauline Gulliver and others, 'Surveys, Social Licence and the Integrated Data Infrastructure' (2018) 30(3) *Aotearoa New Zealand Social Work* 57, 59; Richard Parsons and Kieren Moffat, 'Constructing the Meaning of Social Licence' (2014) 28(3-4) *Social Epistemology* 340.

²⁸⁵ Parsons and Moffat (n 284) 341.

²⁸⁶ Charles Mather and Lucia Fanning, 'Is Social Licence "Going Rogue"?' (2019) 185(4) *The Geographical Journal* 498, 500.

²⁸⁷ Parsons and Moffat (n 284); Carter and others (n 164).

²⁸⁸ Mather and Fanning (n 286) 498.

²⁸⁹ Aitken and others, 'Establishing a social licence for Financial Technology: Reflections on the role of the private sector in pursuing ethical data practices' (n 173); Raman and Mohr (n 22).

²⁹⁰ Jathan Sadowski, 'When Data is Capital: Datafication, Accumulation, and Extraction' (2019) 6(1) *Big Data & Society*.

²⁹¹ Aitken and others, 'Establishing a social licence for Financial Technology: Reflections on the role of the private sector in pursuing ethical data practices' (n 173).

professions and society in terms of the need for a licence and a mandate.²⁹² A licence, in broad terms, is described as the privilege of doing something that others either do not do, or perhaps are not allowed to do.²⁹³ Hughes notes that this may require the need for ‘elbow room’ for a profession to learn in a specific way or to adopt a mode of thought that might be quite different to that used by the surrounding society.²⁹⁴ He couches this in terms of ‘...a bargain, implicit or explicit, with the world [s]he lives in and the society [s]he studies’.²⁹⁵ Meanwhile a mandate is ‘...the claim of the people in a line of work to the right to define some important matter not merely for themselves, but for society at large’.²⁹⁶ In return, Hughes indicates that society may expect something in return from the profession. He further observes that occupations can seek to expand their mandate, but that ‘[t]he lay public or publics may, however, be very ambivalent about what they really want of a professional group’.²⁹⁷ As Dixon-Woods and Ashcroft note in their consideration of regulation and the social licence for medical research, Hughes was particularly interested in what any dispute over the bargain struck between society and professionals might reveal about hidden aspects of this bargain.²⁹⁸ In their analysis they point to the impact on the development of health research governance in the UK of key ‘scandals’, such as matters in relation to organ retention that were examined by The Royal Liverpool Children’s Inquiry Report in 2001²⁹⁹ and the disputed events surrounding the provision of continuous negative extrathoracic pressure (CNEP) to premature babies at North Staffordshire Hospital.³⁰⁰ I analyse a more recent controversy around the unlawful transfer of health data from the NHS to a commercial organisation in Chapter 6, in order to illustrate how publicness delivers a concept that can support the review and revision of data-intensive initiatives, where there are multiple and related interests at play, throughout the full research lifecycle. But, for now, the point to be made is that the disruption of a social licence has the

²⁹² Everett C Hughes, *Men and Their Work* (The Free Press 1958); Everett C Hughes, ‘The Dual Mandate of Social Science: Remarks on the Academic Division of Labour’ (1959) 25(4) *The Canadian Journal of Economics and Political Science* 401.

²⁹³ Hughes 1959 (n 292) 403.

²⁹⁴ *ibid.*

²⁹⁵ *ibid.*

²⁹⁶ *ibid* 403–04.

²⁹⁷ *ibid* 404.

²⁹⁸ Dixon-Woods and Ashcroft (n 282) 382.

²⁹⁹ Royal Liverpool Children’s Inquiry, ‘The Royal Liverpool Children’s Inquiry Report’ (*GOV.UK*, 30 January 2001) <www.gov.uk/government/publications/the-royal-liverpool-childrens-inquiry-report>.

³⁰⁰ For a range of opinions on this see, for example: Teresa Wright, ‘The Stoke CNEP Saga – How It Damaged All Involved’ (2010) 103(7) *Journal of the Royal Society of Medicine* 277 Sage UK: London, England; Graeme Catto, ‘The Stoke CNEP Saga – a View from the General Medical Council’ (2010) 103(8) *J R Soc Med* 313; Edmund Hey and Iain Chalmers, ‘Mis-Investigating Alleged Research Misconduct Can Cause Widespread, Unpredictable Damage’ (2010) 103(4) *Journal of the Royal Society of Medicine* 133.

potential to reveal much about the basis on which this unwritten and intangible agreement has been struck.

In the context of science, various appeals to social licence can be seen in the last two decades. For example, when launching the Universal Ethical Code for Science in 2007 the then HM Government Chief Scientific Adviser proposed that: 'Our social licence to operate as scientists needs to be founded on a continually renewed relationship of trust between scientists and society'.³⁰¹ More recently, there has been a groundswell of interest in how this idea can be brought to bear in the context of health research regulation. Muller et al identify nine different descriptions or definitions of social licence in the biomedical literature, most of which were published since 2019. From these they draw together a refined specification for a social licence in the context of data-intensive research which refers to:

'...the non-tangible social permission or approval that is granted to either public or private researchers and research organisations. This allows them to collect, use, and share health data for the purposes of health research by virtue of those activities being trustworthy, which is meant trusted to be in line with the values and expectations of the data subject communities, stakeholders and the public'.³⁰²

This emphasis on reciprocity,³⁰³ mutual relationships between stakeholders,³⁰⁴ and trust and trustworthiness³⁰⁵ can also be seen elsewhere in the literature in relation to the conditions under which a social licence may be granted and sustained. In short, rather than focusing on legal and/or regulatory authority (like the public interest) or ethical permissibility (like social value), social licence engages with the social side of research through consideration of '...whether a given data use is accepted by stakeholders'.³⁰⁶

Publicness can also be used as an analytical framework here in order to interrogate social licence further. Turning first to *relationality*, the role that notions of social licence play in regulation can be contrasted with those of the public interest and social value, in that social licence provides a direct link to the views of stakeholders in health research. In this way notions of social licence can provide more room for an evidence base about what actual

³⁰¹ Government Office for Science, 'Rigour, Respect, Responsibility: A Universal Ethical Code for Scientists' (September 2007)
<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/283157/universal-ethical-code-scientists.pdf>.

³⁰² Muller and others (n 170) 4.

³⁰³ Carter and others (n 164); Raman and Mohr (n 22).

³⁰⁴ Aitken and others, 'Establishing a social licence for Financial Technology: Reflections on the role of the private sector in pursuing ethical data practices' (n 173).

³⁰⁵ *ibid.*

³⁰⁶ Angela Ballantyne and Cameron Stewart, 'Big Data and Public-Private Partnerships in Healthcare and Research' (2019) 11(3) ABR 315, 318.

publics want and think, whereas public interest and social value may be largely determined by an elite group of decision makers. Indeed, Aitken et al go as far as suggesting that:

‘developing and maintaining a [social licence] *requires* public engagement incorporating diverse perspectives and interests, beyond those of professional communities, to ensure that current and future practices are aligned with the values of society’.³⁰⁷ [*emphasis added*]

In circumstances where public engagement and involvement activities may range from sharing information *about* research with publics, to ‘...research that is done ‘with’ or ‘by’ the public, not ‘to’, ‘about’ or ‘for’ them’,³⁰⁸ social licence has the potential to foreground the need for dialogue between the ‘social and the scientific’, and the ways that these may shape and bear upon one another.³⁰⁹

However, the lens of publicness, which also draws attention to the diversity that exists within publics, underlines that this relationship - between seeking the views of different stakeholders and/or groups of stakeholders, and securing public acceptance - is complex and non-linear. Indeed, Stewart has described the implementation of public involvement in health services as ‘... an area of policy where ostensibly good intentions appear to repeatedly fail in implementation’.³¹⁰ Further, caution is urged in relation to attempts to use public engagement and involvement activities to ‘capture’ opinion, for example by securing people’s agreement to a predetermined agenda.³¹¹ This not only risks calling into question the legitimacy of the process followed, but, it has been suggested, is also unlikely to be successful in securing public acceptance.³¹² ‘Thin’ forms of engagement may instead look more like an attempt at ‘window-dressing’, rather than the ‘thicker’ dialogue required to sustain a social licence for health research activities.³¹³ In order to be more meaningful, forms of public engagement and involvement are likely to require careful consideration of, for example, the existence of different types of ‘publics’ – a term used to signal that publics are not homogenous, but rather varied and diverse.³¹⁴

³⁰⁷ Aitken and others, ‘Establishing a social licence for Financial Technology: Reflections on the role of the private sector in pursuing ethical data practices’ (n 173) 2.

³⁰⁸ Health Research Authority, ‘Public involvement’ (n 23).

³⁰⁹ Raman and Mohr (n 22) 258.

³¹⁰ Ellen Stewart, ‘Governance, Participation and Avoidance: Everyday Public Involvement in the Scottish NHS’ (University of Edinburgh 2012).

³¹¹ Raman and Mohr (n 22) 268.

³¹² *ibid.*

³¹³ Mhairi Aitken and Sarah Cunningham-Burley, ‘Forms of Engagement’ in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021) 114.

³¹⁴ *ibid* 117.

Publicness also requires consideration of *temporality*. Here the preceding discussion of stakeholder ‘capture’, can be contrasted with the potential for deeper ‘co-construction of research agendas by science and society’.³¹⁵ The latter is only possible where there is ‘...a willingness to rethink existing arrangements and agendas’³¹⁶ as opposed to presenting stakeholders with a closed set of possible futures. Together this suggests that ‘[m]aking research social is a *process*—it cannot be brought about just by edict’.³¹⁷ This emphasis in the literature on ‘developing and maintaining’ a social licence over time, can be contrasted with the more static approaches to the public interest and social value outlined above. Nonetheless, challenges remain in seeking to sustain a social licence over time, in the context of an intangible agreement with diverse publics.

Finally, publicness directs us to consider *accountability* when decisions are made about the regulation of health research. A strength of social licence is that it has the potential to open up questions around what, whether, how and with whom health research is conducted to people beyond the professions and the state, thereby extending the boundaries of what ‘good health research’ looks like.³¹⁸ It underlines that adherence to formal frameworks, whether these are legal frameworks that turn on the public interest, or ethical guidelines that contain a social value requirement, will not always be enough to secure social legitimacy, which goes beyond compliance in this narrower sense.³¹⁹ Therefore, while the public interest can create a space in which health research activities are legally legitimate, and social value can embody a promise of some return to the collective from research, social licence may in turn help to gauge the acceptability to publics of the activities that take place within and beyond these spaces.

However, while the emergence of new societal actors in health research has the potential to widen participation in its regulation, this is by no means a given. As discussed above, the design and delivery of meaningful public involvement and engagement initiatives may be an inhibiting factor to meaningful dialogue. Further considerations include the degree of organisation that stakeholders require if they are to effectively engage with professionals or institutions that are seeking public acceptance for their current or future activities.³²⁰ Without support it may be difficult to establish the type of reciprocal relationship that is envisaged to

³¹⁵ Raman and Mohr (n 22) 271.

³¹⁶ *ibid* 273.

³¹⁷ *ibid* 265.

³¹⁸ *ibid* 267.

³¹⁹ Carter and others (n 164).

³²⁰ Raman and Mohr (n 22) 261; Neil Gunningham and others, ‘Social License and Environmental Protection: Why Businesses Go Beyond Compliance’ (2004) 29 *Law and Social Inquiry* 307.

build and maintain a social licence, where both parties engage, listen and respond.³²¹ This suggests there will be areas where social licence alone is insufficient, and legal-regulatory measures are important where the pressure of societal norms are not enough to effect real change.³²² For example, in the environmental domain it has been suggested that where legislation enables participation in decision making, or requires the disclosure of compliance information, this can have a significant impact on the empowerment of publics as ‘social licencees’.³²³ This indicates that, while, as suggested above, social licence may go beyond a legal permission, there may also be circumstances in which legal authority can serve to support the development of a social licence. Further, it should also be self-evident that merely doing what a public or publics think they want does not render an action ethical, nor is it necessarily determinative of what counts as legitimate social value. Taken together this analysis begins to reveal a more nuanced account both of social value individually, and how this interacts with other related concepts in the HRR ecosystem.

Revisiting publicness: discussion across disciplinary boundaries

In this Chapter publicness has been used to explore a phenomenon in HRR – namely the tension between collective and individual interests – in a way that transcends disciplinary boundaries and provides a common language to talk about the interests in play. Rather than conflating existing concepts, publicness helps to tease these apart, revealing aspects of the work that these do in HRR.

To do so publicness has been used as a framework for analysis, in order to examine three existing concepts. In particular, publicness has been operationalised by drawing on its three facets– relationality, temporality and accountability - in order to reimagine the familiar health research landscape in a different way and to facilitate discussion across disciplinary boundaries. The existing concepts considered – the public interest, social value, and social licence – were chosen, in part, because of what they have in common and their interchangeable and/or proximal use in the HRR literature. Their evaluation above has indeed shown how each of these engage, in different ways, with the social side of research, and the relationship between (biomedical) science and society. However, this selection was also made in order to better understand the apparent differences between these concepts, and several insights emerge from this scrutiny.

³²¹ Raman and Mohr (n 22) 261; Gunningham and others (n 320).

³²² Gunningham and others (n 320).

³²³ *ibid.*

At a high level, publicness helps to delineate the work that is done by the public interest, social value and social licence, both individually and in relation to one another. In crude terms, these concepts are variously concerned with what we *can* do (the public interest), with what we *should* do (social value), and what people *think and feel* about what has or will happen (social licence).³²⁴ However, the preceding discussion deepens and extends this analysis in ways that reveal more about both the existing concepts under scrutiny, and publicness itself.

Consideration of the public interest, and the interaction of individual and collective in this context, shows ways in which this carves out a legally legitimate space within which research activities that infringe on individual interests, but have potential public benefits, can be conducted, which otherwise would not be permitted. In contrast to this, social value speaks to the ethical acceptability of health research, and acts as a promise of the societal good that it is expected to deliver. In further contrast, social licence gauges the acceptability to publics of this research. While these are crude distinctions that cannot do justice to the nuance of each approach, this exercise nonetheless helps to articulate the principal functions of the public interest, social value and social licence in HRR, as set out in **Table 8**.

Table 8: Principal functions of existing concepts		
Public Interest	Social Value	Social Licence
Carves out a legally legitimate space within which research activities that infringe on individual interests but have potential public benefits can be lawfully conducted, which otherwise would not be permitted	Acts as a promise of the societal good that ethically acceptable health research is expected to deliver	Engages with the acceptability to publics of activities that are required to carry out health research which otherwise would not be permitted
P U B L I C N E S S		

³²⁴ Ballantyne and Stewart (n 306).

These distinctions both add value to current understanding of these existing concepts, in circumstances where there is a tendency to collapse these together, and supports the claim that publicness in HRR captures something broader than is engaged by any one of these concepts alone. Further, this analysis speaks to the function of publicness in other ways. For example, in Chapter 2 I highlighted concerns about how terminology that had already been colonised by a particular discipline and could stifle interdisciplinary discussions.³²⁵ Publicness in HRR has consequently been positioned as not being tied to a particular disciplinary approach. This Chapter has demonstrated not only the breadth of this concept, but also how this may be used as a *lingua franca* to facilitate conversations across disciplines. Publicness performs this function through a bottom-up approach that directs attention first to the phenomenon itself - that is the tension between individual and collective interests – and what this means for HRR, rather than to how this is expressed within a particular disciplinary context. In this way publicness provides a foundation from which to analyse the strengths and limitations of a variety of approaches which, in different ways, manifest some facets of publicness (i.e. relationality, temporality and accountability).

The use of publicness as the foundation for a tripartite framework for analysis in this Chapter also supports a further normative claim, that publicness is not only able to tease apart existing concepts, but can also help point to concrete ways in which these can be optimised in HRR. This assertion is grounded by the preceding examination of the public interest, social value, and social licence using three facets of publicness as a diagnostic framework. These facets are summarised in **Table 9** together with some of the key features of each approach across these three domains.

³²⁵ Hewer and others (n 150).

Table 9: Operationalising facets of publicness					
Publicness	Public Interest	Social Value	Social Licence	Challenges	
P U B L I C N E S S	(1) Relationality	<p>Tendency towards a polarised conception of the interests engaged.</p> <p>Inward-looking conception of 'the public' using the notion of the 'reasonable person'.</p>	<p>Potential to accommodate a broader range of interests, though dependent on how the interrelationship between individual and collective interests is itself conceptualised.</p> <p>Focus in the literature on the ethical justification for social licence, rather than how publics may be engaged in constructing social value.</p>	<p>Directly concerned with whether activities are acceptable to publics.</p> <p>Establishing and maintaining a reciprocal relationship may be challenging in the context of an intangible agreement with diverse publics.</p>	Engagement with diverse publics

	(2) Temporality	Predicated on potential public benefits of health research with some limited post-ante review mechanisms	Predicated on potential value that health research is expected to deliver with no formal post-ante review mechanisms	Ongoing requirement though with no formal review mechanisms	Engagement with the multiple interests engaged by health research over time.
	(3) Accountability	Accountability via a legal framework	Accountability via guidance e.g. CIOMS	Weak accountability of intangible and unwritten agreement	Responsive HRR

Starting with *relationality*, the lens of publicness reveals that engagement with diverse publics, which recognises the full range of interests at stake in HRR, is not a given in respect of any one of these existing approaches. This is most pronounced in relation to the analysis of the public interest as a regulatory device, where there is a tendency to polarise individual and collective interests, and to reduce the views of homogenous publics to that of the reasonable person. While social value has the potential to account for a wider range of interests, this too is dependent on how the relationship between individual and collective interests in health research is conceptualised. Here publicness encourages us to challenge accounts that narrowly focus on the individual interests engaged by health research, and therefore overlook broader social aspects of research, and the way in which individual and collective interests interact and build on one another. The use of social licence in regulation provides the most direct link to actual publics' views, with the potential to open up decision making beyond an elite group. Though here too the correlation between the views of different stakeholders and/or groups of stakeholders, and securing public acceptance for health research activities, is complex and non-linear, and requires engagement with varied and diverse publics. Further, whether research is socially acceptable says nothing about its ethical acceptability, nor its lawfulness.

Publicness also draws attention to *temporality*, and in particular how the interests at stake in health research are accounted for over time. In this respect the operation of the public interest and social value are largely predicated on the basis of *prospective* decisions made on the basis of the expected future harms and/or benefits of health research. Decision in relation to

the public interest may be amenable to some limited forms of *retrospective* review, though these mechanisms are also fixed in time, and largely restricted to individual project-level ex-ante damage control, rather than systems-level improvements. Conversely, the need to establish and maintain a social licence for health research is ongoing, albeit fraught with challenges where an intangible agreement is at ongoing risk of unilateral revocation. As with the public interest and social value, these challenges are compounded in circumstances where health research is, by definition, designed to lead to new and as yet unknown findings. In sum, this limits the extent to which the full potential of each of these concepts can be brought to bear throughout the research lifecycle.

Finally, publicness directs our attention to *how HRR accounts for these interests* when decisions are made about how health research is conducted. This may be in respect of existing concepts, as illustrated by the analysis above, where this framework for analysis helps to distinguish, contrast and compare the principal functions of the public interest, social value and social licence. However, publicness also points to ways in which the optimisation of HRR may be limited, for example by challenges related to engagement with varied and diverse publics and the regulation of individual and collective interests over time.

If the reader accepts this analysis, as delivered through the lens of publicness, for its *diagnostic* value, in helping to reveal the work that existing concepts already do in health research regulation, then it might reasonably be concluded that publicness has done all of its work. Further, it might seem logical to deduce that what is required normatively – going forward – is a simple combined model, where public interest, social value and social licence can be made to work better together. If so, why then talk more of publicness? But this would be to perpetuate a fragmented approach to designing the HRR ecosystem that risks bringing disciplinary ‘baggage’ into future debates and policies. By way of example, if ‘the public interest’ is considered solely from a legal perspective my analysis so far has indicated that this would overlook very real concerns in relation to the extent to which this can command social legitimacy when this is considered in the abstract. Furthermore, to perpetuate this siloed single-disciplinary approach would be to ignore that existing concepts in HRR, and publicness, are not mutually exclusive, but rather complementary – focusing on publicness going forward equips us to be responsive to new challenges and in new ways that might require us to look across disciplines and go beyond existing concepts. Based on my research, no single discipline uses the terminology of ‘publicness’. This opens up an opportunity to initiate cross-disciplinary dialogue as to its meaning and potential value. The view offered in this thesis is merely one perspective, but it is grounded in literatures from other disciplines in ways that promote recognition of common features, while also promoting new dialogue going beyond

existing disciplinary boundaries (and their associated limitations). In this way the use of publicness resists fragmentation and promotes cohesion.

Finally, my analysis gives rise to the claim that there can be a normative appeal in publicness itself, beyond its mere diagnostic value. The practical application of publicness in this respect is explored in the Chapters that follow in Part II, as I come to further below. However, I pause here in order to elaborate on the ways in which I have suggested that publicness – both as a concept and as the foundation for a framework for analysis - may have normative force, in the sense that publicness can help us to form new ideas about how HRR should be viewed and/or conducted. It should be emphasised that I do not claim that publicness, per se, automatically or necessarily brings a normative imperative. Any normative claim must be fully explored and justified. Rather, in what follows I lay out some of the key considerations that would have to be addressed if one were to seek to go about the task of bringing normative force to publicness.

As I have argued so far, publicness, in its simplest terms, is a way to look at the interrelationship between collective and individual interests to reveal deeper understandings of what is at stake. In this thesis I have suggested, variously, that this is a relationship that has been overlooked, or has tended to be viewed as one that is inherently oppositional or antagonistic. Further I have proposed, in Chapter 1 and 2, that contemporary data-intensive health research demands a new approach to the complexities of the relationship between collective and interests that better reflects how and with whom health research is now conducted. To appeal to publicness qua concept is, therefore, to take a new position on how this relationship should be named, framed and valued in modern health research and its regulation. To elaborate further, the concept of publicness serves to *name* the interrelationship between individual and collective interests in a way that does not fall back on a ‘collective versus individual’ or ‘public versus private’ binary. But more fundamentally, it draws attention to sameness and difference and invites us to ask what we might actually share in common when we speak of interests. Put another way, this can be seen as a form of moral framing that seeks to elucidate the values that are at stake and which values are shared (or if they are not shared, to invite further exploration as to why). Further, publicness *frames* this interrelationship as a central concern of HRR that should not be overlooked, thus ascribing *value* to this relational approach to the interests that are at stake in HRR. There is both value in such a relational approach precisely because it engages our moral values, in the plural sense. In doing so, it invites the further important question: what good reasons do people have to follow a particular course of action or to form a particular judgment as to what ought to be done? This is precisely the basis of any normative claim. Publicness provides us with a basis to ask and answer this question.

I have argued from the outset of this thesis that the HRR ecosystem risks falling short of the highest standards or quality when it fails to adequately reflect the complexities of the interrelationship between individual and collective interest that are in play, and how these may change over time, which in turn may impact on the social and regulatory legitimacy of HRR. I therefore posit here that publicness is a strong basis for new normative claims to be formulated, as compared to existing approaches, in that it approaches the relationship between individual and collective interests in a way that, until now, has been absent in HRR. This is not to deny that other approaches also do so, but there is a novelty here in that publicness seeks to engage a fuller range of values and interests that are in play. In this respect, it can be argued that publicness might have a stronger claim to grounding normative claims on a more solid basis.

A point worthy of clarification here is that the normative force of publicness is not derived from any one of the existing concepts that have been considered in this Chapter – namely the public interest, social value and social licence. Rather, the tripartite framework of analysis that operationalises publicness has been deployed in order to evaluate these concepts and to identify areas where they may manifest certain features of publicness. Indeed, my analysis suggests that in this respect these existing concepts are both limited and limiting.

Consideration of this task of evaluation also brings us neatly to consideration of the use of publicness qua the foundation for a framework of analysis, which directs attention to relationality, temporality and accountability. Here the normative force of publicness is more explicit, in that this tripartite framework draws attention to three specific features that, I argue, are inherent to a publicness-informed approach, and require attention if the interrelationship of individual and collective interests in HRR is to be centred. As such, and on the basis of the argumentation I have delivered thus far in this thesis, this framework for analysis provides more concrete guidance on how publicness should be operationalised in HRR in a normative sense. The language of ‘should’ used here is deliberate. The analysis that reveals these three features is grounded on a view of publicness that seeks to engage with a wider range of values and interests than occurs at present. As such, there are arguably good and better reasons to pursue the totality of interests in ways that embrace the richness and range of those interests. It is an overt normative claim that these three features are best positioned to promote this. As such, the view of publicness offered in this thesis helps us to move beyond what already exists in the current HRR landscape. This is a claim that I will explore further through the application of publicness, as the foundation for a framework of analysis, to the examination of (i) imagined futures and homogenous publics in Chapter 4; (ii) the public interest in Chapter 5; and (iii) a contemporary example of data intensive innovation in Chapter 6.

Conclusion

In this Chapter I have argued that existing conceptual approaches are limited and limiting, in that these are not sufficient to fully enact publicness in HRR; rather an examination of each, using publicness as the foundation for a tripartite framework for analysis, reveals that these each only capture some aspects of this concept. Thus, the claim is made that a robust conceptualisation of publicness is necessary to provide a common means to facilitate meaningful interdisciplinary conversations about what is at stake in HRR. This discussion illustrates that publicness serves two purposes: first it helps us to understand better the nature and role of existing mechanisms within HRR, and second, it provides a solid theoretical and practical basis to move beyond what already exists in the sub-optimal HRR ecosystem. Each of these claims are explored further in Part II of this thesis.

Recap and introduction to Part II

In Part I of this thesis, I began by considering ***how the interrelationship between individual and collective interests is understood in HRR at present***. I have traced how regulation has sought to engage with each of these interests, and identified a turn towards a more nuanced understanding of how they relate over time. However, I have argued that the fundamental idea that emerges from this analysis – that there is something about the quality of human health research that is focused on realising and promoting collective interests that builds on, but also goes beyond, the protection of individuals who contribute that that research - is not adequately captured by the either/or terminology of ‘individual or collective’ and ‘private or public’ interests. These reflections have led me to consider how the new concept of publicness could assist, in circumstances where this thesis seeks to engage with the multiplicity of ways in which decisions about the conduct of health research might impact on our lives. I have approached the introduction of this new concept with caution. In particular, I have used the ‘threshold concept’ framework to demonstrate the potential for the concept of publicness to elucidate the complexities of the interrelationship between individual and collective interests, and therefore to facilitate interdisciplinary discussions about how this might be operationalised in order to optimise HRR.

This conceptual work has led to further consideration of ***the extent to which publicness is currently operationalised in the HRR ecosystem, and what this might tell us, both about existing concepts in HRR, and about publicness itself?*** As such, I have used publicness as the foundation for an analytical framework in order to interrogate three existing concepts: the public interest, social licence and social value, which are often used interchangeably and/or in close proximity to one another. By using the three facets of publicness as the basis for a diagnostic framework, my analysis has revealed the strengths and limitations of these approaches and shed light on their functions, both individually and in relation to one another. This discussion has also elucidated a stronger sense of the breadth of publicness itself, and the work this can do to facilitate interdisciplinary conversations and add value to existing concepts.

Publicness as a broad concept has both shaped, and been shaped by, the analysis that has been delivered so far. This necessitates a revision of the working definition that was first proposed in Chapter 2. In addition to the three features that publicness directs our attention towards, the analysis in Chapter 3 has also highlighted the diagnostic and normative value this brings to HRR, as captured in **Table 10**.

Table 10: A (revised) working definition of publicness in HRR

Publicness is a concept used to describe the interrelationship between collective and individual interests, thereby drawing attention to the context in which this interplay takes place, as well as the implications of the interrelationship between individual and collective interests for HRR, both now and in the future.

Publicness also provides the foundation for a framework of analysis that directs attention to:

- **Relationality:** the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness, therefore moving away from oppositional ways of thinking about the interests at stake;
- **Temporality:** temporal aspects of these interests in health research, including how these may change over time;
- **Accountability:** how these interests can be accounted for when decisions are made about what, whether, how and with whom health research is conducted.

In this way publicness performs a diagnostic and normative role in that it:

- helps us to understand better the nature and role of existing mechanisms within HRR;
- provides a theoretical and practical basis to move beyond what already exists in the sub-optimal HRR ecosystem

In Part II, I will therefore build on this conceptual foundation in order to explore three different types of contribution that can be made by publicness, as set out in Chapters 4, 5 and 6. In Chapter 4 I begin by considering ***the ways in which publicness can help us to better understand and to enrich aspects of the HRR ecosystem***. More specifically, I explore (1) the temporal implications of regulating individual and collective interests over time and (2) engagement with varied and diverse publics in HRR. In Chapter 5, I turn to an analysis of ***how publicness can facilitate an examination of the public interest as a regulatory device in HRR***. Here I will show how publicness can help to reconceptualise the public interest, with a focus on the intersection the public interest and extra-legal insights provided by empirical evidence. Finally, in Chapter 6, I will apply the preceding analysis to a contemporary case study in relation to data sharing arrangements between public and private collaborators. In this way I will identify potential ways to optimise HRR by both elucidating ‘lessons learned’, and also through the identification of positive steps that can support future data-sharing initiatives and therefore better account for a publicness-informed approach to HRR.

Part II

Chapter 4: Optimising the HRR ecosystem: Using publicness to explore imagined futures and homogenous publics

Introduction

In this Chapter, I consider two interrelated ways in which publicness can flesh out and enrich the HRR ecosystem through consideration of (1) the temporal aspects of regulating individual and collective interests over time and (2) the mutability and diversity of and within publics in HRR. The analysis in Part I, through the lens of publicness, highlights these both as areas where the optimisation of HRR may be stymied in circumstances where the full range of interests in play, and how these are accommodated throughout the research lifecycle, are overlooked. Here I use publicness to maintain this focus on the relationship between individual and collective interests in the health research endeavour and how these may change over time, and to deepen and extend this analysis.

Both of the issues considered in this Chapter are relevant considerations across the HRR landscape but are examined here in the context of data-intensive health research. As described in Chapter 1, this type of research is typically conducted at scale, often involving data that were originally collected for routine purposes at a large group or population level. Whereas in traditional ‘hands-on’ clinical research there may be a direct relationship between those conducting and participating in research, the scientists or clinicians involved in data-intensive research are unlikely to have contact with those whose data are used.³²⁶ This creates a potential disconnect between ‘science’ - meaning those actors engaged in conducting research - and ‘society’, in the sense of those who are impacted by this research. At the same time, people and publics remain central to the research process, both as the essential source of the data used, and as users of health systems that are informed by outputs from health research more widely.³²⁷

This Chapter proceeds as follows. First, I consider the challenge of regulating individual and collective interests over time, and then the related issue of engagement with multiple and diverse publics. Using publicness as a lens, I draw out several challenges that each of these

³²⁶ Hobbs and Tully (n 52); Aitken and others, ‘Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research’ (n 50).

³²⁷ Aitken and others, ‘Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research’ (n 50) 1; also drawing on Wenner’s argument here, as explored in Chapter 3, that essentially all research is directed at changing health systems that none of us can effectively ‘opt out’ of.

features pose for HRR. The first is the creation of what I refer to as imagined futures. Here I do not use ‘imagined’ in the sense that such futures cannot, or will never, come to be true – rather the expression is used to denote that these are not certainties, but rather expected or hoped for outcomes. This, in turn, has implications for regulatory decisions that are made on this basis. As I go on to argue below, reliance on imagined futures may be problematic in circumstances where this informs *ex-ante* decisions, such as those made by a data access committee or research ethics committee, which are neither reviewed nor revisited. This may be compounded by the second and related challenge I identify, viz. when prospective decisions are made on the basis of a homogenised conception of *who* the stakeholders are who are to be engaged, and the *multiple perspectives* they may have on what socially legitimate research looks like. In the second part of this Chapter I therefore consider how publicness can provide a new perspective on conceptions of publics in the context of the regulation of data-intensive research. In relation to each of the challenges discussed in this Chapter, I delineate the distinctive contribution of publicness *per se*, and identify ways in which the HRR ecosystem can be enhanced.

Regulating individual and collective interests over time

Using publicness as the foundation for a framework for analysis, Chapter 3 paid particular attention to how this concept foregrounds the temporal aspects of interests in health research, and accounts for the individual and collective interests at stake in HRR over time. This, in turn, revealed different ways that existing concepts engage with time, and the uncertainty that is inherent in the conduct of research. This exercise highlighted that existing regulatory concepts, such as the public interest and social value, are predicated on the expected future harms and/or benefits of health research at the time at which decision(s) are made about whether and, if so, how research should be carried out. Conversely, the need to establish and maintain a social licence for health research is ongoing, albeit far from straightforward in the context of an intangible accordance with multiple and undefined parties. I have argued that to overlook these vital temporal aspects of regulation limits the extent to which the full potential of each of these concepts can be brought to bear throughout the research lifecycle. The role of publicness has, so far, been to bring these temporal considerations to the fore. In this Chapter I go further: publicness is used to deepen this analysis in order to identify concrete ways in which the HRR ecosystem can be enhanced. To do so, I bring together four bodies of literature – on regulatory space, liminality, law and time, and posthumous medical data donation (a novel governance structure which can facilitate the use of health data after death) in order to further develop the concept of publicness, and then apply this to move beyond conventional understandings of time in HRR.

The idea of ‘regulatory space’ is a well-established metaphor in the wider context of regulation. This has some synergies with publicness in that it moves away from an oppositional approach to what, in regulatory terms, are understood as public and private interests. Instead, regulatory space draws attention to the physical spaces in which regulation takes place, and the interactions between regulatory actors and the political and institutional contexts in which regulation is performed.³²⁸ In the context of economic regulation, Hancher and Moran’s seminal work identifies the main influences that bear on understandings of regulatory space as being: (1) place; (2) timing; and (3) organisational structure.³²⁹ In this way, their analysis pays attention, first, to the setting in which regulation takes place, and how this mediates the regulatory process. Second, they highlight the importance of historical timing, in the sense that times of crisis may be crucial to the development of regulation.³³⁰ Third, Hancher and Moran suggest that organisational structures, whether these are ‘labelled’ public or private (or, more likely, contain diverse features of each), are key to governing access to regulatory spaces and influencing how regulation takes place. While these three features are important to the conceptualisation of regulatory space, the role of time is particularly pertinent to the development of my argument. In particular, time is primarily understood by Hancher and Moran in historical terms thus:

‘The key analytical point is that understanding regulatory arrangements in the present depends on understanding the historical configuration out of which they developed’.³³¹

The idea of regulatory space has more recently been reimagined in the context of HRR using the concept of liminality.³³² The Liminal Spaces project, led by Laurie, drew on the work of the anthropologists Van Gennep³³³ and Turner.³³⁴ In this way:

‘Liminality challenges us to engage with the processual and experiential dynamics of research, including the ways in which practices, people, and entities are affected by regulation.’³³⁵

³²⁸ Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press 2007).

³²⁹ Leigh Hancher and Michae Moran ‘Organizing Regulatory Space’ (1989) excerpt in *ibid.*

³³⁰ *ibid.* This chimes with the point made in Chapter 3 in relation to social licence, that discord and scandals can reveal much about the interests that are in play, as I explore further in Chapter 7.

³³¹ *ibid* 67.

³³² Samuel Taylor-Alexander and others, ‘Beyond Regulatory Compression: Confronting the Liminal Spaces of Health Research Regulation’ (2016) 8 *Law, Innovation and Technology* 149.

³³³ Arnold van Gennep, *The Rites of Passage* (University of Chicago Press 1960).

³³⁴ Victor Turner, *The Ritual Process: Structure and Anti-Structure* (Cornell University Press 1969).

³³⁵ Taylor-Alexander and others (n 332).

With a focus on clinical research, this in turn directs attention to processual forms of regulation that:

‘Over time, recognises the flexibility and fluidity inherent to laboratory and clinical research;

In space, focuses on iterative interactions that adapt with new developments in science and medicine, as well as with changes in law and regulation; and

Through experience, reflects the complete investigative endeavour and is able, for example, to guide the different involved parties through the entire research process.’³³⁶

The temporal-spatial aspects of liminality are developed with reference to concepts, such as ‘boundary work’³³⁷ and ‘boundary objects’,³³⁸ as borrowed from Science and Technology Studies.³³⁹ By way of example, and drawing on Jasanoff’s work,³⁴⁰ the fluidity of the distinction between science and policy may be used by scientists to draw a distinct line around matters that are presented or treated as exclusive to science, in order to exclude non-scientist actors from participating.³⁴¹ Liminality has been used to highlight, amongst other matters, the liminality of people and things,³⁴² as well as the way that categories (or silos) of ‘subject’ and ‘object’ are created by the law to the detriment of HRR.³⁴³ In relation to time more specifically, liminal analysis has pointed to the ‘rigidity’³⁴⁴ of the prospective test for social value as a regulatory mechanism, in circumstances where, as discussed in Chapter 3, by definition this value may never be realised or revisited.³⁴⁵

In sum, notions of regulatory space and liminality both underline the relevance of temporality in HRR. In particular, liminality, with its focus on transformation as entities move through time and space, points to the ways that time can constrain the operation of regulatory mechanisms, and their application throughout the research life-cycle. The use of publicness as a lens which draws attention to temporality and relationality together, however, invites further scrutiny of the ways in which time, and the multiple interests engaged by the HRR endeavour, interact.

³³⁶ *ibid* 158.

³³⁷ Thomas F Gieryn, *Cultural Boundaries of Science: Credibility on the Line* (University of Chicago Press 1999).

³³⁸ Susan Leigh Star, ‘This is Not a Boundary Object: Reflections on the Origin of a Concept’ (2010) 35(5) *Science, Technology, & Human Values* 601.

³³⁹ Taylor-Alexander and others (n 332).

³⁴⁰ Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press 1990).

³⁴¹ Taylor-Alexander and others (n 332).

³⁴² *ibid*.

³⁴³ Catriona McMillan and others, ‘Beyond Categorisation: Refining the Relationship between Subjects and Objects in Health Research Regulation’ (2021) 13(1) *Law, Innovation and Technology* 194.

³⁴⁴ Taylor-Alexander and others (n 332) 174.

³⁴⁵ Emanuel and others (n 247); Wendler and Rid (n 258); Rid (n 45).

Therefore, just as liminality highlights the processual and the idea of time moving *through* the regulatory space, publicness leads us to ask how the multiple interests occupying that regulatory space might, and will, change *over* time, and therefore shape, and be shaped by, regulation. To understand this even more deeply, I draw on two further literatures on temporality in regulation, in relation to time and law, and then specifically in the context of posthumous medical data donation, in order to develop this understanding further.

The relationship between the law, time and temporality was the focus of the ‘Regulating Time’ project, led by Grabham and Beynon-Jones.³⁴⁶ They argue, drawing on Mawani,³⁴⁷ that often time is assumed to be a ‘natural’ backdrop to events, rather than problematised and critically analysed.³⁴⁸ This, they suggest, is curious in circumstances where the law is so often involved in the ‘production of time’.³⁴⁹ Examples of this may include:

‘...the temporal operation of precedent in common law, commencement dates and sunset clauses in legislation, and even through horizons of time created through legal doctrine and discourse (e.g. constitutional originalism, foreseeability in tort).’³⁵⁰

An illustration of this, outside of the HRR context, is provided by Keenan’s discussion of the role of land registration – that is a legal mechanism through which legal ownership of property can be passed from one person to another – as a fictional ‘time machine’. She argues, that: ‘Title registries operate on the basis of fictional accounts of land which portray it as a market commodity with a short and entirely contained history’.³⁵¹ In particular, she points to the temporal dislocation that arises between the land and those that have lived on this, and the registry users who benefit from the system. In relation to the colonial transfer of land in South Australia she finds that this creates:

³⁴⁶ As Grabham et al note in Emily Grabham and others, ‘Exploring Relationships between Time, Law and Social Ordering: A Curated Conversation’ (2018) 8(2) *feminists@law*: ‘The AHRC funded Regulating Time Network ran between 2015 and 2017 and was coordinated by Siân Beynon-Jones (Sociology, University of York, UK) and Emily Grabham. The intention was to create an interdisciplinary, international network of scholars to support collaborative research into law, regulation and time. Further information here: <https://www.kent.ac.uk/law/time/>.

³⁴⁷ Renisa Mawani, ‘Law As Temporality: Colonial Politics and Indian Settlers’ (2014) 4(1) *UC Irvine Law Review* 65.

³⁴⁸ Emily Grabham and Siân M Beynon-Jones, ‘Introduction’ in Siân M Beynon-Jones and Emily Grabham (eds), *Law and Time* (Taylor & Francis 2019).

³⁴⁹ *ibid* 1.

³⁵⁰ *ibid*.

³⁵¹ Sarah Keenan, ‘From Historical Chains to Derivative Futures: Title Registries as Time Machines’ (2019) 20(3) *Social & Cultural Geography* 283.

‘...racial-temporal categories of white subjects whose entitlement to land is transcendental, and non-white subjects whose entitlement to land is either confined to the past or to a future that never comes.’³⁵²

Likewise, in the context of medicines and the law, and in relation to her own examination of the regulation of traditional medicines, Cloatre advocates for careful examination of the role of time, and in particular the new realities that this may shape:

‘Paying attention to the question of time in legal movements and, in particular the idea that legal temporalities are productive of their own realities, enables us to see that attempts by law to engage with new therapeutic practices also reshape the very nature of those practices and their own alternative temporalities,’³⁵³

Taken together these accounts move temporal considerations beyond a matter solely of ‘historical timing’, as it is characterised by Hancher and Moran in relation to the metaphor of regulatory space, where context unilaterally shapes regulation. Instead, this more recent analysis suggests that law and regulation are also capable of shaping context – such as the interests that are engaged or overlooked by these structures - and creating their own horizons of time.

The new perspective that publicness brings to temporality in HRR can be illustrated in the context of data-intensive health research using the example of posthumous medical data donation (PMDD). In short, PMDD is a novel governance structure that is closely related to data philanthropy, whereby corporations or individuals donate data to be used by a range of actors, including researchers, for altruistic purposes.³⁵⁴ As envisaged by Krutzinna and Floridi,³⁵⁵ PMDD is intended to be a widespread undertaking whereby individuals can opt in, at some point in the lives, to donate their data for use after their death. PMDD bears some similarity to the current system of organ donation, though there are also significant differences that limit the use of this analogy, given that organs tend to be transplanted once, while the use and value of data can increase over time.³⁵⁶

³⁵² *ibid.*

³⁵³ Emilie Cloatre, ‘Traditional Medicines, Law and the (Dis)Ordering of Temporalities’ in Emily Grabham and Siân M Beynon-Jones (eds), *Law and Time* (Taylor & Francis 2019) 138.

³⁵⁴ Mariarosaria Taddeo, ‘Data Philanthropy and the Design of the Infraethics for Information Societies’ (2016) 374(2083) *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences*; Mariarosaria Taddeo, ‘Data Philanthropy and Individual Rights’ (2017) 27(1) *Minds and Machines* 1.

³⁵⁵ Jenny Krutzinna and Luciano Floridi, ‘Ethical Medical Data Donation: A Pressing Issue’ in Jenny Krutzinna and Luciano Floridi (eds), *The Ethics of Medical Data Donation* (Springer International Publishing 2019).

³⁵⁶ Sorbie, ‘Medical Data Donation, Consent and the Public Interest After Death’ (n 109).

When viewed through the lens of publicness, two key interrelated features that arise from this initiative are those of time and interests. Together these create a temporal disjuncture (akin to the temporal dislocation described by Keenan),³⁵⁷ as I have described elsewhere:

'[In PMDD], the consent of live data donors' to the posthumous collection and use of their data is held in stasis at the point they die. This is so because there is, self-evidently, no scope to go back to the deceased donor to provide *any* information about how their data will be used, or by whom. This static consent can be contrasted with the use and value of the data provided by the donor, which proliferates over time and might be used for a multitude of research projects by a range of stakeholders in the public and commercial sectors. Given that consent to donation may come at any time prior to death, there is a considerable temporal disjuncture between the giving of consent and the use of the data; this even includes the act of collecting the data (to say nothing of its subsequent use in research) because these events will likely take place many years later. Further... it is probable that, both due to the passage of time and the breadth of the information contained within a donor's PMR, the data collected will subsequently be used in ways that simply cannot be anticipated at the point of consent. This practical reality underscores the impact of the temporal aspect of PMDD governance, where the necessarily static interaction with the (dead) donor, through the medium of consent, contrasts starkly with the continuing use of the data itself. Indeed, the subject – namely the donor – is *never* temporally co-located with the object of use – the donor's data – given that this is only collected and used for research once the subject is no more.'³⁵⁸

Here publicness draws attention to how, in the context of PMDD, these temporal considerations have direct implications for the range of interests that may be taken into account by regulatory structures. For example, a regulatory device, such as informed consent, is not only limited temporally, as described above, but the focus on the individual living donor fails to take into account the variety of interests at play. For example, PMDD could impact not only on any interests of the deceased donor that continue after death,³⁵⁹ but also on the interests of the living who are left behind, such as the donors' children or other relatives, as well as wider publics. This is particularly the case where, as noted by Krutzinna et al, health data is unlikely to relate solely to a single individual,³⁶⁰ and where there may be unanticipated future uses of the data for public benefit, long after a donor's death. As such, when temporality

³⁵⁷ Keenan (n 351).

³⁵⁸ Sorbie, 'Medical Data Donation, Consent and the Public Interest After Death' (n 109).

³⁵⁹ Daniel Sperling, *Posthumous Interests: Legal and Ethical Perspectives* (Cambridge University Press 2008).

³⁶⁰ Jenny Krutzinna and others, 'Enabling Posthumous Medical Data Donation: An Appeal for the Ethical Utilisation of Personal Health Data' (2019) 25(5) *Sci Eng Ethics* 1357.

and relationality are examined together this draws out the interplay between these facets of publicness.

The preceding discussion therefore brings me to a key contribution of publicness, which highlights how perceptions of time may be tied to particular interests, and *vice versa*. As well as pointing to the rigidity of HRR, as identified by the Liminal Spaces project, the perspective provided by publicness draws out further tangible ways that conceptions of time can impact on the interests that are recognised by HRR, and those that are included and excluded. This scrutiny of the *multi-directional interaction of time and interests in HRR* reveals how an imagined future is created by regulatory structures where research is expected to deliver public benefits and/or to have social value which may (or may not) come to pass. In circumstances where such decisions are made on the basis of the hypothetical 'reasonable man',³⁶¹ this imagined future therefore informs *ex-ante decisions*, made on the basis of a homogenised conception of *who* the stakeholders are in this scenario, and the *multiple perspectives* they may have on what socially legitimate research looks like – all assessed at a fixed point in time. However, to consider time and publicness together requires that we must constantly keep under review whether that imagined future bears any relation to evolving reality, as research unfolds, as well as the range of interests that are actually at stake.

The example of PMDD underlines that the regulation of data-intensive health research is undoubtedly put under strain in circumstances where the proliferation of data over time exacerbates issues in relation to its governability. Current understandings of HRR recognise the relevance of temporality to HRR in different ways, as outlined above, although time is too often characterised merely as part of the historical backdrop against which regulation takes place. In contrast to this conventional approach, publicness (which draws attention to both temporality and relationality):

- demands further scrutiny of the *multi-directional interaction* of time and interests in HRR;
- reveals that not only can time and context shape regulation, but that law and regulation are also capable of shaping context and creating horizons of time, which has implications for who is included and excluded by regulatory structures;
- challenges the tendency of HRR to narrow the range of interests that are taken into account, and therefore to overlook wider collective interests that build on, but also go

³⁶¹ This was illustrated in Chapter 3 by the tendency of the law to rely on the hypothetical 'reasonable man' or 'man on the top of the Clapham Omnibus' as the legal barometer of what members of the public would expect in different circumstances.

beyond, the protection of individual interests, especially as these might develop *over time*.

While the tendency of the law and regulation is to prefer an approach that is neat and conclusive, the analysis in this Chapter requires that we consider new solutions that engage with the messy complexities of ever-changing context and reality. In particular, the preceding discussion highlights how HRR creates imagined futures, which have the potential to impact both on the legitimacy of decisions made about research *ex-ante*, and the ability to build in learning to systems of regulation. This creates a disconnect from the people and publics whose (public) interests³⁶² or (social) values are at stake. Further, it limits the ability of HRR both to respond to the uncertainties inherent in health research, and also to learn from the ways in which these may become clearer over time, as research is carried out and the interests at stake become more fixed through action. This is exacerbated in circumstances where it is not only possible, but expected, that new and unanticipated findings will emerge from health research, and where the environment in which health research and data sharing takes place is in constant flux. The use of health data during the Covid-19 pandemic to manage the spread of the outbreak provides a recent and high profile illustration of the potential for there to be sudden and (to some extent) unanticipated³⁶³ changes in the data sharing landscape.³⁶⁴ It therefore remains to be seen how increased levels of data sharing during this period may impact on publics' attitudes towards the regulation of data going forward, both in pandemic and non-pandemic environments. This provides an example of a future that was, for many, *not* imagined, but rather unimaginable.

What, then, is to be done in circumstances where regulation creates a static 'horizon of time' that contrasts sharply with the dynamic nature of research and society? Put another way, what might a 'learning health research regulation system'³⁶⁵ look like, which can account for publicness, in the sense that this recognises the *multi-directional interaction of time and interests*, in circumstances where the nature of those interests – and priorities given between them – may also shift within any given timeframe?

Vayenna and Blasimme have argued that 'adaptive governance' is particularly suitable for the governance of big data health research, given the fast pace of developments in technoscience,

³⁶² University of Edinburgh and others (n 235).

³⁶³ Philippe J Sansonetti, 'COVID-19, Chronicle of an Expected Pandemic' (2020) 12(5) EMBO Molecular Medicine e12463.

³⁶⁴ 'Template: COVID-19 Privacy Notice' (NHS Transformation Directorate, 17 September 2020) <www.nhs.uk/information-governance/guidance/covid-19-privacy-notice/> accessed 16 March 2022.

³⁶⁵ Graeme Laurie, 'Afterword' in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021).

the multiple actors engaged and the lack of a single shared research culture.³⁶⁶ Adaptive governance can be understood as a framework that can respond to the demands of the object – in this case data - that it is designed to govern.³⁶⁷ The authors advocate for a principles-based approach to regulation and the ‘AFIRRM’ framework, which incorporates: Adaptability, Flexibility, Inclusivity, Responsiveness, Reflexivity and Monitoring.³⁶⁸ A key feature, which cuts across each of these six principles, is the idea of ‘social learning’, through the gathering of new evidence, the review of outcomes or periodic policy revisions.³⁶⁹ Similarly, Laurie suggests that a key component of a learning health research regulation system should be the: ‘[e]xistence of, and where appropriate closing of, regulatory feedback loops to deliver authentic learning back to the system and to its users’.³⁷⁰ In relation to data access specifically, Banner proposes a reflexive approach when applications are made to access data ‘in the public interest’ – for example to the HRA’s Confidentiality Advisory Group, as described in Chapter 3. She suggests that rather than a ‘pipeline’ from data access to data use, a more cyclical approach is adopted, with two specific features:

- ‘ 1. When data is accessed and used, the outcomes (whether positive, negative, null or unsuccessful) are reported back to inform future data access decisions.
2. A public/participant panel scrutinises previous data access decisions and their outcomes. It uses these insights to provide feedback, advice and recommendations to the access group or committee, to inform their future decision-making.’³⁷¹

The aim of this public/participant panel would be ‘...to contribute to the access group’s future criteria and decision-making’.³⁷² In particular, it is suggested that the type of question that a public/participant panel might ask could include:

‘Did we ask the right questions of the data applicants?’

What (or who) is missing from our decision-making process?’

³⁶⁶ Effy Vayena and Alessandro Blasimme, ‘Towards Adaptive Governance in Big Data Health Research’ in Agomoni Ganguli-Mitra and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021).

³⁶⁷ *ibid*; See also Kieran C O’Doherty and others, ‘From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks’ (2011) 73 *Social Science & Medicine* 367.

³⁶⁸ Vayena and Blasimme (n 366) 261.

³⁶⁹ Vayena and Blasimme (n 366).

³⁷⁰ Laurie (n 365) 399.

³⁷¹ Natalie Banner, ‘A New Approach to Decisions about Data’ (*Understanding Patient Data*, 2020) <<http://understandingpatientdata.org.uk/news/new-approach-decisions-about-data>> accessed 4 February 2022.

³⁷² *ibid*.

How should the outcomes of previous projects inform our future thinking on potential risks and benefits from proposals to use data?

What could help us make better decisions for future applications?³⁷³

Each of these proposals resonates with the concept of publicness that has been proposed thus far in this thesis, which challenges the tendency of HRR to narrow the range of interests that are taken into account. For example, the high-level principles of the AFFIRM approach to health research using Big Data requires, amongst other attributes, that governance should be able to adapt over time to new evidence.³⁷⁴ Both Laurie and Banner call for the incorporation of feedback loops whereby learning can be delivered back into systems of HRR. Further, Banner provides an example of how, in the context of data access decisions, opportunities can be created for greater and more meaningful input from stakeholders that can improve decision-making. However, as well as endorsing such approaches, appealing to publicness can help us to go further in the development of accounts of data-intensive research. I illustrate this next by responding to Banner's proposal for managing data access requests that are made in the public interest, and by pointing to how this this can be augmented using publicness.

A key strength of the model proposed by Banner is that: 'Public views and values are embedded in a cycle of decision-making but remain external to it and hold the decision-makers to account.'³⁷⁵ This approach has the potential to address some of the temporal issues related to the creation of an imagined future that have been outlined above, in circumstances where research is expected to be in the public interest, and public benefits are anticipated, but where these may (or may not) come to pass. Using the analysis of temporality offered above, as developed in the context of publicness, the use of feedback loops can be characterised as a way of mitigating the impact of time seen only as an historical backdrop (i.e. the fixed point at which a decision is made) on how health research is regulated (i.e. on the basis of prospective, *ex-ante* decisions, that may or may not come to pass). Banner's model meets this challenge by providing a mechanism to review and provide feedback on past data access decisions in order to provide information that can be used to inform decisions taken in the future, for example by identifying instances of 'hype and overpromise'.³⁷⁶

However, publicness also demands further scrutiny of the *multi-directional* interaction of time and interests in HRR. This reveals that not only can time and context shape regulation (as in

³⁷³ *ibid.*

³⁷⁴ Vayena and Blasimme (n 366) 258.

³⁷⁵ Banner (n 371).

³⁷⁶ *ibid.*

the example above of prospective decision-making) but that law and regulation are also capable of shaping context and creating their own horizons of time, where some interests are foregrounded at the expense of others. Any such status quo should not be left unquestioned and publicness provides us with a means to do so. In other words, whereas feedback loops can address temporality in one sense, consideration of publicness underlines that dynamic decision-making in health research, that embeds patient and/or publics views, may still be constrained by its pre-existing regulatory context. An example of this is provided above in relation to PMDD, where a regulatory focus on the *consent* of the individual living donor limits the extent to which other relevant interests can be taken into account, and how these may change over time. In the context of decisions about data access that are *not* based on consent, but rather made *in the public interest*, this brings our attention to a different regulatory device. However, as set out in Chapter 3, I have pointed to several ways in which the public interest may also operate to limit the extent to which the full range of interests engaged by data-intensive research can be taken into account, as well as how these may change over time. This could be in circumstances where public interest decisions are made at fixed points in the research or data lifecycle, as in the example given by Banner above. However, my analysis also identifies further ways that the public interest could operate sub-optimally with regard to its antagonistic framing of the interests at stake in HRR, and its tendency towards a self-referential approach to the views of diverse publics, when these are reduced to the judicial construction of a fictional 'reasonable man' or a 'reasonable public'. These are concerns that may not be fully addressed by Banner's proposal, where the regulatory *status quo* is preserved. An appreciation of publicness in HRR therefore suggests that it may be necessary not only to revisit *decision-making processes*, but also to review the *regulatory structures and devices* that shape those decisions. In other words, while it is important to take steps to actively engage with publics' views and values, and for these to impact on how decisions are made about future data usages, publicness also requires that we scrutinise how familiar aspects of the HRR landscape may facilitate or restrain how these are brought to bear on how HRR is conducted over time. A prime candidate for review in this respect is the notion of the public interest – as I come to in Chapter 5. In these various ways, publicness teases out the complexities of the multi-directional interplay between time, on the one hand, and the interests that are engaged or overlooked by HRR, on the other. This re-framing of a familiar aspect of HRR helps to identify how specific proposals can help to optimise HRR, but also sheds new light on the wider context within which these are delivered.

HRR and engaging with the diversity of and within publics

My consideration thus far of the regulatory challenges posed by reliance on imagined futures in HRR has suggested, but not yet unpacked, that this may be compounded by a second and related challenge. This is where prospective decisions are made on the basis of a homogenised conception of *who* the stakeholders are who are to be engaged, and the *multiple perspectives* they may have on what socially legitimate research looks like. This consideration further resonates with my analysis in Chapter 3, as elaborated above, where publicness highlights the tendency of existing regulatory approaches in HRR, such as the public interest, to flatten conceptions of the public to the views of the ‘reasonable person’.

In the remainder of this Chapter I do not attempt to address these matters wholesale – as I come to below, the question of how to ‘do’ the many and varied activities that come under the umbrella of public engagement and involvement (PE&I)³⁷⁷ is well outside of the scope of this thesis. However, I do seek to explore the ways in which publicness can provide a new perspective on the diversity of and within publics in the regulation of data-intensive research. This can, I believe, provide a first step, from a legal and regulatory perspective, towards the complex and interdisciplinary task of bridging the gap between outputs from PE&I activities, and the incorporation of these into HRR frameworks. This is in circumstances where Stilgoe et al argue that: ‘The legitimacy of public engagement does not just depend on its inputs, but also on its outputs, in particular its impact on governance.’³⁷⁸ The contribution I make is in no way a silver bullet, and indeed it might only be modest, but there is nonetheless value in considering where and how appeals to publicness can assist these processes.

I have already claimed that publicness draws our attention to the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness. However, the discussions in this Chapter have further emphasised that publicness requires that we look beyond a homogenised conception of *who* ‘the public’ are in data-intensive research and consider the *multiple perspectives* that people may have on what socially legitimate research looks like. In circumstances where there is a tendency in HRR to narrow the range of interests that are taken into account, I argue that the lens of publicness draws our attention to the heterogeneity and mutability both *of and within* publics.

I approach this task by first outlining why notions of ‘the public’ are a particular concern in the context of data-intensive research, with reference to what has been termed: the ‘problem of

³⁷⁷ I use PE&I as an abbreviation here, but draw on my summary of the differences between engagement and involvement activities as set out in Chapter 3.

³⁷⁸ Jack Stilgoe and others, ‘Why Should We Promote Public Engagement with Science?’ (2014) 23(1) Public Understanding of Science 4, 6.

stakeholdership'.³⁷⁹ I then borrow from literature around the conduct of PE&I in order to provide a more nuanced conception of publics. Next, I return to publicness, and in particular to how its focus on the relationality of interests in HRR, can enhance these accounts. This leads to consideration of the literature on intersectionality, which was briefly introduced in Chapter 1. Finally, I revisit Banner's model of a learning data governance model,³⁸⁰ in order to illustrate some of the implications of the preceding discussion for HRR.

Data-intensive research, which uses data from large cohorts of people or populations, '...presents challenges about whom to engage and whether, or how, PI&E should reach everyone whose data are used in health ecosystems'.³⁸¹ This stubborn issue is identified by Taylor and Purtova as 'the problem of stakeholdership'.³⁸² They explain that this 'problem' (I come to the shortcomings of this terminology below) relates to difficulties in defining *who* is affected by the conduct of, and outputs from, data science, and therefore who should be involved in decisions around governance.³⁸³ Reasons that Taylor and Purtova offer for this include that people are unaware that their data are being used or that they are being impacted by data-driven decisions, as well as the scale at which data are used, often across institutions and national borders.³⁸⁴ Temporality is also invoked in that:

'This problem of stakeholdership is further complicated by the dimension of time: as more datasets become available data's utility will grow, and the larger the pool, the more detailed the analysis. Thus increase in value will be in inverse proportion to data's governability. As data is shared for new purposes, understanding of who the stakeholders are will decrease over time. Data may also be de-identified, making the task of identifying individual stakeholders difficult but nevertheless enabling data-driven decision making through creation and application of profiles.'³⁸⁵

This quote starkly illustrates the juxtaposition of the widespread impact of data-driven research with the tendency of HRR to narrow the range of interests that are taken into account. As I have established above, publicness encourages us to consider the issues of temporality and relationality together, and to recognise and challenge any such narrowing. However, this

³⁷⁹ Linnet Taylor and Nadezhda Purtova, 'What is Responsible and Sustainable Data Science?' (2019) 6 *Big Data & Society* 1.

³⁸⁰ Banner (n 371).

³⁸¹ Aitken and others, 'Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research' (n 50).

³⁸² Taylor and Purtova (n 379) 4.

³⁸³ Taylor and Purtova (n 379).

³⁸⁴ *ibid.*

³⁸⁵ *ibid.*; Linnet Taylor and others, 'Introduction: A New Perspective on Privacy' in Linnet Taylor and others (eds), *Group Privacy: New Challenges of Data Technologies* (Springer International Publishing 2017).

leaves open the question of whether and, if so, how, analysis through the lens of publicness can contribute to a better understanding of the diversity of and within publics in this context, that moves beyond the homogenisation of ‘the public’ writ large. This is the question I focus on in the remainder of this Chapter.

This drive towards a deeper understanding of how publics are imagined in relation to science and engagement activities is not, of course, a new consideration. I therefore borrow from PE&I literature to explore this topic, while recognising that this is an area where the path from ‘good intentions’ to meaningful and effective implementation is neither linear nor certain.³⁸⁶ Indeed, common criticisms of attempts to engage with and involve publics include ‘...questions of representativeness, articulation, impacts and outcomes’,³⁸⁷ and poorly conducted PE&I activities risk exclusivity and tokenism.³⁸⁸ Detailed discussion of how to avoid these pitfalls in order to do ‘good’ PE&I, falls outside of the scope of this thesis. Instead, I focus on conceptions of publics in the regulation of data-intensive research, and how an appreciation of the mutability and diversity of and within publics can enhance HRR in this context.

As Chuong and O’Doherty note,³⁸⁹ Beresford traces the rise of mainstream interest in ‘user involvement’ in research since the 1990s, and identifies two distinct approaches to involvement, namely the consumerist and democratic approaches.³⁹⁰ The former is market driven and associated closely with the political right leaning ‘individual rights and choice’³⁹¹ agenda, whereas the latter prioritises inclusion and collective action, highlighting ‘...issues of power and the (re)distribution of power’.³⁹² As discussed in Chapter 1, an example of this is the social movement that shifted the relationship between people with HIV/AIDS and the production of biomedical knowledge.³⁹³

Over a similar period changes can also be seen in the relationship between science and society, in the move away from a deficit model of PE&I and towards more dialogical

³⁸⁶ Stewart (n 310); Annie Sorbie, ‘Sharing Confidential Health Data for Research Purposes in the UK: Where Are “Publics” in the Public Interest?’ (2020) 16 *Evidence & Policy: A Journal of Research, Debate and Practice* 249.

³⁸⁷ Stilgoe and others (n 378) 5–6.

³⁸⁸ Josephine Ocloo and Rachel Matthews, ‘From Tokenism to Empowerment: Progressing Patient and Public Involvement in Healthcare Improvement’ (2016) 25 *BMJ Qual Saf* 626.

³⁸⁹ Kim H Chuong and Kieran C O’Doherty, ‘Participatory Governance in Health Research’ in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021).

³⁹⁰ Peter Beresford, ‘User Involvement in Research and Evaluation: Liberation or Regulation?’ (2002) 1 *Social Policy and Society* 95.

³⁹¹ *ibid* 96.

³⁹² *ibid* 97.

³⁹³ Epstein (n 42).

approaches.³⁹⁴ In short, the deficit model presumed that a lack of knowledge by non-scientific publics drove misunderstandings and disputes over science, which can therefore be remedied by one-way transmissions of knowledge.³⁹⁵ In the late 20th century this approach was increasingly challenged,³⁹⁶ for example by Wynne's seminal study of the response by sheep farmers in the Lake District to scientific advice in relation to the impact of the Chernobyl disaster on their livestock.³⁹⁷ Rather than attributing farmers' distrust of science to their ignorance, his ethnographic work drew out the cultural and historical context of this interaction, and the assumptions that shaped the scientific knowledge imparted, including that 'local lay knowledge was effectively worthless'.³⁹⁸ A UK House of Lords Report in 2000 subsequently signalled a 'new mood for dialogue' between science and society.³⁹⁹ This led to a participatory turn that includes features such as recognition of the value of cultural and experiential knowledge as well as scientific knowledge,⁴⁰⁰ and 'upstream' two-way engagement that can inform innovation as well as its impacts.⁴⁰¹ This increased emphasis on the value of lay and experiential knowledge⁴⁰² is reflected institutionally through RRI initiatives that emphasise the need for societal actors, including citizens and researchers, to collaborate throughout the research process.⁴⁰³ Nonetheless, and despite these aspirations, Stilgoe, Lock and Wilsdon note that:

'The move from 'deficit to dialogue' is now recognised and repeated by scientists, funders and policymakers. Social scientists and engagement practitioners have also announced this move, for reasons that are sometimes analytical and sometimes rhetorical. But for all of the changing currents on the surface, the deeper tidal rhythms of science and its governance remain resistant.'⁴⁰⁴

³⁹⁴ Kathrin Braun and Susanne Schultz, "'... a Certain Amount of Engineering Involved": Constructing the Public in Participatory Governance Arrangements' (2010) 19 Public Underst Sci 403.

³⁹⁵ Matthew C Nisbet and Dietram A Scheufele, 'What's next for Science Communication? Promising Directions and Lingering Distractions' (2009) 96 Am J Bot 1767; Cathelijne M Reincke and others, 'From Deficit to Dialogue in Science Communication' (2020) 21(9) EMBO reports e51278.

³⁹⁶ Alan Irwin, 'From Deficit to Democracy (Re-Visited)' (2014) 23(1) Public Underst Sci 71.

³⁹⁷ Brian Wynne, 'Misunderstood Misunderstandings: Social Identities and Public Uptake of Science' in Alan Irwin and Brian Wynne (eds), *Misunderstanding Science?: The Public Reconstruction of Science and Technology* (Cambridge University Press 1996).

³⁹⁸ *ibid.*

³⁹⁹ Science and Technology Committee, *Science and Technology - Third Report (HL 1999-2000, 23 February 2000)* <<https://publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3801.htm>> accessed 16 March 2022.

⁴⁰⁰ Reincke and others (n 395).

⁴⁰¹ Brian Wynne, 'Public Engagement as a Means of Restoring Public Trust in Science--Hitting the Notes, but Missing the Music?' (2006) 9(3) *Community Genet* 211.

⁴⁰² Stilgoe and others (n 378).

⁴⁰³ *Horizon 2020* (n 25).

⁴⁰⁴ Stilgoe and others (n 378) 5.

The discussion so far (albeit in brief and incomplete from a socio-historical perspective) is sufficient for the purposes of this thesis to serve as the backdrop to current understandings that, as summarised by Aitken and Cunningham-Burley: ‘On the whole, publics are constructed or ‘come into being’ within [public engagement] practices rather than being self-forming.’⁴⁰⁵ This disrupts the idea that ‘the public’ (or indeed different types of publics) exist in the world as pre-formed entities and suggests instead that:

“The public”... is never immediately given but inevitably the outcome of processes of naming and framing, staging, selection and priority setting, attribution, interpellation, categorisation and classification.⁴⁰⁶

Aitken and Cunningham-Burley point to the work of Braun and Schultz who have developed a typography of four dominant constructions of the public in the context of formal deliberation processes relating to the conduct of genetic testing in the UK and Germany.⁴⁰⁷ This provides an example of the ‘naming and framing’ process referred to above, and results in the identification of four ‘ideal’ types of publics, which are each described in relation to different modes of public engagement. These are: ‘the general public, the pure public, the affected public and the partisan public’.⁴⁰⁸ In summary, the ‘general public’ are often constructed through polls and surveys. Their input is used to supply knowledge about people’s thoughts and feelings, which is then weighed up by experts, as opposed to directly fed into political decision making.⁴⁰⁹ The ‘pure public’ more commonly appear in the context of citizen juries and citizen and youth conferences, where participants are identified as individuals, as opposed to representatives of bigger groups. Braun and Schultz suggest that these publics are chosen because of their lack of knowledge of the subject matter, and their openness to being educated.⁴¹⁰ The ‘affected public’, for example patients who have a particular disease type, may be recruited to consultative panels and are ‘...considered first hand experts of being affected, directly or indirectly, by a ... disorder; capable of providing a sort of expertise that no other type of experts could provide.’⁴¹¹ And, finally, the ‘partisan public’ are seen as organisations, rather than individuals, who hold strong opinions, such as lobbyists or special interest groups.⁴¹² It is noted that these publics may be held in less high esteem than ‘pure’ publics and used as a resource to gather what are seen as existing and fully formed opinions

⁴⁰⁵ Aitken and Cunningham-Burley (n 313) 117.

⁴⁰⁶ Braun and Schultz (n 394) 406.

⁴⁰⁷ Aitken and Cunningham-Burley (n 313); Braun and Schultz (n 394).

⁴⁰⁸ Braun and Schultz (n 394) 405.

⁴⁰⁹ *ibid* 408–09.

⁴¹⁰ *ibid* 409–11.

⁴¹¹ *ibid* 411.

⁴¹² *ibid* 413.

that are already 'out there' in the world. These typologies help to understand how different publics, whose interests are being represented, may be constructed by various modes of PE&I and, crucially, the impact this may have on who is, and is not, heard. They also underline the limitations inherent in all PE&I activities where:

'...no form of participation, whether informal or formal, government-sponsored or initiated by civil society, offers an unlimited variety of speaking positions from which participants can freely choose at any time, since there will always be formal or informal rules, expectations and conventions.'⁴¹³

These issues were recently scrutinised by international stakeholders in order to produce a consensus statement on PE&I with data-intensive health research.⁴¹⁴ This group found that there are good reasons for data-intensive health research to require 'special consideration' in relation to the scale of the data used, the potential gap between researchers and those whose data are used, to connect data use with public values and interests and to establish a social licence for the use of data in this way.⁴¹⁵ However, in contrast to the terminology of stakeholderhood as a 'problem', they note that:

'Our key premise is that the public should not be characterised as a problem to be overcome but a key part of the solution to establish socially beneficial data-intensive health research for all.'⁴¹⁶

In particular, the authors of the consensus statement propose a number of key principles for public engagement and involvement activities in this area. There are: '(1) have institutional buy in; (2) have clarity of purpose; (3) be transparent; (4) involve two-way communication; (5) be inclusive and accessible to broader publics; (6) be ongoing; (7) be designed to produce impact; and (8) be evaluated.'⁴¹⁷ While these principles are directed to the *conduct* of PE&I activities (which I do not directly address in this thesis), they also have resonance when considering how to *regulate* health research more broadly and manifest elements of publicness in the HRR ecosystem. For example, a number of the recommendations in the consensus statement – around dialogue and reflectivity over time - echo the points made above in relation to the need to account for temporality in HRR and integrate this into a learning governance system. Similarly, transparency – in relation to purpose, process and impacts –

⁴¹³ *ibid* 414.

⁴¹⁴ Aitken and others, 'Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research' (n 50).

⁴¹⁵ *ibid* 3–4.

⁴¹⁶ *ibid* 1.

⁴¹⁷ *ibid* 4–5.

and the use of evidence to make a difference are equally important in HRR, and themes I return to in Chapter 5, when considering the public interest as a regulatory device.

My analysis so far has borrowed from PE&I literature in order to provide a more nuanced conception of publics, which stands in contrast to those discussed in the context of existing approaches to, for example, the public interest, in Chapter 3. Yet, while the search for meaning around notions of ‘the public’ is an ontological question relating to *type*, the quality of publicness is an ontological question relating to *attribute*. In this respect consideration of publicness highlights at least three strengths of the conceptualisation of publics that has been developed so far. First, this directs attention to the value of lay and experiential expertise and the potential contribution of publics to improving HRR throughout the research lifecycle. In this way publics are part of the solution, rather than ‘the problem’, and have the potential to input upstream, for example on what and how research is conducted, as opposed to solely on the impacts of research, after the event. Second, this discussion highlights that there are different types of publics and, crucially, that these are usually constructed in the course of PE&I activities, rather than pre-existing in the world. As I come to below, this further raises questions in relation to those publics that have no voice or presence. Third, it has been suggested that where publics’ views are sought then careful consideration should be given to how this information is used in order to make an impact on the conduct and regulation of health research. Taken together the thrust of these observations accord with the use of the terminology of ‘publics’ (plural) in both policy and academic discourse, to indicate the existence of more than a singular and homogenous public.⁴¹⁸ However, despite the emphasis that the term ‘publics’ puts on the reality of multiple and different types of publics, arguably it too has become as abstract as the term it is designed to replace (i.e. the public).

In contrast, publicness pushes us further to consider not only the multiple and different types of publics that are at stake in HRR, but also the implications of the diversity that exists within and between these publics and what it means to have the attribute of ‘publicness’ itself. This is important in the context of data-intensive research in circumstances where, as implied by the quote from Taylor and Purtova at the start of this section, when data proliferate the tendency may be to fall back on a homogenised or faceless view of those whose data is used. As introduced in Chapter 1, a recent body of literature has specifically considered how intersectionality can be employed in the context of the conduct of health research. To recap, intersectionality is a way of thinking that draws attention to identities and power,⁴¹⁹ sameness

⁴¹⁸ Aitken and Cunningham-Burley (n 313).

⁴¹⁹ Abrams and others (n 7).

and difference.⁴²⁰ Abrams et al point to the wider applicability of this framework to health research on the basis that:

‘...insofar as intersectionality contends that all people are members of multiple social categories or groups, which contain a dimension of power or inequality, this framework is applicable to all groups.’⁴²¹

Hill Collins and Bilge conceptualise these relations as occurring within four domains of power, which in practice overlap. The structural domain ‘..refers to the fundamental structures of social institutions such as...education and health’.⁴²² The cultural domain ‘...emphasizes the increasing significance of ideas and culture in the organisation of power relations’.⁴²³ The disciplinary domain ‘refers to how rules and regulations are fairly or unfairly applied to people based on race, sexuality, class, gender, age, ability and nation, and similar categories’.⁴²⁴ The individual domain ‘...refers to how individuals experience the convergence of structural, cultural and disciplinary power’.⁴²⁵ In these ways intersectionality brings a ‘power-conscious lens’ that seeks to identify hidden as well as explicit power,⁴²⁶ and address inequality.⁴²⁷ These elements of intersectionality align with a democratic approach to PE&I, as outlined above, that has its roots in social activism.⁴²⁸

There is a growing body of research on how intersectional sensitivities and methodologies can be used in the conduct of both qualitative and quantitative health research.⁴²⁹ More recently, the relationship between big data and intersectionality has also come under scrutiny. This is pertinent in circumstances where the technoscientific capability to analyse large quantities of data is growing, but there are also limitations to how this is understood, when, as posited above, there is considerable diversity within publics. In the context of the conduct of quantitative research, Dubrow and Ilinca note that:

⁴²⁰ Cho and others (n 8).

⁴²¹ Abrams and others (n 7) 2.

⁴²² Hill Collins and Bilge (n 9) 7.

⁴²³ *ibid* 9.

⁴²⁴ *ibid* 12.

⁴²⁵ *ibid* 15.

⁴²⁶ *ibid* 225.

⁴²⁷ *ibid* 227.

⁴²⁸ Michael Oliver, *Understanding Disability: From Theory to Practice* (Macmillan 1996); Beresford (n 390); Chuong and O’Doherty (n 389).

⁴²⁹ For some examples see: Abrams and others (n 7); Else-Quest and Hyde (n 18); Greta R Bauer, ‘Incorporating Intersectionality Theory into Population Health Research Methodology: Challenges and the Potential to Advance Health Equity’ (2014) 110 *Social Science & Medicine* 10; Lisa Bowleg, ‘The Problem With the Phrase Women and Minorities: Intersectionality—an Important Theoretical Framework for Public Health’ (2012) 102 *Am J Public Health* 1267.

‘... there is no straight line from big data to “intersectionality.” Big data and “drilling down into subgroups” do not mean that we understand the identities of the people and groups, and it does not mean that we account for power structures. Without identity and power structures, we may not have intersectional analysis.’⁴³⁰

Similarly, D’Ignazio and Kein emphasise, in relation to their work on data feminism that the first principle of this approach is to ‘examine power’. They highlight three key questions in this regard: ‘*Data science for whom? Data science by whom? Data science with whose interests and goals in mind?*’⁴³¹ Within this literature, the focus tends to be on *conducting* qualitative and quantitative intersectional health research, rather than on the considerations that underpin an intersectional approach to the *regulation* of health research. Regulation is, however, touched on by Abrams et al who highlight the ‘ethical concerns’⁴³² that may arise when working with individuals and groups with marginalised identities. They suggest that an intersectional approach requires careful consideration of so-called standard practices such as ‘informed anonymity, privacy, confidentiality, and consent’ when conducting research.⁴³³ For example, whereas the anonymisation of participants may often be understood as a means of protecting participants or communities, this could also be experienced as the silencing of the voices of those who have historically experienced this treatment because of their intersectional identities.⁴³⁴ This has led to increasing recognition that in certain circumstances participants in research may wish to use their own names rather than being assigned a pseudonym.⁴³⁵ Conversely, those with stigmatised identities may not wish to follow ‘standard’ procedures such as signing written consent forms.

This literature on intersectionality in health research therefore augments both the conception of publics set out above, and our understanding of publicness itself. By providing a focus on the multiple and overlapping interests that are at stake in HRR when publics are invoked, publicness underlines that an intersectional approach to the *regulation* of health research does not prescribe that a particular method or approach is adopted. Instead, this points to the need to consider inequalities when considering diversity within publics and how these might

⁴³⁰ Dubrow and Ilinca (n 19).

⁴³¹ Catherine D’Ignazio and Lauren F Klein, ‘Seven Intersectional Feminist Principles for Equitable and Actionable COVID-19 Data’: (2020) 7(2) *Big Data & Society*, 2.

⁴³² Abrams and others (n 7) 6.

⁴³³ *ibid.*

⁴³⁴ *ibid.*; James Giordano and others, ‘Confidentiality and Autonomy: The Challenge(s) of Offering Research Participants a Choice of Disclosing Their Identity’ (2007) 17 *Qual Health Res* 264.

⁴³⁵ Bonnie J Scarth, ‘Bereaved Participants’ Reasons for Wanting Their Real Names Used in Thanatology Research’: (2015) 12(2) *Research Ethics* 80; Mollie Gerver, ‘Exceptions to Blanket Anonymity for the Publication of Interviews with Refugees: African Refugees in Israel as a Case Study’ (2013) 9(3) *Research Ethics* 121.

intersect. Further, this may require the re-examination of long accepted practices in health research regulation, such as the routine anonymisation of participants. This approach aligns with a democratic model of PE&I which shares an explicitly power-aware and political agenda⁴³⁶ and participatory approaches⁴³⁷ that provide opportunities for involvement of those whose interests are impacted. This analysis also draws attention to the importance of context, and the need for an understanding of how past issues can inform current practice. For example, the benefits of cultural and structural awareness training have been explored in the context of researchers conducting research:

‘Though the specific content of the training may vary based on the population of interest, at minimum team members should be made aware of the tenets of intersectionality, historical issues of health-related research, cultural mistrust, identifying and addressing stereotypes and relevant consequences, and effective communication skills (including appropriate verbal/written terminology and body language/gestures). Further, cultural humility also requires team members to be reflexive and aware of the boundaries of their own understanding, predicated on power differentials and privilege associated with their own identities as well as their positionalities as researchers.’⁴³⁸

While this advice applies to those *doing* research, this knowledge and skill-set are equally applicable in the context of those who *regulate* health research, for example for decision makers on data access committees or research ethics committees. In sum, the preceding analysis, through the lens of publicness, underlines various ways that conceptions of publics have been developed in HRR, particularly in the context of PE&I activities, that recognises:

- the value of lay and experiential expertise and the potential contribution of publics to improving HRR throughout the research lifecycle;
- the existence of *different types of publics* and, crucially, that these publics are not pre-existing, but tend to be *constructed* in the course of PE&I activities;
- that where publics’ views are sought then careful consideration should be given to how this information is used in order to make an impact on the conduct and regulation of health research.

⁴³⁶ Beresford (n 390).

⁴³⁷ Abrams and others (n 7).

⁴³⁸ *ibid*; Michael Muhammad and others, ‘Reflections on Researcher Identity and Power: The Impact of Positionality on Community Based Participatory Research (CBPR) Processes and Outcomes’ (2015) 41 *Critical Sociology* 1045.

However, publicness also encourages us to scrutinise the *mutability and diversity within different publics* in relation to the multiple perspectives that people may have on what socially legitimate research looks like. It leads us to ask what the quality of publicness looks like as an attribute of any given group, and therefore to interrogate the extent to which different types of publics include a range of viewpoints when publics are constructed, named and framed. To assist in this task publicness may be considered in light of the literature on intersectionality, which foregrounds three different but interrelated considerations, which are relevant not only to the conduct of health research, but also, I argue, to its regulation:

- **Relationality:** Rejects ‘single axis’ thinking⁴³⁹ and recognises that people may be members of multiple social categories or groups, with the potential for some to be multiply burdened.⁴⁴⁰ This draws attention to context and the need to scrutinise the operation of power and inequality in HRR,⁴⁴¹ in circumstances where some interests may be underrepresented or unrepresented, yet are still impacted by data access decisions and health research.
- **Temporality:** Highlights the changing social, political and historical contexts that shape, and in turn are shaped by, power and inequality in HRR. *Past* discrimination should not be repeated and/or compounded in the *future*. Equally, new risks might emerge over time for new or existing groups.
- **Accountability:** This consideration has implications for HRR *throughout the research lifecycle*, from the appointment and training of decision-makers, through the decision-making process, and to the consideration of opportunities for involvement.

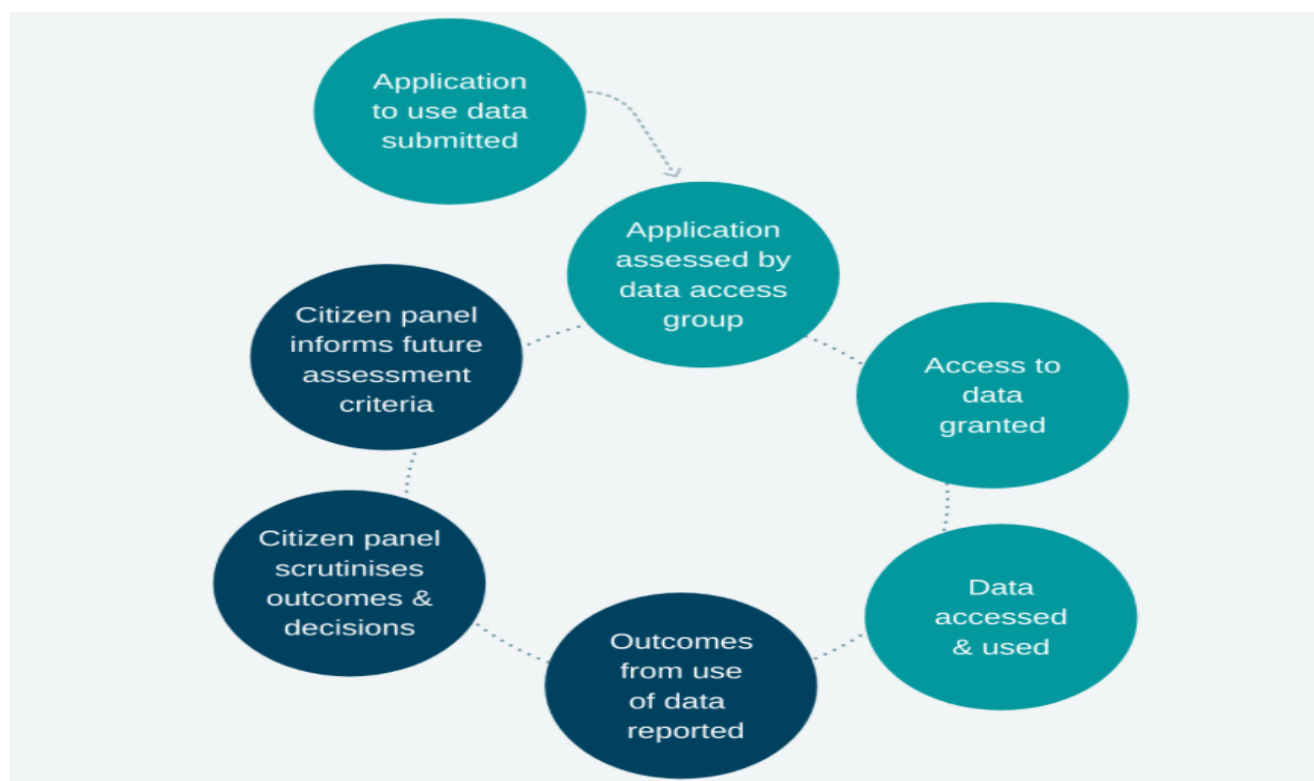
Finally, having reflected on how publicness can develop existing perspectives on the conceptualisation of publics in HRR, I return to Banner’s proposal for managing data access requests that are made *in the public interest*, and again consider how this this can be augmented using publicness. To recap, the learning data governance model she proposes, as described above, is set out in diagrammatic form in **Table 11**.

⁴³⁹ Crenshaw (n 14).

⁴⁴⁰ Abrams and others (n 7); Else-Quest and Hyde (n 18).

⁴⁴¹ Hill Collins and Bilge (n 9).

Table 11: Learning Data Governance Model, Understanding Patient Data



With a focus on temporality, I have already argued that publicness suggests that it may be necessary not only to revisit *decision-making processes*, but also to review the *regulatory structures and devices* that shape those decisions. Here I focus on how publics are conceptualised in the context of the regulation of data-intensive research. In Banner’s model the form and constitution of the proposed public/participant panel (or citizen panel, as it is described elsewhere) is left open, in that this ‘...could be anything from an online platform with thousands of participants responding to a series of data use scenarios through to a dedicated grouping of engaged patients and research participants meeting regularly.’⁴⁴² Further, it is made clear that this is proposed in addition to, as opposed to instead of, existing public/participant involvement.⁴⁴³

As outlined above, in the context of data-intensive research the ‘problem of stakeholderhood’ has the potential to complicate this model when data is used from very large numbers of people or at a population level. In these circumstances, boundaries can become blurred as between patients, participants and publics, which may make it more difficult to identify ‘engaged patients’ or ‘active research participants’.⁴⁴⁴ This distinction is drawn as compared

⁴⁴² Banner (n 371).

⁴⁴³ *ibid.*

⁴⁴⁴ *ibid.*

to some other forms of health research that are conducted on a smaller scale, and where it may therefore be possible to ‘target’ particular patients, service users or publics, perhaps by disease group (who could be the ‘engaged patients’ described above), or on the basis of active research participation (perhaps where there is greater contact between participants and researchers).⁴⁴⁵ How, then, can the perspective provided by publicness, as developed above, help to conceptualise publics in the ‘big data’ context, which still recognises the value of lay and experiential expertise throughout the research lifecycle, and the diversity that exists within this?

A key contribution from the PE&I literature is that this suggests, to some extent at least, that publics are constructed, rather than pre-existing in the world. But this arguably only speaks to the type of entity that is being described and does not say anything necessarily about its attributes. Publicness allows us to go further in this respect. And, as the analysis of relational aspects of publicness above emphasises, even when a particular patient group is a target of PE&I activities (or an ‘affected public’, to use Braun and Schultz’s typology) there is likely to be diversity within that public which affects how people or groups of people are heard or overlooked.⁴⁴⁶ This persistent issue was reflected in a recent Delphi study that I conducted with colleagues, which indicated that:

‘Although patient involvement is becoming a more routine part of medical research, respondents described how ‘the same token patients’ attending meetings ‘tend to be white, retired and middle class’ (6, regulator). This a problem across many kinds of engagement initiatives that rely on voluntary participation. Individuals who have the resources to participate in such activities are usually educated and articulate, leading to the danger that the needs and priorities of other groups are not recognised.’⁴⁴⁷

Braun and Schultz’s work also emphasises that while the mode of PE&I activity undertaken may impact on the publics reached, there are always constraints that mean that, regardless of the mode of PE&I chosen, no one approach ‘...offers an unlimited variety of speaking positions from which participants can freely choose at any time’.⁴⁴⁸ The identification of these challenges of conceptualising publics across PE&I activities is not to detract from the value of thoughtfully conducted PE&I and its outputs, nor the very real difficulties that have been identified in relation to understanding *who* publics are in the context of data-intensive research.

⁴⁴⁵ Aitken and others, ‘Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research’ (n 50).

⁴⁴⁶ Jo Brett and others, ‘Mapping the Impact of Patient and Public Involvement on Health and Social Care Research: A Systematic Review’ (2014) 17 Health Expectations 637.

⁴⁴⁷ Fletcher and others (n 1) 11.

⁴⁴⁸ Braun and Schultz (n 394) 414.

Rather this serves to illustrate that when we talk of publics in HRR, we are always framing and forming who these publics include and exclude. As such, these are not concerns that are unique to the use of ‘big data’ research, albeit that this is, undoubtedly a context where the choices we make (for example about ‘whether, or how, PI&E should reach everyone whose data are used in health ecosystems’)⁴⁴⁹ expose the messy complexities of how we understand publics. What then can publicness add that can help us to anchor and elucidate the responsibilities that come with these choices?

First, publicness draws attention to relationality, and the need to consider context and patterns of inclusion and exclusion in HRR throughout the research/data lifecycle. This requires reflection on the attributes of different types of publics, with respect to how far – if at all – any given public reflects diversity of opinions and nuances of interests. By way of example, it is well documented in relation to the use of health data that:

‘...structural inequalities, biases, and racism in society are easily encoded in datasets and in the application of data science, and ...this practice can reinforce existing social injustices and health inequalities’.⁴⁵⁰

Second, consideration of temporality emphasises that past discrimination should not be repeated and/or compounded in the future, for example because of the non-use of data (where there are gaps in data or research that could help to point to injustice) or its problematic use (where data use compounds or embeds existing injustice).⁴⁵¹ Finally, accountability further emphasises that these consideration have implications for HRR *throughout the research lifecycle*. In the context of Banner’s model, ways of reflecting the diversity of and within publics could impact on matters such as:

- the form and constitution of the ‘citizen panel’ proposed by Banner, bearing in mind that different modes of PE&I construct different publics, and some interests may still be under or unrepresented yet still have an interest in data use and HRR;
- the appointment of ‘data access group’ and ‘citizen panel’ members with a variety of lived experiences;
- training of members of the ‘data access group’ and ‘citizen panel’ to facilitate the scrutiny of applications to use data (either current applications, or the outcomes of past applications) in light of matters relating to cultural and structural awareness.

⁴⁴⁹ Aitken and others, ‘Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research’ (n 50).

⁴⁵⁰ Hannah E Knight and others, ‘Challenging Racism in the Use of Health Data’ (2021) 3 The Lancet Digital Health 144.

⁴⁵¹ Nancy Krieger, ‘Structural Racism, Health Inequities, and the Two-Edged Sword of Data: Structural Problems Require Structural Solutions’ [2021] Front Public Health.

None of these suggestions can alone ensure that matters of power and inequality in health research are accounted for in HRR. However, in different ways these each work to foreground the power dynamics that are at play, and point to the differential impact on people and groups of regulatory structures.⁴⁵²

Conclusion

To recap, publicness, in this thesis, reflects the interrelationship between collective and individual interests, thereby drawing attention to the context in which this interplay takes place, as well as the (potential) positive and negative consequences that might result – both now and in the future. In this Chapter, I have focused on two ways in which publicness can flesh out and enrich the HRR ecosystem through consideration of (1) the temporal implications of regulating individual and collective interests over time and (2) the mutability and diversity of and within publics.

The lens of publicness, which brings into focus the multi-directional interaction of time and context in HRR, reveals how an imagined future is created by the law where research is expected to be of public benefit and/or to have social value which may (or may not) come to pass. This imagined future therefore informs *ex-ante decisions*, that are made on the basis of a homogenised conception of *who* the stakeholders are in in this scenario, and the *multiple perspectives* they may have on what socially legitimate research looks like. PMDD provides an example of how these temporal considerations can have direct implications for the range of interests that are taken into account by regulatory structures. While current understandings of HRR recognise the relevance of temporality to HRR in different ways, time is commonly characterised as part of the historical backdrop against which regulation takes place. In contrast, publicness demands further scrutiny of the *multi-directional interaction* of time and interests in HRR and reveals that not only can time and context shape regulation, but that law and regulation are also capable of shaping context and creating horizons of time. Thus, the lens of publicness provides a new perspective on a familiar aspect of HRR. In response to this re-framing I have explored modes of adaptive governance that can account for the uncertainties that are inherent in the regulation of data-intensive health research. However, as well as feedback loops within existing decision-making processes, I have argued that it is also necessary to revisit and revise the regulatory structures within which such decisions are made.

⁴⁵² Sariola (n 19).

The discussion in this Chapter also suggests that greater attention should be paid to how publics are understood in HRR. This has been explored using literature on ‘publics’ from the PE&I context to help engage with the ‘problem of stakeholderhood’ in data-intensive health research. However, publicness also pushes us further to consider the mutability and diversity *within* different publics in relation to the multiple perspectives that people may have on what socially legitimate research looks like. Here an intersectional lens does not prescribe a ‘one size fits all’ regulatory approach – but rather requires that attention is paid to inequalities and how these might intersect. Some substantive ways of foregrounding the power dynamics that are at play in HRR are considered, such as in the choice of modes of PE&I, and in the selection and training of decision makers.

Taken together this analysis has pointed to ways that publicness can help to optimise HRR and further refined how publicness *per se* is understood. The discussion has highlighted both the breadth of publicness as a concept, and how this can resist a narrowing of the way in which HRR frames the multiple and overlapping interests that are in play, and how these can change over time. By considering what the quality of publicness looks like as an attribute of any given group, this requires consideration of matters including not only the publics that are constructed, but also those that are not. In this way, publicness reminds us very starkly that some groups may not be included, despite best efforts, but that they will still have multiple and varied interests that must also be taken into account. In summary, when publicness is made a constant feature of our regulatory concerns, this requires that we take seriously this ever-changing heterogeneity across the lifecycle of HRR. New issues are also raised, such as how existing regulatory devices can operate to flatten conceptions of publics, and therefore require reconsideration. I therefore take up this challenge to reimagine the public interest as a regulatory device in HRR in Chapter 5.

Chapter 5: Examining the public interest as a regulatory device: using publicness to reconceptualise a contested concept

Introduction

So far in Part II, I have used publicness to explore particular sub-optimal features of HRR and to identify how publicness can better account for the full range of interests in play throughout the research and data lifecycle. My analysis has highlighted both how individual and collective interests can build on one another in HRR (Chapter 3), and the mutability and diversity of and within publics over time (Chapter 4). In this way, publicness has been used to provide a solid theoretical and practical basis to move beyond what already exists in the HRR ecosystem, and to make suggestions for improvement. In this Chapter, I remain with the theme of the optimisation of the HRR ecosystem but narrow my focus to the public interest as a regulatory device in HRR. This reflects my finding, in Chapter 4, that an appreciation of publicness in HRR suggests that it may be necessary not only to revisit decision-making processes, but also to review the regulatory structures and devices that shape those decisions.

The concept of the public interest was first substantively introduced in this thesis in Chapter 3, where publicness was used to engage with its strengths and limitations, and to better delineate the role that this performs in HRR. I have recognised the *potential* for the public interest to act as a 'hair shirt' that provides a framework that can account for the multiple and related interests that are at play when the public interest is at stake. However, my analysis, through the lens of publicness, has also highlighted several shortcomings of the public interest. These include: (i) its tendency towards an antagonistic framing of the interests at stake in HRR; (ii) its temporal limitations, in circumstances where public interest decisions are made at fixed points in the research or data lifecycle, with limited scope for review; and, in particular, (iii) its tendency towards a self-referential approach to the views of diverse publics, when these are reduced to the judicial construction of a fictional 'reasonable man' or a 'reasonable public'. These challenges are non-trivial and contribute in different ways to a central critique of the use of the public interest in HRR, namely that it lacks conceptual clarity. This concern is shared by critics and proponents of the public interest, where there is some consensus that if this concept is to be reclaimed as a legitimate regulatory tool in HRR it requires further elaboration.⁴⁵³

⁴⁵³ Ballantyne and Schaefer (n 163); Norah Grewal and Ainsley J Newson, 'The Perils of a Broad Approach to Public Interest in Health Data Research: A Response to Ballantyne and Schaefer' (2021) 47 *Journal of Medical Ethics* 580; Schaefer and others (n 163).

A recent Delphi study in relation to stakeholders' experiences of contemporary HRR in the UK has also indicated that the public interest remains an elusive concept, '...residing in case law and judges' superior consciousness'.⁴⁵⁴ This is in circumstances where the literature in HRR contains numerous calls for the public interest in HRR to be informed by empirical evidence of actual publics' views,⁴⁵⁵ for example in relation to public attitudes towards data sharing for public benefit, but provides few details on how this might best be approached.⁴⁵⁶ In this Chapter, I therefore focus on this much-vexed intersection between the public interest as a regulatory device and extra-legal insights provided by empirical evidence. As in previous Chapters, my aim remains determinedly not to seek to provide a 'how to' guide on either conducting different modes of PE&I, nor on the practicalities of incorporating outputs from this into law and policy.⁴⁵⁷ Rather, I use publicness and its facets - of relationality, accountability, temporality - as a way of facilitating an examination of this neglected issue. On the basis of this analysis, I offer a reconceptualisation of the public interest through the lens of publicness. The approach I suggest: (i) explores the notion of 'the public' in the public interest and how context can shape these interests; (ii) points to the ways in which the research path and the public interest overlap and intersect each other throughout the entire life cycle; and (iii) emphasises the nuanced role of transparency in multi-factorial decision-making. In conclusion I offer some suggestions in relation to how publicness-informed guidance could help to frame robust judgments as to whether proposed data usages are in the public interest. This approach directs attention not only to 'the public interest' in terms of how this may be realised from the (expected) findings from research, but also to the ways in which this may be manifested in processes of research and regulation in relation to data use.

I begin with a consideration of a practical example of why a tendency towards a self-referential and inward-looking conception of the public interest is problematic in HRR, with reference to the paradigmatic example of the failed *care.data* initiative in England. This indicates that legal and regulatory authority may not alone command social legitimacy, and so it is unlikely that a

⁴⁵⁴ Fletcher and others (n 1) 107.

⁴⁵⁵ Here I rely on Blackham's simple definition in that: 'Empirical research is defined broadly as inquiry via direct methods to learn about the world, using either qualitative or quantitative data.' Alysia Blackham, 'Legitimacy and Empirical Evidence in the UK Courts' (2016) 25 Griffith Law Review 414, 417.

⁴⁵⁶ Annie Sorbie, 'The Public Interest' in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021); David Townend, 'Privacy' in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021); Mark J Taylor and Tess Whitton, 'Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data' (2020) 9 *Laws* 1, 6; Ballantyne and Schaefer (n 163); Schaefer and others (n 163).

⁴⁵⁷ For a discussion of how to do public engagement that is meaningful and effective see O'Doherty and Hawkins (n 66).

social licence can be maintained for uses of data where the ‘public interest’ is viewed narrowly and solely in legal terms.

Next, I provide a summary of recent work that has been conducted with publics in relation to the acceptability of data sharing practices. Thus far in this thesis I have argued that a key function of the public interest is to carve out a legally legitimate space within which research activities that infringe on individual interests, but have potential *public benefits*, can be conducted, which otherwise would not be permitted. I therefore focus on recent empirical research that engages with participants’ views and attitudes towards the realisation of public benefits in the context of data use, in order to begin to consider the ways in which this could potentially add value to the public interest as a regulatory device. This is followed by consideration of the conditions under which empirical evidence may be used in this way, in light of the law’s propensity towards an inwards looking account of the public interest. To integrate the preceding analysis, I use publicness and its three facets as a way to reimagine the public interest as a regulatory device in HRR that is better equipped to meet the realities and challenges of the contemporary health research environment.

Regulatory and social legitimacy and ‘the public interest’: the case of *care.data*

The analysis in this thesis has already indicated a number of reasons why a disconnect between the public interest as a regulatory device, and the views of actual publics, can lead to sub-optimal HRR. To recap, I have argued from the outset of this thesis that the HRR ecosystem risks falling short of the highest standards or quality when it fails to adequately reflect the complexities of the interrelationship between individual and collective interest that are in play, and how these may change over time, which in turn may impact on the social and regulatory legitimacy of HRR. As this thesis has developed I have addressed the conceptual implications of this, for example in circumstances where a binary or oppositional understanding of this interrelationship fails to capture the full range and depth of interests that are at stake and therefore should be accounted for by HRR, as set out in Chapter 2. However, as my work has developed, I have also confronted the practical implications of sub-optimal HRR. This was initially drawn out in Chapter 3, in my discussion of social licence (i.e. the intangible and unwritten accordance between communities and researchers to permit certain work, such as using identifiable health data for research without consent). There it was suggested that, in some circumstances, the absence of social legitimacy has the potential to pose an equal, if not greater, threat to the ability to carry out such activities than a lack of regulatory authority. In Chapter 4, I highlighted that a distance between (biomedical) science and society can limit the responsiveness of regulation, in the context of an evolving and dynamic health research landscape. The example that I provided is the potential impact

(positive or negative) on publics' views on secondary data uses in the context of the increased visibility of data sharing practices during the Covid-19 pandemic. Taken together, this serves to explain why it is 'sub optimal' for the regulatory concept of public interest to operate without reference to the views of actual publics. In this Chapter, I explore the *care.data* initiative (as described in **Table 12**)⁴⁵⁸ as a further and paradigmatic example of the complexities of the relationship between regulatory and social legitimacy, and the consequences that can flow when these pull apart from one another.

Table 12: An overview of *care.data*

Care.data was an NHS England initiative whereby information would be extracted routinely from GP practices by the Health and Social Care Information Centre and then linked. This would be made available for specified purposes, including audit and research, in a format that was stripped of identifiable information. Following widespread concerns about the scheme – including around its transparency and oversight - the programme closed in 2016.

A key feature of *care.data* was that a legal framework was in place that was able to facilitate the data sharing that was proposed, but the social licence to do so was not.⁴⁵⁹ In summary, the Health and Social Care Information Centre (HSCIC) had been established pursuant to the Health and Social Care Act 2012.⁴⁶⁰ HSCIC's powers included those to request and require the provision of information from health and social care bodies and those who provide health services, including General Practitioners (GPs).⁴⁶¹ In turn, GPs were under an obligation to provide information to HSCIC in accordance with their NHS contract.⁴⁶²

This infrastructure for *care.data* was created against a backdrop of a growing body of evidence on patients' attitudes towards data sharing for matters beyond direct care.⁴⁶³ Indeed, the Academy of Medical Sciences (AMS) had previously called for a 'new pathway for the

⁴⁵⁸ NHS England, 'NHS England Sets out the next Steps of Public Awareness about Care.Data' (16 October 2013) <<https://www.england.nhs.uk/2013/10/care-data/>> accessed 14 January 2022; Mark Taylor, 'Information Governance as a Force for Good? Lessons to Be Learnt from Care.Data' (2014) 11 SCRIPTed; as reproduced from Sorbie, 'Sharing confidential health data for research purposes in the UK' (n 386) 251.

⁴⁵⁹ Carter and others (n 164).

⁴⁶⁰ Chapter 2 s252.

⁴⁶¹ *ibid* s259.

⁴⁶² Carter and others (n 164).

⁴⁶³ *ibid*.

regulation and governance of health research'.⁴⁶⁴ Their 2011 report, of the same name, pointed to persistent legislative and other barriers to data sharing that required attention,⁴⁶⁵ and a social climate that was amenable to a more streamlined approach to data sharing. For example, the AMS drew attention to six reports, dated between 2006-2010, which each examined public views on the use of patient data. While these reports were different in scope, together they conveyed the message that, when properly informed, people were '...generally happy for their data to be used in research' in the presence of certain safeguards.⁴⁶⁶ The 'new pathways' report further recommended a programme of public engagement:

'...to develop information materials that provide patients, the public and healthcare professionals with information about the use of data in health research. We recommend that this work should continue and that the primary aim of these materials should be to provide information on what is meant by the use of data in health research and that this should inform decisions relating to 'opt-out'.⁴⁶⁷

Driven by considerations of publicness, the analysis in this thesis so far highlights, with the benefit of hindsight, a number of points about the AMS's approach, which are illustrated by the preceding quote. First, the 'new pathways' report suggests that a deficit model of engagement⁴⁶⁸ was adopted by the AMS, as discussed in Chapter 4, whereby a lack of knowledge by non-scientific publics is blamed for any misunderstandings and disputes over science, which can therefore be remedied by one-way transmissions of knowledge.⁴⁶⁹ Second, that the crossover from empirical evidence (in this case, six reports that indicated that the publics who had been consulted were, in broad terms, supportive of secondary uses of data if certain conditions were met) to public support for a specific initiative is not linear, and cannot be assumed. Indeed, as argued in Chapter 4, and as I return to below, the concept of publicness points to the *mutability and diversity within different publics* in relation to the multiple perspectives that people may have on what socially legitimate research looks like. And third, that this narrow focus – on the provision of information to publics, the general appetite for data sharing, and the legislative framework which facilitates data sharing - overlooks other factors that can mitigate for or against the social legitimacy of health research.

⁴⁶⁴ The Academy of Medical Sciences, 'A New Pathway for the Regulation and Governance of Health Research' (January 2011) <<https://acmedsci.ac.uk/policy/policy-projects/a-new-pathway-for-the-regulation-and-governance-of-health-research>> accessed 14 January 2022.

⁴⁶⁵ *ibid* 57–68.

⁴⁶⁶ *ibid* 67.

⁴⁶⁷ *ibid* 57.

⁴⁶⁸ Aitken and Cunningham-Burley (n 313).

⁴⁶⁹ Nisbet and Scheufele (n 395).

This complexity aligns with findings that public trust in science is not easy to define, and may be 'contextual, experiential and ambivalent'.⁴⁷⁰ Quiroz-Aitken et al's report on the conduct of public engagement in the context of the Scottish Health Informatics Programme (SHIP), also indicates that 'the public's relationships of trust and/or mistrust in science and research are not straightforward'.⁴⁷¹ The authors point to the importance of transparency, and its relationship with trust, in circumstances where efforts to engage may be viewed with public scepticism. Drawing on considerations relating to authenticity, it is suggested that evidence that decision makers are 'suffering' or exerting effort in their endeavours⁴⁷² may help to demonstrate that they are 'meaningfully grappling with the challenges of addressing disparate viewpoints'.⁴⁷³ Further, Armstrong et al have shown that individuals may not make 'ideal' decisions in relation to participation in health research, that are based on institutional information, such as written patient information leaflets. Rather, their findings resonate with a relational understanding of publicness, in that:

'...decisions about participation, rather than being fully reasoned or based on a rational evaluation of options, were made in a relational context. Verbal discussion with members of the clinical team and trusting relationships established with those clinicians tended to be far more significant in the decision-making process than was the [patient information leaflet].'⁴⁷⁴

Dixon-Woods et al's study, in the context of the childhood cancer community, also points to the importance of reciprocity and a belief in the '...benefits and wholesomeness of the research endeavour, and...of consenting as an altruistic act in the service of the public good'.⁴⁷⁵ Amidst these uncertainties, Carter et al suggest that:

'What is clear is that individuals' cooperation with specific research studies is usually secured through three principal mechanisms: their expectations about how research is conducted and regulated; their trust in the institutions and individuals who recruit them; and their beliefs in the wholesomeness and public value of the research endeavour. More broadly, the public legitimacy and acceptability of health research

⁴⁷⁰ Gill Haddow and Sarah Cunningham-Burley, 'Tokens of Trust or Token Trust? Public Consultation and "Generation Scotland"' in Julie Brownlie and others (eds), *Researching Trust and Health* (Routledge 2008).

⁴⁷¹ Mhairi Quiroz-Aitken and others, 'Moving from Trust to Trustworthiness: Experiences of Public Engagement in the Scottish Health Informatics Programme' (2016) 43(5) *Science and Public Policy* 713, 720.

⁴⁷² Nik Brown and Mike Michael, 'From Authority to Authenticity: The Changing Governance of Biotechnology' (2002) 4 *Health, Risk & Society* 259.

⁴⁷³ Quiroz-Aitken and others (n 471) 721.

⁴⁷⁴ Natalie Armstrong and others, 'Do Informed Consent Documents for Cancer Trials Do What They Should? A Study of Manifest and Latent Functions' (2012) 34 *Sociology of Health & Illness* 1230, 1240.

⁴⁷⁵ Mary Dixon-Woods and others, 'Human Tissue and "the Public": The Case of Childhood Cancer Tumour Banking' (2008) 2 *BioSocieties* 57, 74.

rests heavily on its status as a socially valuable enterprise conducted in the service of the public good.⁴⁷⁶

In the context of *care.data*, Carter et al identify a number of ways that this initiative fell short in each of these areas and suggest that together this impacted negatively on its ability to meet the conditions for a social licence. These related to: the ‘warrants of trust’⁴⁷⁷ that were (or indeed were not) in place, in circumstances where a lack of detail in the information provided to professionals and publics did not provide the necessary cues of the trustworthiness of the initiative; a ‘rupture in expectations’⁴⁷⁸ of the doctor/patient relationship where data was shared for purposes beyond individual care; and uncertainty over the extent to which *care.data* was a public good.⁴⁷⁹ The latter point holds particular importance in circumstances where:

‘Much depends... on the extent to which uses of personal data are seen as serving the public interest and conducted by those with a public interest orientation.’⁴⁸⁰

So far in this thesis, I have argued that there is a *prima facie* disconnect between the public interest as a regulatory device in HRR and extra-legal insights, such as the views of actual publics on the health research endeavour. Further, this disconnect is problematic for a number of reasons, as exemplified by the failure of the *care.data* initiative. Here regulatory authority was in place to facilitate the data sharing in question, but the social licence was not. The preceding discussion indicates that a ‘thin’ conception of the public interest, which is couched solely in terms of a legal notion of legitimacy, seemingly cannot be relied upon to generate the social legitimacy that was lacking in the case of *care.data*.

This position is compounded in HRR, in circumstances where the public interest in health research remains a ‘notoriously uncertain idea’⁴⁸¹ that requires clarification.⁴⁸² For example if, as I have posited, a function of the public interest is to carve out a space within which research activities that infringe on individual interests but have potential public benefits can be conducted with legitimacy, then who decides what these expected ‘public benefits’ look like and which are sufficiently acceptable? One answer is that this is the sole preserve of the courts, or other elite regulatory actors, such as members of data access committees or research ethics committees. However, the preceding discussion has underlined the multitude of ways that this inward-looking approach alone may be inadequate to the task of breathing

⁴⁷⁶ Carter and others (n 164) 406.

⁴⁷⁷ *ibid* 406–07.

⁴⁷⁸ *ibid* 407.

⁴⁷⁹ *ibid*.

⁴⁸⁰ *ibid*.

⁴⁸¹ Taylor, *Genetic Data and the Law* (n 229) 29.

⁴⁸² Ballantyne and Schaefer (n 163); Schaefer and others (n 163); Grewal and Newson (n 453).

life into this contested and context specific concept, which may change over time. Contrariwise, another way that the public interest may be animated is with reference to actual publics' values, views and attitudes. Taylor and Whitton indicate that: 'What people can be shown empirically to be willing to accept will thus have evidential value to the application of the public interest'.⁴⁸³ Schaefer et al echo this sentiment:

'Because public interest, by definition, appeals to the sensibilities and the needs of the public – and in recognition that these matters will change over time with social mores and values and exposure to the benefits of research efficiency - the final conceptualisation of public interest adopted by institutions must incorporate public attitudes and values, or at least be able to give a robust account relative to the same'.⁴⁸⁴

Elsewhere I have also argued that, despite the apparent impasse between the public interest as a regulatory device with significant legal connotations on the one hand, and public attitudes and views on the other, these can and should be reconciled.⁴⁸⁵ However, and as argued above, the cautionary tale of *care.data* suggests that the relationship between evidence of publics' views and attitudes, and support for a specific initiative, is complex and non-linear.

Taken together then, and against the background of the 'dialogical turn' in health research more generally, this underlines the extent to which there is an emerging consensus that a robust conception of the public interest in HRR cannot rely solely on the law or legal institutions in order to derive its legitimacy. However, to extrapolate 'the public interest' from outputs from PE&I activities may be equally problematic. This brings us next to a closer consideration of a recent body of empirical evidence in relation to publics' expectations of the public benefits that might conceivably inform the public interest, and thereafter to the question of the conditions under which extra-legal insights, such as these, may be used to inform the public interest as a regulatory device.

The public interest and publics' expectations of data sharing for 'public benefit'

In line with the rise of mainstream interest in 'user involvement' in research since the 1990s⁴⁸⁶ there have been increasing numbers of attempts to gauge publics' opinions and attitudes towards data sharing practices in health research. These have been led by, or conducted in collaboration with, a range of stakeholders, including those within the Academy,⁴⁸⁷ but also

⁴⁸³ Taylor and Whitton (n 456) 18.

⁴⁸⁴ Schaefer and others (n 163) 7.

⁴⁸⁵ Sorbie, 'Sharing confidential health data for research purposes in the UK' (n 386).

⁴⁸⁶ Beresford (n 390).

⁴⁸⁷ Quiroz-Aitken and others (n 471); Mhairi Aitken and others, 'Public Responses to the Sharing and Linkage of Health Data for Research Purposes: A Systematic Review and Thematic Synthesis of Qualitative Studies' (2016)

funders⁴⁸⁸, regulators⁴⁸⁹ and statutory bodies such as the National Data Guardian.⁴⁹⁰ Many of these exercises have focussed on different aspects of the *acceptability* to publics of data sharing proposals⁴⁹¹ in circumstances where: 'Public acceptance is recognised as crucial for ensuring the legitimacy of current practices and systems of governance.'⁴⁹² More specifically, studies in relation to data linkage and sharing have sought to identify the conditions that can underpin public support and/or acceptability in this area, and indicated that:

'...in cases where participants perceived there to be actual or potential *public benefits* from research and had trust in the individuals or organisations conducting and/ or overseeing data linkage/sharing, they were generally supportive.'⁴⁹³ [*emphasis added*]

Research conducted on behalf of the Wellcome Trust⁴⁹⁴ on public attitudes to commercial access to health data found a number of drivers of acceptability, as illustrated in **Table 13**.

17 BMC Medical Ethics 73; Sara Davidson and others, 'Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes' (Social Research Series, Scottish Government, 2013); Aitken and others, 'Who benefits and how?' (n 168).

⁴⁸⁸ Ipsos Mori, 'The One-Way Mirror: Public Attitudes to Commercial Access to Health Data' (Wellcome Trust 20 November 2017).

⁴⁸⁹ Victoria Chico and others, 'Public Views on Sharing Anonymised Patient-Level Data Where There is a Mixed Public and Private Benefit' (September 2019).

⁴⁹⁰ Hopkins Van Mil, 'Putting Good into Practice: A Public Dialogue on Making Public Benefit Assessments When Using Health and Care Data' (GOV.UK, April 2021) <<https://www.gov.uk/government/publications/putting-good-into-practice-a-public-dialogue-on-making-public-benefit-assessments-when-using-health-and-care-data>> accessed 14 January 2022.

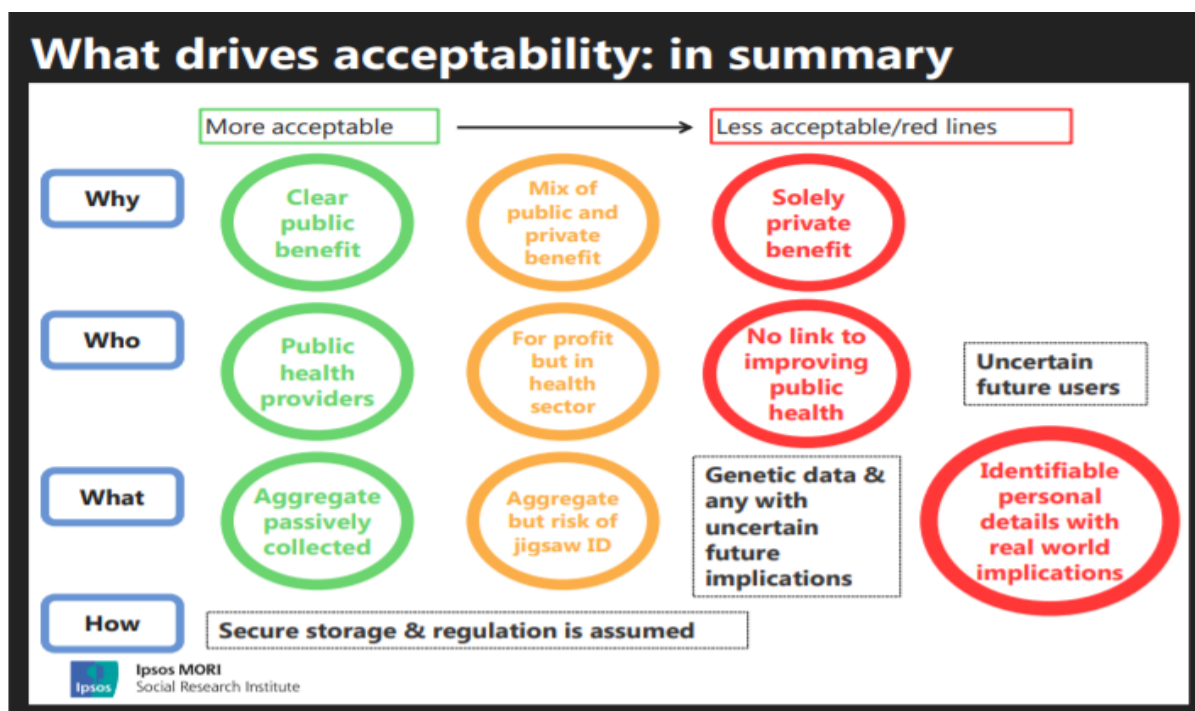
⁴⁹¹ Quiroz-Aitken and others (n 471) 715.

⁴⁹² Aitken and others, 'Public responses to the sharing and linkage of health data for research purposes' (n 487) 1.

⁴⁹³ *ibid.*

⁴⁹⁴ As they were known then. Now known as 'Wellcome'.

Table 13: Extracted from *The One-Way Mirror: Public attitudes to commercial access to health data*



However, this study also found that:

*'A clear benefit both to individuals and to wider society was seen as the only good rationale for breaking privacy, and this was the primary driver of acceptability for participants. When these benefits are perceived (and the organisation is trusted to deliver them) all participants in the workshops accepted commercial access to health data in principle.'*⁴⁹⁵ [emphasis added]

This focus on public benefits⁴⁹⁶ is significant in relation to the public interest where, as argued above, the potential for *public benefits* to be realised by research using data is implicated both in relation to its legal and social legitimacy.

Nonetheless, it has been found that 'the term 'public benefit' is rarely, if ever, clearly defined'⁴⁹⁷ and may be 'glossed over as impacts that are 'in the public interest'⁴⁹⁸ or using other terminology. In response to this gap, more recent research with stakeholders has sought to

⁴⁹⁵ Ipsos Mori, 'The One-Way Mirror' (n 488) 10.

⁴⁹⁶ For another example see Davidson and others (n 487).

⁴⁹⁷ Understanding Patient Data and others, 'Data for Public Benefit: The Risks and Benefits of Data Sharing' (April 2018) 6.

⁴⁹⁸ *ibid* 21.

interrogate how people understand this term in the context of the use of data. For example, research involving workshops with people working for public services providers (e.g. local councils and local authorities) indicated that data sharing for public benefit should meet the triple test of being purposeful, proportionate and responsible.⁴⁹⁹ In the specific context of data-intensive research, a study conducted with people in Scotland considered their expectations in relation to both the 'public' and 'benefit' aspects of this terminology.⁵⁰⁰ This indicated that those who participated were generally inclined to prefer an inclusive definition of the public, so that research could benefit as many people as possible.⁵⁰¹ However, this was complemented with recognition of 'need led'⁵⁰² considerations, in that there may also be value in research that benefits a smaller group or number of people. Further, these benefits (to the smaller group) were 'far from incompatible' with the desire for broad public benefit in circumstances where it was suggested that to benefit those who needed it most would also accrue broader societal benefits.⁵⁰³ These findings resonate with the examination of publicness thus far in this thesis which recognises that there is diversity within and between publics, and the role of context in understanding how HRR engages with matters such as social inequality.

In terms of the types of benefits expected, again it was reported that the preference from participants was to keep these broad in scope. Participants referred to health and health system benefits, but also to wider types of public benefits which could accrue, both now and at later points in time:

'More broadly than just cures and increased medicalization, considerable time in the discussions focused upon improving lives; with a focus on health improvement, better quality of life and enhanced lifestyle, with people living longer and healthier lives and lives that are less stressful. Linked to better quality of life and outcomes, participants suggested that future generations should be thought about so they do not face similar health and lifestyle burdens, with better understanding and implementation of preventative measures. Participants also stated that benefits of research should be measurable, through better quality care and services. Improved allocation of resources was also a way in which participants thought the public could benefit.'⁵⁰⁴

⁴⁹⁹ Understanding Patient Data and others (n 497).

⁵⁰⁰ Aitken and others, 'Who benefits and how?' (n 168).

⁵⁰¹ *ibid* 7.

⁵⁰² *ibid*.

⁵⁰³ *ibid*.

⁵⁰⁴ *ibid*.

As indicated by the final sentence of the preceding quote, a key finding of this study was that participants were particularly interested in whether the benefits under discussion (such as the findings from a research project) would *actually* be realised, for example through action ‘...by policy makers, governments and/or the health service’.⁵⁰⁵ Here the temporal facet of publicness is evident with regard to the attention paid by participants not just to the *anticipated* public benefits of research at a fixed point in time, but to how these emerge over time.

Most recently a public dialogue conducted in England in 2021, ‘Putting Good into Practice’, further probed this specific issue of how public benefit assessments should be made when using health and care data.⁵⁰⁶ Building on research that has indicated that public benefit is key when decisions are made about how health data is used, this study asked: what counts as public benefit, and what should be considered when decisions are made about whether data use and sharing is ‘for’ public benefit? Its findings, as summarised in **Table 14**, were designed in order to inform policy advice or guidance that will be issued by the National Data Guardian.⁵⁰⁷

⁵⁰⁵ *ibid* 8.

⁵⁰⁶ Hopkins Van Mil (n 490).

⁵⁰⁷ *ibid* 3–4.

Table 14: Putting Good into Practice: summary of key findings

1. Prerequisites for public benefit



Transparency cannot be separated from public benefit. It is not an add-on or nice to have. Health and social care data use requests *only* demonstrate public benefit if they have integrated communications within their application including activity which demonstrates the value of data use to society



To demonstrate public benefit, transparency is required throughout the whole data life cycle (collection, storage, assessment and use), not just at the point of application



Public benefit is undermined if authentic public engagement is not integrated into data assessment. This requires engaging people from a cross-section of society in data assessment processes.

2. Areas that matter most to dialogue participants



Equitable distribution of benefits of data use in health and social care with safeguards to protect against discrimination and geographic disparities



Identifiable and sensitive data should be treated with the utmost care, if it is, it has the potential to bring public benefit. Data was perceived as being particularly sensitive if it is of a personal nature, such as genomics or mental health data, or because greater care is needed in its interpretation, such as qualitative data



Safeguards and provisions in place to protect society from data manipulation, where the outputs from the data use could be interpreted in different ways, for example, to achieve political or financial ends. This includes publication of statements of data users' credentials and sources of funding



Public benefit must outweigh profit with profitable uses of data rigorously scrutinised for demonstrations of public benefit before access is granted. There is a recognition that data use in this context can enable health and social care improvements and innovations



Being ambitious for health and care data use - to realise public benefit from global collaboration; exploratory research driving breakthroughs; and using profit for new developments, such as drugs, treatments and services.

3. Areas that matter least to dialogue participants



Did not feel that the data use needed to remain close to the original purpose of its collection to bring public benefit. They were more concerned about the relevance of the data - should it be used beyond the purpose of its original collection. However, all changes in direction must still be predicated on the prerequisites for public benefit being in place



The scale of benefits is not a significant factor in determining whether a data use has public benefit as there is inherent value in data use which produces an impact, even if only for a small number of people.

The results of this report confirm and extend previous findings. For example, as well as emphasising the value of engagement with publics, transparency throughout the data lifecycle is presented as a prerequisite for public benefit. In relation to the publics to whom benefits accrue, this report also points to the value of benefits that are delivered to smaller groups of those in need, rather than it being required that these are always universal.

The preceding synthesis of a number of reports, that each consider aspects of publics' expectations of the use of data for public benefit, provides a brief overview of some recent engagement with publics on this topic. These studies are pertinent to consideration of the public interest in circumstances where the potential for public benefits to be realised by research using data is implicated both in relation to its legal and social legitimacy. This emerging focus on how public benefits are understood by participants suggests an appetite for asking publics about increasingly complex and abstract core questions in HRR, as well as more well-established matters, such as preferred or acceptable models of consent.⁵⁰⁸ It further indicates that participants in these studies are not only concerned with the *type* of public benefits they expect data usages to deliver, such as new treatments, or improvements in health systems, but also matters such as *which publics* participants expect to benefit from data usages, as well as *how* and *when* public benefits are realised. While, I have previously used publicness primarily as a way of engaging with regulatory structures, here its elements of relationality, temporality and accountability can also be identified in participants' responses. An implication of this for the public interest, as a regulatory device in HRR, is that this disrupts a siloed view of the messy subjectivities of publics' views, on the one hand, and the neat procedural approach of the law, on the other. Rather, it suggests that the contribution that may be made by empirical evidence to the public interest has the potential to cut across and enrich each of these domains.

Notwithstanding the above, and despite the aforementioned promise of publicness and the plethora of studies that have sought to gauge public attitudes, the question of what to do with these extra-legal insights, and the conditions under which they can be used to inform the public interest as a regulatory device in HRR has often been overlooked.⁵⁰⁹ I therefore next consider this intersection between the public interest as a regulatory device, and extra-legal insights provided by empirical evidence.

⁵⁰⁸ Mark J Taylor and Natasha Taylor, 'Health Research Access to Personal Confidential Data in England and Wales: Assessing Any Gap in Public Attitude between Preferable and Acceptable Models of Consent' (2014) 10 Life Sci Soc Policy.

⁵⁰⁹ Stephanie R Morain and Emily A Largent, 'Public Attitudes toward Consent When Research Is Integrated into Care-Any "Ought" from All the "Is"?' (2021) 51 Hastings Cent Rep 22 set this out in the context of consent in pragmatic trials, but this can equally be seen in relation to the plethora of literature on publics' attitudes to the use of health data, as reviewed in this Chapter.

What are the conditions under which empirical evidence may be used to inform the public interest as a regulatory device?

The discussion so far in this Chapter has pointed to a number of ways that empirical evidence might usefully be employed in order to inform and enrich the public interest as a regulatory device in HRR. Yet, as outlined in Chapter 3, the law has a propensity towards an inwards-looking account of the public interest, where the views of diverse publics are reduced to the judicial construction of a fictional 'reasonable man' or a 'reasonable public'. A criticism of some previous examinations of the public interest,⁵¹⁰ that argue that public views and attitudes should be accounted for, is that insufficient attention has been paid to the legal roots of this regulatory device, and how these may inform or limit this concept.⁵¹¹ This is in circumstances where, in the context of data-intensive research, '[t]he law often calls on the concept of public interest for assistance'.⁵¹² Other conceptions of the public interest are firmly anchored by consideration of the law, but these too stop short of a detailed examination of the conditions under which the law may be able to incorporate empirical evidence.⁵¹³ Next, I therefore probe this intersection between empirical evidence and the law, in order to consider its implications for the public interest as a regulatory device, and indeed HRR more widely.

In the remainder of this section I first briefly consider how the use of empirical evidence has recently been considered in the context of HRR from a bioethical perspective. I then look to an analogous body of literature in order to examine the use of empirical evidence in the legal context. Given the gap in the literature identified above, the legal studies considered are necessarily outside of the HRR context and focus on negligence and discrimination cases. However, there are parallels here with HRR, in that these are all areas which are '...concerned with the behaviour of people and institutions, and the nature of the world and society'.⁵¹⁴ In summary, this analysis indicates that that courts and tribunals can and do use empirical evidence, albeit that this is rare and inconsistent.⁵¹⁵ I therefore conclude this Chapter by returning to the framework provided by publicness, in order to consider how this analysis can be used to inform a holistic conception of the public interest as a regulatory device that can, indeed, incorporate empirical evidence of publics' views.

⁵¹⁰ Ballantyne and Schaefer (n 163); Schaefer and others (n 163).

⁵¹¹ Grewal and Newson (n 453).

⁵¹² *ibid* 580.

⁵¹³ Taylor and Whitton (n 456).

⁵¹⁴ Blackham (n 455); citing to Kylie Burns, 'It's Not Just Policy: The Role of Social Facts in Judicial Reasoning in Negligence Cases' (2013) 21 *Torts Law Journal* 73.

⁵¹⁵ Blackham (n 455) 416.

Morain and Largent have recently considered whether empirical evidence on patients' and publics' attitudes towards consent for pragmatic clinical trials can be used to inform bioethics.⁵¹⁶ For the purpose of this thesis it is not necessary to set out these views on consent, but rather I focus on the question of what to do with this information *about* people's views. Morain and Largent find that '...empirical evidence alone – even robust empirical evidence – cannot yield definitive ethical guidance.'⁵¹⁷ Nonetheless: '...accepting that one cannot divine moral truth from empirical evidence alone in no way implies that empirical evidence is irrelevant to ethics and policy debates.'⁵¹⁸ This clears the ground for a middle way in which '...empirical data on attitudes towards consent are neither wholly irrelevant nor wholly determinative of the issue.'⁵¹⁹ Having reached this conclusion the authors highlight a number of matters to be taken into account when considering the impact of empirical evidence on ethical debate and policy. These conditions include that: (i) that the quality and relevance of the data itself will need to be evaluated in the decision-making process;⁵²⁰ (ii) that while widely held views may be persuasive, even these may be thoughtfully dismissed in circumstances where this risks succumbing to the tyranny of the majority;⁵²¹ and that (iii) social and historical contexts that shape minority interests should be carefully considered.⁵²²

However, the public interest does not just have normative force from an ethical perspective; it is also embedded in HRR as a legal device.⁵²³ One way that legal scholars have described the law's inward-looking approach is in terms of the use of 'social facts' by judges in the course of making legal decisions. In this context social facts are understood as '...statements about human behaviour, but also statements about the nature of society and social values and the nature and behaviour of social institutions'.⁵²⁴ These are often used by the courts as a way of providing context, for example to paint a picture of society,⁵²⁵ or a statement of the likely social consequences of an action.⁵²⁶ An example of the use of a social fact in the context of discrimination law is the claim that workers' performance declines with age, and that older

⁵¹⁶ Morain and Largent (n 509).

⁵¹⁷ *ibid* 26.

⁵¹⁸ *ibid*.

⁵¹⁹ *ibid* 7.

⁵²⁰ *ibid*.

⁵²¹ *ibid* 27.

⁵²² *ibid* 28.

⁵²³ Ballantyne and Schaefer (n 163); Grewal and Newson (n 453).

⁵²⁴ Kylie Burns, 'The Way the World is: Social Facts in High Court Negligence Cases' (2004) 12 *Torts Law Journal* 215. Social facts are further differentiated by Burns from a finding of fact in the case (for example, on what a party to the legal action did or did not do) or a statement of the law (for example, the elements of the common law duty of confidentiality).

⁵²⁵ *ibid* 227–28.

⁵²⁶ *ibid* 228–29.

workers find it harder to find new job opportunities.⁵²⁷ By extension, an example taken from case law in relation to the application of the common law duty of confidentiality to the use of health data (and which is often drawn on in a policy context)⁵²⁸ is the contention that future patients are less likely to visit their doctor if the confidentiality of medical records is not preserved.⁵²⁹ A study of judgments of the Australian High Court (in negligence cases) indicated that social fact statements of this type tend either not to be referenced to an external source of authority in some way, or to be justified by reference to other case precedents or legal texts (thereby referring, in a somewhat circular way, to other unreferenced assumptions of social fact).⁵³⁰ The point to be made here is not that these social facts cannot be true, but rather to underline that these statements reflect ‘judicial experience and intuition’⁵³¹ about the world and are based on what might be described in everyday language as ‘common sense’.⁵³² The commonality of such understandings may, however, be highly contested in circumstances where the judiciary is taken from a narrow social and demographic strata of society, particularly in senior roles.⁵³³ This dilemma has been neatly expressed by Lady Hale:

‘If the life-blood of the law is experience and common sense, then whose experience and common sense are we talking about? Surely it cannot only be the experience and common sense of the judges, many of whom have led such sheltered lives? As I was once rude enough to say publicly, ‘one man’s common sense is another woman’s hopeless idiocy.’⁵³⁴

This is perhaps most pronounced in situations when:

‘...the social facts referred to by judges are incorrect, incomplete, out of date or tell the story of some members of society but shut out the reality of others.’⁵³⁵

⁵²⁷ Blackham (n 455) 420–21.

⁵²⁸ Nicola Byrne, ‘Data-Driven Innovation: Why Confidentiality and Transparency Must Underpin the Nation’s Bright Vision for the Future of Health and Care’ (*National Data Guardian*, 2021) <<https://www.gov.uk/government/news/data-driven-innovation-why-confidentiality-and-transparency-must-underpin-the-nations-bright-vision-for-the-future-of-health-and-care>> accessed 12 February 2022.

⁵²⁹ See, for example, comments by Rose J in *X Health Authority v Y* [1988] 648, 653.

⁵³⁰ Burns, ‘The way the world is: social facts in High Court negligence cases’ (n 524) 229.

⁵³¹ *ibid* 237.

⁵³² Kylie Burns, ‘Judges, “Common Sense” and Judicial Cognition’ (2016) 25 *Griffith Law Review* 319.

⁵³³ Ministry of Justice, ‘Diversity of the Judiciary: Legal Professions, New Appointments and Current Post-Holders – 2021 Statistics’ (*GOV.UK*, 15 July 2021) <<https://www.gov.uk/government/statistics/diversity-of-the-judiciary-2021-statistics/diversity-of-the-judiciary-2021-statistics-report>> accessed 19 January 2022.

⁵³⁴ David Barrett, ‘Judges Lead “Sheltered Lives”, Warns Britain’s Most Senior Female Judge’, *The Telegraph* (6 April 2013) <<https://www.telegraph.co.uk/news/uknews/law-and-order/9976400/Judges-lead-sheltered-lives-warns-Britains-most-senior-female-judge.html>> accessed 19 January 2022.

⁵³⁵ Burns, ‘The way the world is: social facts in High Court negligence cases’ (n 524) 238.

Given these shortcomings it has been proposed that the greater use of empirical evidence may be one way to connect law and society, and therefore to increase the legitimacy of decision making.⁵³⁶ It is of note, then, that the Australian study discussed above did identify a low incidence of references in the High Court judgments it reviewed to ‘social scientific’ material, such as government statistics or, in one case, a scholarly book.⁵³⁷ However, overall the study indicated that there was ‘...discomfort within the judiciary and the legal profession regarding the use and utility of social scientific evidence, because of lack of expertise and training or legalistic views on the judicial process’.⁵³⁸ In the UK courts the same use of ‘social facts’ can be seen in the context of negligence and discrimination law.⁵³⁹ Further, this UK study also indicated that while the courts do use empirical evidence in some limited ways, this is often ‘ad hoc, unprincipled and unpredictable’.⁵⁴⁰ To return to the employment law example referred to above, this inconsistency can be seen when tribunals have taken different approaches to the need to provide empirical evidence to support the claim that performance declines with age, and impacts on job opportunities.⁵⁴¹ Alternatively, where empirical evidence is used by courts (for example, in negligence cases) there are also challenges in how this is ‘evaluated and applied’.⁵⁴² This is particularly at issue when courts must make decisions about whether a negligent act caused the harm complained of (known as ‘causation’), where complex statistical evidence may be introduced to seek to prove the likelihood of the cause of the harm. This relationship - between evidence and intuition - was addressed by Lady Hale in the course of delivering a judgement of the UK’s Supreme Court on two complex cases involving liability for occupational exposure to asbestos dust, where causation of the fatal disease mesothelioma was at issue:

‘Fact finding judges are told that they must judge a conflict of oral evidence against “the overall probabilities” coupled with the objective facts and contemporaneous documentation.... Millions of pounds may depend upon their decision. Yet judges do not define what they mean by “the overall probabilities” other than their own particular hunches about human behaviour. Surely statistical associations are at least as valuable as hunches about human behaviour, especially when the judges are so unrepresentative of the population that their hunches may well be unreliable? Why should what a (always middle aged and usually middle class and male) judge thinks

⁵³⁶ Blackham (n 455).

⁵³⁷ Burns, ‘The way the world is: social facts in High Court negligence cases’ (n 524) 230.

⁵³⁸ *ibid* 231.

⁵³⁹ Blackham (n 455).

⁵⁴⁰ *ibid* 416.

⁵⁴¹ *ibid* 420–21.

⁵⁴² *ibid* 423.

probable in any given situation be thought more helpful than well-researched statistical associations in deciding where the overall probabilities lie? As it seems to me, both have a place. Finding facts is a difficult and under-studied exercise. But I would guess that it is not conducted on wholly scientific lines. Most judges will put everything into the mix before deciding which account is more likely than not. As long as they correctly direct themselves that statistical probabilities do not prove a case, any more than their own views about the overall probabilities will do so, their findings will be safe.⁵⁴³

This quote, and the discussion that precedes this on the use of empirical evidence in law, highlight some overlap with the conditions under which empirical evidence can impact on ethical debate and policy. In particular, this suggests that empirical evidence and ‘individual intuition’ are each relevant to legal decision-making, but neither is determinative in circumstances where both may go ‘into the mix’. However, the discussion of the use of empirical evidence by the law also draws particular attention to the representativeness and positionality of those making decisions, and the benefits of transparency in relation to how evidence is (or is not) taken into account (points I develop further below). The potential for decisions to be challenged is also raised; this is relevant in the HRR context in circumstances where there is plainly scope for disagreement over the procedural or substantive approach to a decision about, for example, whether the use of data is in the public interest. A failure to adequately account for this range of views could therefore not only affect the social acceptability and legitimacy of a decision (see, for example, the *care.data* example above) but also, albeit rarely, result in legal challenge.⁵⁴⁴ In both legal and ethical spheres the impact of including some voices, and/or excluding others, are considered, as well as a lack of proficiency in the use of empirical data. Further, the need for careful evaluation of empirical evidence, which itself is ‘...not neutral or objective’ is emphasised.⁵⁴⁵ This may involve the consideration of matters such as the relevance, completeness and quality of the evidence under consideration,⁵⁴⁶ as well as acknowledgement that there will likely be areas where there is an absence of relevant evidence.⁵⁴⁷ This is particularly the case where, as noted in the PE&I literature, common criticisms of attempts to engage with and involve publics include

⁵⁴³ *Sienkiewicz (Administratrix of the Estate of Enid Costello Deceased)(Respondent) v Greif (UK) Limited (Appellant); Knowsley Metropolitan Borough Council (Appellant) v Willmore (Respondent)* [2011] UKSC 10 172.

⁵⁴⁴ Although I am not aware of any challenge made to HRA decisions taken on the advice of its Confidentiality Advisory Group, the HRA is a public body whose decisions are, therefore, amenable to judicial review. See, for example, *R (on the application of Richmond Pharmacology Ltd) v The Health Research Authority* [2015] EWHC 2238 (Admin). In the next Chapter I discuss a case where an NHS Hospital was referred to the ICO following a challenge to a decision to share data with Google Deepmind.

⁵⁴⁵ Blackham (n 455) 417.

⁵⁴⁶ Blackham (n 455).

⁵⁴⁷ *ibid.*

'...questions of representativeness, articulation, impacts and outcomes.',⁵⁴⁸ and poorly conducted PE&I activities risk exclusivity and tokenism.⁵⁴⁹

In sum, the preceding analysis indicates that there is no barrier *per se* to using empirical data to inform ethical and policy debates, and legal decision-making processes, though this is often done in a way that is ad hoc and unprincipled. Further, the cautionary tale of *care.data* suggests that the relationship between empirical evidence of publics' views and attitudes, and support for a specific initiative, is complex and non-linear. Indeed, this complexity is borne out by consideration of outputs from studies of publics' expectations of data-intensive research for the public benefit, which relate not only to the *type* of public benefits expected from data usages, but also raises questions such as *how*, *when* and *for whom* research is conducted.

From all of the above it can be suggested that the conditions under which empirical evidence may be used to inform ethical discourse or the law overlap in a number of ways. This in relation to matters including the need to consider: (i) the quality and relevance of empirical evidence; (ii) its reach in terms of the publics affected and the relationship between majority and minority views; and (iii) the social, historical and political contexts in which evidence is deployed. The legal literature further highlights the need for thought to be given to *how* and *by whom* empirical evidence is used in decision-making processes, thereby inviting examination of the need for transparency, and for diversity amongst decision makers.

However, in circumstances where different literatures are grappling with the intersection between empirical evidence and HRR, the principal challenge remains. How can the analysis thus far be brought together so that it may be used to inform a defensible and holistic conception of the public interest as a regulatory device, that relies neither on a 'thin' legal conception of this concept, nor unquestioningly picks up outputs from public engagement exercises and presents these as 'the public interest'? As can be seen so far, elements of publicness can be observed in each approach, signalling the potential for this to operate as a *lingua franca*, to bring together the preceding analysis in order to provide a new perspective on a familiar device. In order to integrate my findings so far I therefore return to publicness in order to reconstruct the public interest as a regulatory device in HRR.

Using publicness to reimagine the public interest as a regulatory device

As noted earlier in this Chapter, publicness has already been used as a lens through which to view the public interest in order to draw out why a disconnect between the public interest as a

⁵⁴⁸ Stilgoe and others (n 378).

⁵⁴⁹ Ocloo and Matthews (n 388).

regulatory device, and the views of actual publics, can lead to sub-optimal HRR. However, here I use publicness to reimagine the public interest in light of the preceding analysis. In order to do so, I return to the tripartite framework of relationality, temporality and accountability. By way of recap, a working definition of publicness, which has been revised throughout this thesis, is set out in **Table 15**.

Table 15: A (revised) working definition of publicness in HRR

Publicness is a concept used to describe the interrelationship between collective and individual interests, thereby drawing attention to the context in which this interplay takes place, as well as the implications of the interrelationship between individual and collective interests for HRR, both now and in the future.

Publicness also provides the foundation for a framework of analysis which directs attention to:

- **Relationality**: the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness, therefore moving away from oppositional ways of thinking about the interests at stake;
- **Temporality**: temporal aspects of these interests in health research, including how these may change over time;
- **Accountability**: how these interests can be accounted for when decisions are made about what, whether, how and with whom health research is conducted.

In this way publicness performs a diagnostic and normative role in that it:

- helps us to understand better the nature and role of existing mechanisms within HRR;
- provides a theoretical and practical basis to move beyond what already exists in the sub-optimal HRR ecosystem

Publicness first directs attention to *relationality* and the co-existence of (multiple) kinds of overlapping interests in health research. As I have previously argued, the lens of publicness encourages us to resist HRR's narrowing of the range of interests that are taken into account. This points to two key considerations that impact on the re-imagination of the public interest.

First, and as I have argued in Chapter 4, publicness requires that we look beyond a homogenised conception of *who* 'the public' are in data-intensive research and consider the *multiple perspectives* that people may have on what socially legitimate research looks like. In turn, this draws attention not only to the diversity and mutability of and within publics, and therefore also of what is 'in the public interest', but also to the differential impact on people and groups of regulatory structures and devices. This analysis challenges a conventional,

law-internal view of the public interest, which is anchored by the views of a 'reasonable man' or a 'reasonable public'. Rather, this points to the way that publics in HRR, and in relation to data-intensive health research more specifically, are formed and named,⁵⁵⁰ and how these may change over time. These insights prompt a move away from an approach to empirical evidence that presents this as representing a universal truth about what 'the public' want, require or reject in relation to the conduct of data-intensive research in the public interest. Instead, publicness sensitises policy and decision makers to the need to consider empirical evidence in its historical, social and political context relative to the moral community in which decisions are being taken (indeed, it might even be more apt to talk of moral *communities*).⁵⁵¹ By way of example, empirical evidence of a majority opinion that data should be used for a particular purpose should still be considered in relation to its potential impact on minority interests. This new framing underlines, in the context of HRR, what is perhaps trite for PE&I practitioners: that outputs from PE&I activities do not (and indeed, on my interpretation, could never) represent the full gamut of interests that are at play in health research that uses data at a large group or population level. In this way publicness problematises notions of who 'the public' are in 'the public interest'. Nonetheless, this approach need not paralyse decision-making processes, nor preclude the use of empirical evidence on the basis that it is not fully representative. Rather, what I propose leaves space for the contextual use of empirical evidence to inform the public interest, albeit as viewed in context, and relative to the interests of the moral communities in which decisions are being made. This provides a pragmatic way forward, that allows for a more nuanced and realistic use of empirical evidence to inform the public interest (as I come to in more detail at the end of this section).

This leads to a second point on relationality, in connection with the *context* in which multiple interests in HRR play out over time. Here publicness, and its focus on relationality, draws attention to factors beyond public benefits alone that may shape, and be shaped by, people's views on the legitimacy of data-intensive health research.⁵⁵² For example, this may include participants' perceptions of the trustworthiness of those conducting research.⁵⁵³ In the context of data-intensive health research, where there is often little or no contact between those whose data are used and researchers, this consideration may extend to institutional trustworthiness, an attribute that was lacking in the case of *care.data*.⁵⁵⁴ Kerasidou has recently described this in the following terms:

⁵⁵⁰ Braun and Schultz (n 394).

⁵⁵¹ Hill Collins and Bilge (n 9).

⁵⁵² Armstrong and others (n 474) 1240.

⁵⁵³ Armstrong and others (n 474).

⁵⁵⁴ Carter and others (n 164).

'When it comes to institutions, their trustworthy character is revealed in their professed goals and aims, [in] their institutional structures, internal rules and regulations as indicators for their moral motivations, and in their reputation and track record as indicator for their skill and commitment to right action.⁵⁵⁵

However, demonstrating institutional trustworthiness is not merely a matter of following the rules for self-interested purposes (for example, to avoid sanction).⁵⁵⁶ Rather, this requires deeper engagement with the core aims of responsible data-intensive research, and that these are embedded throughout the institutional structure.⁵⁵⁷ Such aims may include addressing inequality (as proposed in Chapter 4) as well as delivering research with demonstrable public benefit(s) (as discussed above). This is not a prescriptive list, but rather an illustration of the way in which publicness, as a concept, extends our gaze beyond public attitudes, views, values and informed opinions in isolation, and draws into view the bigger picture in HRR. This emphasises, in relation to the public interest, that there are other contextual variables, beyond empirical evidence of publics' views, that might bear on this, such as how decisions are made and by whom.

Next, and as already touched upon above, publicness also foregrounds *temporality* and how the interests engaged by HRR may change over time. This is a recurring theme in a number of the empirical studies considered above which variously suggest that public benefits may not only accrue now, but also to 'future generations'.⁵⁵⁸ As I come to further below, another study found that transparency was indivisible from public benefit, and is a requirement 'throughout the whole data lifecycle'.⁵⁵⁹ The perils of overlooking the dynamic nature of these interests is demonstrated by the legal literature which indicates that decisions made on this basis risk being '...incorrect, incomplete, out of date or tell the story of some members of society but shut out the reality of others'.⁵⁶⁰ These criticisms may equally apply to the public interest, in circumstances where this is approached as a static consideration. Publicness therefore urges us to revisit the public interest throughout the data and research lifecycle, recognising that the interplay between the public interest and actual public views (amongst other considerations) is not a one-off event. In this way, the temporal element of publicness draws attention to *when* public interests are considered and highlights, for example, the

⁵⁵⁵ Angeliki Kerasidou, 'Trustworthy Institutions in Global Health Research Collaborations' in Graeme Laurie and others (eds), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021) 86.

⁵⁵⁶ Kerasidou (n 555).

⁵⁵⁷ *ibid.*

⁵⁵⁸ Aitken and others, 'Who benefits and how?' (n 168).

⁵⁵⁹ Hopkins Van Mil (n 490).

⁵⁶⁰ Burns, 'The way the world is: social facts in High Court negligence cases' (n 524) 238.

differences between cursory *ex post* engagement, and meaningful up-front consideration which has the potential to embed public interests in research design. Publicness pushes us to reimagine the research trajectory and therefore the role of the public interest in this context. Rather than thinking of this as a linear course of action with fixed points for consideration of the public interest, this generates an image of a double helix where the research path and the public interest overlap and intersect each other throughout the entire life cycle.

A third consideration in respect of publicness, which builds on each of the points set out above, is *how multiple interests in HRR can be accounted for* throughout the research life cycle. Here the preceding discussion, from different disciplinary perspectives, reveals the fallacy of the 'objective decision maker' who makes judgments based on 'objective facts'. This is illustrated in the legal context, which provides the archetypal setting in which decisions are scrutinised for bias and subjectivity and, if found lacking, challenged. Even in these stringent circumstances, Lady Hale identifies that decisions may not be made in a formulaic way along 'wholly scientific lines'.⁵⁶¹ Rather, she suggests that judges tend to 'put everything into the mix' before reaching a decision'.⁵⁶² Nonetheless, she opines that these decisions will be 'safe' (i.e. able to resist legal challenge) where judges correctly follow the law and make it clear that neither empirical evidence nor their own views are definitive.⁵⁶³ This brief consideration of the decision-making process is sufficient to expose the perhaps rather obvious position - that decisions, including those made in relation to the public interest in data-driven research - are likely to be multi-factorial and context specific. Not least, this observation points to the need for transparency in relation to how the public interest is understood, whether by reference to intuition, empirical evidence, historical context, or (most likely) a combination of different components. Drawing on the conception of the public interest that has been developed by Taylor, alone and with others,⁵⁶⁴ this emphasises that trade-offs, for example between individual control and research access to data, are inevitable when decisions are made about whether research is, or is not, in the public interest.⁵⁶⁵ However, a hallmark of Taylor's approach is that '...people can access reasons for a particular trade-off that they "have reason to accept"'.⁵⁶⁶ This accords with studies reported on above, that have emphasised the importance of transparency throughout the research process, when coupled with authenticity,

⁵⁶¹ *Sienkiewicz v Greif* (n 543).

⁵⁶² *ibid.*

⁵⁶³ *ibid* at 172.

⁵⁶⁴ Mark J Taylor, 'Health Research, Data Protection, and the Public Interest in Notification' (2011) 19 *Med L Rev* 267; Taylor and Taylor (n 508); Taylor and Whitton (n 456).

⁵⁶⁵ Taylor and Whitton (n 456).

⁵⁶⁶ *ibid* 17 Taylor and Whitton further indicate that '...what people are willing to accept in practice remains an important consideration' as addressed above.

and as a prerequisite for public benefit.⁵⁶⁷ Taken together, this approach to the public interest, that emphasises accountability and transparency, has the potential to move away from a position where collective or individual interests are used to trump one another, and towards a framework where interests can be accounted for, albeit that there may be good reasons that these are, or are not, taken up. Indeed, making sure that publicness itself is done ‘in public’ can help to ensure not only that the decisions taken are more robust, but also that those among publics who might disagree with those decisions are given good reasons to believe that a wide and inclusive range of views were at least taken into account.

In sum, and drawing on the preceding analysis, publicness-informed guidance that could help to frame robust judgements in relation to whether data usage is in the public interest could usefully address matters such as:

- the relationship between the public interest and public benefits. I have argued, in short, the public interest can legitimate research activities such as data usages that infringe on individual interests, but have potential *public benefits*. As set out in Chapter 3, publicness can aid clarity here by helping to distinguish between the plethora of terms in this area which may be used interchangeably.
- the interrelationship between individual and collective interests in data use and non-use (where publicness emphasises that these interests can co-exist and build on one another; in other words, the existence of an individual interest in a particular data usage does not preclude there also being collective interests in that usage).
- *how* public benefits may be understood in the context of the public interest in HRR, in that these are highly contextual and can be construed beyond the clinical benefits of the use of data, to include wider benefits such as improvements in systems of care and quality of life, amongst other matters.
- *to whom* such benefits are expected to accrue – in other words, who are the publics in the public interest? In particular, if it is accepted that ‘the public’ is not a homogenous entity then benefits are unlikely to always be universal, thus encouraging acknowledgment of the potential for (and more detailed scrutiny and articulation of) differential and/or unequal impacts across society. Consider, for example, the hypothetical proposal that we use population level NHS data to undertake research in relation to a rare disease that has a severe impact on a small number of people. A publicness-informed approach, which foregrounds relationality, draws attention to the interrelationship between individual and collective interests, and how these may build

⁵⁶⁷ Quiroz-Aitken and others (n 471); Hopkins Van Mil (n 490).

upon one another. In other words, although a direct benefit from the research may accrue to people with the rare disease in a way that it will not accrue to the wider population, this does not preclude there also being a collective benefit to the wider community of those in need receiving that treatment. On the other hand, there may be other instances where research is expected to deliver a benefit to a larger group, but would impact negatively on a smaller group. Here considerations of publicness guards against a majoritarian approach.

- *when* public benefits are expected to accrue over time, in the shorter or longer term. Publicness draws out attention to the temporality of the public interest as a dynamic, rather than static, concept, and therefore the limitations of an approach that overlooks the need for ongoing review throughout the data use / research lifecycle. For example, what mechanisms are in place in order to gauge, in due course, whether these benefits have *actually* come to fruition and how can this be fed back into a learning system of regulation?
- where public benefits are expected, or have been delivered, these should be *clearly articulated and communicated*. If publicness is to be done ‘in public’, rather than behind closed doors, then decisions in relation to the public interest should be explained in such a way that is explicit and widely accessible, not just to an expert and/or elite audience.

Some, but not all, of these features are reflected in a recent consultation by the Information Commissioner’s office on draft guidance on the research provisions within the UK GDPR and the DPA 2018,⁵⁶⁸ which refers to processing ‘in the public interest’.⁵⁶⁹ However, using publicness as a touchstone, the preceding (non-exhaustive) list also reaches beyond what is proposed in that consultation, particularly with regard to relationality (in terms of recognising the mutability and diversity of and within publics in the context of an outwards-looking conception of the public interest) and temporarily (such as how the public interest may change over time). Moreover, while the draft guidance focuses on public interest decision making on a case-by-case basis, publicness pushes us not only to consider ‘the public interest’ in terms of how this may be realised from the (expected) findings from research, but also as something that may be manifested in *processes of research and regulation in relation to data use*. This

⁵⁶⁸ Information Commissioner’s Office, ‘ICO Consultation on Draft Guidance for the Research Provisions within the UK GDPR and the DPA 2018’ (22 April 2022) <<https://ico.org.uk/about-the-ico/ico-and-stakeholder-consultations/draft-gdpr-research-provisions/>>.

⁵⁶⁹ *ibid* 27–28.

expands our consideration to include matters such as *who* participates and benefits from this endeavour, as well as *how* and *when* public benefits are realised and communicated.

Conclusion

In this Chapter I have focussed on the intersection between the public interest as a regulatory device, and extra-legal insights from empirical evidence. At the outset I recognised the *potential* for the public interest to act as a 'hair shirt' that provides a framework that can account for the multiple and related interests that are at play when the public interest is at stake. However, I also pointed to several shortcomings of this concept, and in particular the *prima facie* impasse between a law-internal conception of the public interest and empirical evidence of the views of actual publics. The case of *care.data* has served to illustrate the pitfalls of such an approach.

My analysis has indicated the need for a defensible and holistic conception of the public interest, that relies neither on a 'thin' legal notion of this concept, nor unquestioningly picks up outputs from public engagement exercises and presents these as constituting 'the public interest'. I have further shown that the public interest need not remain disconnected from empirical evidence. Indeed the law has a history of using extra-legal insights, albeit in an inconsistent and unprincipled way: a point that until now has not been directly addressed in the context of the public interest in HRR. However, it is the framework provided by publicness that has facilitated the grounding and extension of this analysis, and offers further insights in relation to this contested device in three key respects.

First, I have proposed a relational conception of the public interest that recognises the mutability and diversity of and within publics. This challenges a conventional, law-internal view of this concept, which is anchored by the views of a 'reasonable man' or a 'reasonable public'. While this analysis problematises notions of who 'the public' are in the public interest, it also points to a pragmatic way forward. This is that empirical evidence can be viewed in its historical, social and political context, and alongside other considerations, such as the trustworthiness of institutions. Second, I have engaged with temporal aspects of the public interest. Here I have reimagined the research trajectory, and the role of the public interest, as overlapping and intersecting one another throughout the entire data or research life cycle. This has implications for HRR in relation to the opportunities that are provided for public interest considerations to be proactively reviewed and refined over time. Third, I have highlighted the need for accountability and transparency, as explored further in the next

Chapter, where public interest decisions are made that are, as I have argued above, necessarily multi-factorial and context specific.

Through its consideration of relationality, temporality and accountability, publicness does not operate here to define what the public interest 'is' or where it may lie in a given situation. Rather, it helps to provide the parameters within which decisions can be made and robustly defended, and evidence may be deployed or rejected (as thought to be appropriate).

Chapter 6: Publicness in action: optimising contemporary HRR

Introduction

This Chapter provides an opportunity to reflect on the analysis I have delivered thus far in this thesis and to consider how this speaks to a high profile example of the secondary use of health data. My focus is on the collaboration between The Royal Free London NHS Foundation Trust (the Royal Free) and Google DeepMind⁵⁷⁰ (DeepMind) in relation to the creation of an application to help to detect and manage acute kidney injury, known as ‘Streams’.⁵⁷¹ As I come to below, concerns were raised about the large scale sharing and use of identifiable health data, and in particular, the use of around 1.6 million identifiable partial patient records in the testing phase of the Streams application. This resulted in an investigation by the Information Commissioner, which concluded in 2017 and found that the Royal Free (as the data controller) had breached data protection legislation in a number of respects, and its actions had fallen short of the requirements of the common law duty of confidentiality.⁵⁷²

This collaboration has been selected for examination as an example of a high profile dispute in relation to the use of a large quantity of identifiable health data to facilitate the improvement of clinical care through the use of technology. While the data transfer in question was for safety testing of the Streams app, as opposed to for research, conflicts of this type have the potential to reveal much about the interests – of science, and of society – that are at stake when data is used in the course of innovation, and how this may impact on regulation.⁵⁷³

I begin by outlining the details of the Royal Free and DeepMind collaboration. Next, I use the tripartite framework provided by publicness to analyse these events, paying particular attention to the domains of relationality, temporality and accountability. I conclude this Chapter by considering the insights that a publicness informed approach to the use of confidential health data without consent reveals. This case study illustrates how publicness represents a concept that can support the robust review and revision of data-intensive initiatives, where there are multiple and related interests at play, throughout the full research lifecycle. This has the potential to optimise HRR by both elucidating ‘lessons learned’, and also through the

⁵⁷⁰ Powles and Hodson indicate that DeepMind Technologies Limited is a wholly-owned subsidiary of the Google conglomerate, Alphabet Inc. Julia Powles and Hal Hodson, ‘Google DeepMind and Healthcare in an Age of Algorithms’ (2017) 7 *Health Technol* 351, 351.

⁵⁷¹ Linklaters LLP, ‘Audit of the Acute Kidney Injury Detection System Known as Streams’ (17 May 2018) 1.

⁵⁷² Elizabeth Denham, ‘Information Commissioner’s Office to Sir David Sloman, Chief Executive, Royal Free London NHS Trust Re Provision of Patient Data to DeepMind’ (3 July 2017)

<<https://ico.org.uk/media/2014353/undertaking-cover-letter-revised-04072017-to-first-person.pdf>>.

⁵⁷³ Dixon-Woods and Ashcroft (n 282).

identification of positive steps that can support future data-sharing initiatives to better account for publicness.

The Royal Free, DeepMind and 1.6 Million Patients' Records

The collaboration between the Royal Free and DeepMind began in 2015 with the aim of producing an application (app) that could be used on a mobile device and help clinicians to detect acute kidney injury (AKI) at an early stage.⁵⁷⁴ AKI is described as a widespread and potentially serious concern that affects one in six in-patients, but may be difficult to diagnose.⁵⁷⁵ The result of this collaboration is the Streams app which 'uses a range of patient data to determine whether a patient is at risk of developing AKI and sends an instant alert to clinicians who are able to take appropriate action promptly'.⁵⁷⁶ In this way information that was available in different parts of the system could be hosted in one location, which was easily accessible for clinicians.⁵⁷⁷ As I come to further below, such an app had the potential not only to improve the care provided to individual patients at the Royal Free, but also to streamline healthcare delivery at a systems level, and to be used to benefit publics more widely across the NHS. As such this collaboration provides an example of how technology from the private sector may be used to leverage existing data held by the NHS in order to deliver individual and public benefits.

The partnership between the Royal Free and DeepMind that led to the development of Streams commenced in 2015.⁵⁷⁸ An original Information Sharing Agreement was signed by the parties in September 2015.⁵⁷⁹ This was subsequently criticised by commentators⁵⁸⁰ and

⁵⁷⁴ Royal Free London NHS Foundation Trust, 'Our Work with Google Health UK' <<https://www.royalfree.nhs.uk/patients-visitors/how-we-use-patient-information/our-work-with-deepmind/>> accessed 23 February 2022.

⁵⁷⁵ *ibid.*

⁵⁷⁶ *ibid.*

⁵⁷⁷ As described by a clinician in a presentation at *ibid.*

⁵⁷⁸ The details of these contractual arrangements are gleaned from peer-reviewed academic publications, including as co-authored by Hal Hodson, the investigative journalist who authored of the 2016 *New Scientist* article that first brought these issues to light: Powles and Hodson (n 570); Royal Free London NHS Foundation Trust (n 574).

⁵⁷⁹ The details of these contractual arrangements are gleaned from peer-reviewed academic publications, including as co-authored by Hal Hodson, the investigative journalist who authored of the 2016 *New Scientist* article that first brought these issues to light.

⁵⁸⁰ Powles and Hodson (n 570).

by the Information Commissioner⁵⁸¹ in respect of the breadth of its scope. In particular, it was reported that this covered not only the AKI work related to Streams, but also:

‘...real time clinical analytics, detection, diagnosis and decision support to support treatment and avert clinical deterioration across a range of diagnoses and organ systems’.⁵⁸²

Subsequently, further contractual agreements were put in place between the parties in 2016, although, as noted by the Information Commissioner, at this point data had already been processed by Deepmind.⁵⁸³ The data processing in question ‘...was to carry out clinical safety testing as part of the development of a new clinical detection, diagnosis and prevention application for the Trust in relation to [AKI].’⁵⁸⁴ These data were identifiable and:

‘...included information on persons who had presented for treatment in the previous five years for tests together with data from the Trust’s existing radiology electronic patient record system. Under the terms of the agreement DeepMind would process approximately 1.6 million such partial records for clinical safety testing.’⁵⁸⁵

Streams moved into live use at the Royal Free in 2017. In the Information Commissioner’s findings later that year, she focused on the testing period that preceded this, though noted that her findings had implications for the Streams app more broadly. More specifically, she found that these actions led to breach of the common law duty of confidence, as well as non-compliance with four of the data protection principles:

‘Principle One: Personal data shall be processed fairly and lawfully;

Principle Three: Personal data should be adequate, relevant and not excessive;

Principle Six: Personal data shall be processed in accordance with the rights of data subjects;

Principle Seven: Appropriate technical and organisational controls shall be taken – this includes the need to ensure that appropriate contractual controls are in place when a data processor is used.’⁵⁸⁶

These failures related to matters including a lack of transparency around how data would be used, and the impact this had on the ability of patients to object or opt out. The decision also

⁵⁸¹ Denham (n 572).

⁵⁸² Powles and Hodson (n 570) 352.

⁵⁸³ Denham (n 572).

⁵⁸⁴ *ibid* 3.

⁵⁸⁵ *ibid*.

⁵⁸⁶ *ibid* 2.

referred to the sheer scale of the identifiable data that were processed. Notwithstanding this, it was also noted that the Royal Free had already implemented a number of changes, not only with regard to the updated contractual agreements in place with Deepmind, but also in relation to transparency and the information on its website relating to the use of Streams.⁵⁸⁷ The Royal Free was invited to enter into an undertaking, which included the requirement that it commission an independent third party audit of Streams.⁵⁸⁸

The responses to the Information Commissioner's decision by the Royal Free and DeepMind also bear scrutiny. The Royal Free noted that there were lessons to be learned from the findings that the organisation did not do enough to inform patients that their information was being used by DeepMind, and that this lack of transparency impacted on how patients could use their rights to object to this use.⁵⁸⁹ In particular, they pointed to more recent efforts to provide greater transparency about how patient data is used - both online and within the hospital environment in areas with high footfall - and how patients can opt out of data sharing if they so wish.⁵⁹⁰ While not subject to the decision, which attached to the Royal Free as the data controller, DeepMind also provided their reflections on these findings, as follows:

'...we underestimated the complexity of the NHS and of the rules around patient data, as well as the potential fears about a well-known tech company working in health. We were almost exclusively focused on building tools that nurses and doctors wanted, and thought of our work as technology for clinicians rather than something that needed to be accountable to and shaped by patients, the public and the NHS as a whole. We got that wrong, and we need to do better.'⁵⁹¹

DeepMind pointed to changes they had implemented, including a new patient and public engagement strategy, and scrutiny by a panel of independent reviewers (who they indicate were appointed prior to 'any regulatory or media criticism').⁵⁹²

Since the ICO's decision, Streams has remained in use at the Royal Free, and, it appears, was also rolled out to a number of other NHS Trusts in England.⁵⁹³ In a structural

⁵⁸⁷ *ibid* 5.

⁵⁸⁸ Denham (n 572).

⁵⁸⁹ 'Information Commissioner's Office (ICO) Investigation' <<https://www.royalfree.nhs.uk/patients-visitors/how-we-use-patient-information/information-commissioners-office-ico-investigation-into-our-work-with-deepmind/>> accessed 23 February 2022.

⁵⁹⁰ *ibid*.

⁵⁹¹ Mustafa Suleyman and Dominic King, 'The Information Commissioner, the Royal Free, and what we've learned' (*Deepmind*, 3 July 2017) <[blog/announcements/ico-royal-free](https://blog.announcements/ico-royal-free)> accessed 23 February 2022.

⁵⁹² *ibid*.

⁵⁹³ Natasha Lomas, 'Google Confirms It's Pulling the Plug on Streams, Its UK Clinician Support App' (*TechCrunch*, 26 August 2021) <<https://social.techcrunch.com/2021/08/26/google-confirms-its-pulling-the-plug-on-streams-its-uk-clinician-support-app/>> accessed 24 February 2022.

reorganisation in 2018 the DeepMind team that created the app moved to Google Health UK ‘...so that the app can grow and support more doctors to deliver faster, better care to patients.’⁵⁹⁴ The same year a third party audit report commissioned by the Royal Free, and carried out by Linklaters LLP, indicated that they ‘...consider the Royal Free’s use of Streams is lawful’,⁵⁹⁵ and Royal Free indicated on their webpage that the Information Commissioner had ‘no further outstanding concerns regarding the current processing of personal data within Streams’.⁵⁹⁶ As an aside, during this period DeepMind were also involved in legal proceedings as they sought (unsuccessfully) to obtain an EU Trademark for Streams. Their appeal of this refusal was dismissed by the Court of Justice of the European Union in January 2019.⁵⁹⁷

The clinical impact of Streams was the subject of a peer reviewed service evaluation, as published in 2019 by the Nature group. This describes ‘the successful implementation of this care pathway’, and found that this:

‘...enables a team of specialists to be alerted to potential changes in hospitalised patients’ kidney function in real time, rapidly review a curated set of relevant clinical data, intervene proactively and remotely monitor and follow-up cases. We have demonstrated that through such technology, in-application specialist review of AKI cases can take place in minutes. This care pathway has improved the timeliness and reliability of key aspects of AKI care, but definitive conclusions regarding the clinical impact of the pathway cannot be made at this stage and are limited by the scope and nature of our evaluation.’⁵⁹⁸

It may be considered, then, that despite the difficulties encountered in its early phases, Streams has been a success, both in terms of its current (lawful) governance structure, and also its impact on AKI care. However, recent reports within technology industry press have pointed to two ongoing legacy considerations. The first is that it appears, from technology industry media reports, that Streams is to be decommissioned by Google Health UK, though it is not clear from publically available documents why this is the case.⁵⁹⁹ Indeed, it has been suggested that, as of summer of 2021, Royal Free was the only hospital still using the app.⁶⁰⁰ At the time of writing there is no information about how decommissioning will be managed on

⁵⁹⁴ ‘Information Commissioner’s Office (ICO) investigation’ (n 589).

⁵⁹⁵ Linklaters LLP (n 571).

⁵⁹⁶ ‘Information Commissioner’s Office (ICO) investigation’ (n 589).

⁵⁹⁷ Case T-97/18 DeepMind Technologies Ltd v EUIPO (STREAMS) [2019] ECR-II ECLI:EU:T:2019:43.

⁵⁹⁸ Alistair Connell and others, ‘Evaluation of a Digitally-Enabled Care Pathway for Acute Kidney Injury Management in Hospital Emergency Admissions’ (2019) 2 npj Digital Medicine 1, 1, 5.

⁵⁹⁹ Lomas (n 593).

⁶⁰⁰ *ibid.*

Google Health's Streams website page for clinicians.⁶⁰¹ Nor is this referred to on the Royal Free's own webpage in relation to its work with Google Health UK,⁶⁰² though it has been reported in a technology blog that: 'The Streams app has not been decommissioned for the Royal Free London and our clinicians continue to use it for the benefit of patients in our hospitals'.⁶⁰³ This position has been met with scepticism by some, in circumstances where other NHS providers are no longer using the app, and it is reported that Google Health UK have shifted their attention to a new 'digital offering' which is being developed in connection with US medical care providers.⁶⁰⁴ This is marketed under the trademarked name 'Care Studio', and described as providing 'an integrated view of patient records to clinicians'.⁶⁰⁵

A second consideration is the announcement in September 2021 by the law firm, Mishcon de Reya that they are:

'...bringing a representative action on behalf of Mr Andrew Prismall and the approximately 1.6 million individuals whose confidential medical records were obtained by Google and DeepMind Technologies in breach of data protection laws.'⁶⁰⁶

At the time of writing it appears that this case is yet to be heard.⁶⁰⁷ However, the announcement of these proceedings late in 2021 suggests that, despite DeepMind's step back from Streams in 2018, and the conclusion of the Information Commissioner's investigation in 2019, the Royal Free (as data controller) and, to some extent, DeepMind (as data processor) may still be dealing with the implications of these findings.

The preceding account has provided an overview of some of the key events that have unfolded over a period of around seven years, from the inception of the Royal Free / DeepMind collaboration in 2015, through to the present day. A picture emerges of a number of serious missteps, not least in relation to a (lack of) patient and public engagement, and transparency, which have caused public concern, and resulted in formal regulatory sanction. It appears that the collaborators may have underestimated more widespread concerns about the use by a

⁶⁰¹ Google Health, 'Streams: A Mobile Medical Device' <<https://health.google/for-clinicians/streams/>> accessed 24 February 2022.

⁶⁰² Royal Free London NHS Foundation Trust (n 574).

⁶⁰³ Lomas (n 593).

⁶⁰⁴ *ibid.*

⁶⁰⁵ Google Health, 'Care Studio: Clinical Software to Unify Healthcare' <<https://health.google/for-clinicians/care-studio/>> accessed 24 February 2022.

⁶⁰⁶ Ben Lasserson, 'Confidential Medical Records at the Centre of a New Claim against Google' (*Mishcon de Reya LLP*, 30 September 2021) <<https://www.mishcon.com/news/confidential-medical-records-at-the-centre-of-a-new-claim-against-google>> accessed 24 February 2022.

⁶⁰⁷ On 25th February 2022, in response to a query in relation to the current status of the litigation, the Partner leading the litigation at Mishcon de Reya indicated that they were '...not able to make any comment at this point in time'.

private technology company of people's NHS health data. This could perhaps have been predicted from research undertaken for the Royal Statistical Society in 2014, prior to the launch of Streams.⁶⁰⁸ This indicated that '...public knowledge of what currently happens to [people's] data is low and suspicion is high – particularly where data may move between the public and private sectors'.⁶⁰⁹

Nonetheless, consideration of the Information Commissioner's findings in isolation do not tell the whole story. As the Royal Free⁶¹⁰ and DeepMind⁶¹¹ have indicated, the aim of the Streams app was, and is, to improve patient care in respect of the clinical management of AKI through the application of technology. Indeed, in the context of their criticisms of this collaboration both the Information Commissioner⁶¹² and the National Data Guardian⁶¹³ have expressed that, in principle, they support the use of data for the public good, and the use of technology and innovation to improve clinical care. In addition, a number of early academic commentaries⁶¹⁴ and the Information Commissioner's investigation⁶¹⁵ have tended to focus on the early, testing stages of the app, and the regulatory failures that occurred during this period. This undoubtedly provides a warning of the perils of embarking on a collaboration where all parties do not fully appreciate 'the complexity of the NHS and the rules around patient data'.⁶¹⁶ Yet, this brief discussion also serves to highlight the potential benefits – both public and private, and individual and collective - that may accrue when technology enables existing data to be used in innovative ways. This brings us, therefore, to the role of publicness, as a concept that can support the review and revision of data-intensive initiatives, where there are multiple and related interests at play, throughout the full research lifecycle.

⁶⁰⁸ Ipsos Mori, 'Public Attitudes to the Use and Sharing of Their Data, Research for the Royal Statistical Society' (23 July 2014).

⁶⁰⁹ Ipsos Mori, 'New Research Finds Data Trust Deficit with Lessons for Policymakers' (*Ipsos Mori*, 23 July 2014) <<https://www.ipsos.com/en-uk/new-research-finds-data-trust-deficit-lessons-policymakers>> accessed 24 February 2022.

⁶¹⁰ Royal Free London NHS Foundation Trust (n 574).

⁶¹¹ Dominic King and others, 'Letter in Response to Google DeepMind and Healthcare in an Age of Algorithms' (2018) 8 *Health Technol* 11.

⁶¹² The Information Commissioner nods to this in her decision letter. Denham (n 572).

⁶¹³ Sky News published a leaked copy of the National Data Guardian's letter which can be found here: Alexander J Martin, 'Google Received 1.6 Million NHS Patients' Data on an "Inappropriate Legal Basis"' (*Sky News*, 15 May 2017) <<https://news.sky.com/story/google-received-1-6-million-nhs-patients-data-on-an-inappropriate-legal-basis-10879142>> accessed 24 February 2022.

⁶¹⁴ Powles and Hodson (n 570); Hal Hodson, 'Revealed: Google AI Has Access to Huge Haul of NHS Patient Data' [2016] *New Scientist*; Hal Hodson, 'Did Google's NHS Patient Data Deal Need Ethical Approval?' [2016] *New Scientist*.

⁶¹⁵ Denham (n 572).

⁶¹⁶ Suleyman and King (n 591).

Publicness as a lens of analysis

Here I use the tripartite framework provided by publicness in order to analyse aspects of the collaboration between the Royal Free and DeepMind paying particular attention to the themes identified throughout this thesis of relationality, temporality and accountability. **Table 16** serves as a reminder of the working definition of publicness.

Table 16: A (revised) working definition of publicness in HRR

Publicness is a concept used to describe the interrelationship between collective and individual interests, thereby drawing attention to the context in which this interplay takes place, as well as the implications of the interrelationship between individual and collective interests for HRR, both now and in the future.

Publicness also provides the foundation for a framework of analysis which directs attention to:

- **Relationality:** the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness, therefore moving away from oppositional ways of thinking about the interests at stake;
- **Temporality:** the temporal aspects of these interests in health research, including how these may change over time;
- **Accountability:** how these interests can be accounted for when decisions are made about what, whether, how and with whom health research is conducted.

In this way publicness performs a diagnostic and normative role in that it:

- helps us to understand better the nature and role of existing mechanisms within HRR;
- provides a theoretical and practical basis to move beyond what already exists in the sub-optimal HRR ecosystem

Turning first to relationality, this draws attention to the co-existence of (multiple) kinds of overlapping and interconnected interests, when NHS health data is used to deliver technology such as the Streams app. As I now go on to explore, a number of features in this respect emerge from the analysis above.

It has since been acknowledged, by DeepMind at least, that there was a focus on clinicians, as the 'end users' of the app, to the exclusion of adequate consideration of the potential role and contributions of stakeholders such as patients and wider publics. For example, from the outset of the Streams project it appears that there was good engagement from clinicians at

the Royal Free who ‘brought in’⁶¹⁷ Deepmind to help them address concern over AKI management. This joint approach is to be commended in circumstances where a disconnect between app developers and clinicians in similar projects has been criticised, and led to limited functionality and uptake.⁶¹⁸ It can further be observed that the NHS Trust remained committed to using the app, following the Information Commissioner’s investigation and findings, and continues to provide clinician testimonies to its effectiveness on its website.⁶¹⁹ However, I would argue that this focus was at the expense of adequate engagement with, amongst others, the patients whose data was used. Indeed, following the Information Commissioner’s findings the Royal Free (as data controller) acknowledged that: ‘

One lesson is to provide greater transparency. We are now doing more than any other hospital trust in the country to tell our patients and the public how we use their information.’⁶²⁰

However, while the law may require, at the minimum, the provision of better information to data subjects around how their data will be used, publicness goes beyond this baseline of legal compliance and urges further scrutiny of the multiple and overlapping roles of patients. More specifically, such an approach suggests that patients are not merely passive recipients of the clinical benefits of apps such as Streams, or providers of data, but rather have the potential to be active agents with valuable contributions to make in relation to their own data, its various uses, or indeed the governance of data more generally. This is illustrated by the outputs from public engagement exercises, such as those in relation to understandings of ‘public benefit’, as summarised in Chapter 5. These findings indicate that publics’ may have views not only on *what* research takes place, but also *how* this should be conducted and regulated if data usages are to be socially legitimate. To be clear, this is not to say that publicness requires a consent based approach – this would likely be impractical, or even impossible in the context of initiatives using large quantities of data. Further, this may also exacerbate an issue that I come to below, with regard to the drawbacks of a narrow focus on individual interests in data protection and privacy. Nor do I argue that *all* patients would, or should, have contributions to make in this regard; rather my analysis points to the perils of not considering the various mechanisms through which greater PE&I may be facilitated.

⁶¹⁷ Sarah Boseley and Paul Lewis, ‘Smart Care: How Google DeepMind is Working with NHS Hospitals’, *the Guardian* (24 February 2016) <<http://www.theguardian.com/technology/2016/feb/24/smartphone-apps-google-deepmind-nhs-hospitals>> accessed 28 February 2022.

⁶¹⁸ Eve Macharia, ‘Healthcare Professionals: A Key Element of Sustainable App Development’ (14 October 2013) <<https://www.software.ac.uk/blog/2016-10-07-healthcare-professionals-key-element-sustainable-app-development>> accessed 24 February 2022.

⁶¹⁹ Royal Free London NHS Foundation Trust (n 574).

⁶²⁰ ‘Information Commissioner’s Office (ICO) investigation’ (n 589).

In addition, as well as elucidating the multiple and shifting roles of patients at the Royal Free, consideration of publicness encourages us to scrutinise the relationship between individual and collective interests further, including, but also looking beyond, those whose data were used in the Streams testing phase (comprising around 1.6 million people). In short, I would argue that the development of Streams with DeepMind, and its (anticipated) use within the NHS more broadly, also has implications for wider publics.

Drawing on Wenner's stakeholder model of the research enterprise, as introduced in Chapter 3, these implications may include matters such as 'how both public and private institutions come to view particular fields'.⁶²¹ This could be as a result of the negative publicity around the unlawful sharing of identifiable patient data could impact on how similar research projects are perceived (for example, as being 'risky') by a range of stakeholders, including funders, patients and publics. Alternatively the impact need not be negative, such as where new innovations influence how clinicians deliver care more widely across the NHS, and the types of interventions that are provided and resourced within a publically funded system of healthcare.⁶²² Indeed these ambitions are not merely ancillary to the development of an app such as Stream, but rather wholly consistent with DeepMind's vision of scaling-up Streams in order to '...make a difference to the lives of millions of patients around the world'.⁶²³ On either account, if it is accepted that broader collective interests are engaged by the Streams project, then I further argue that these were neglected, not only by this initiative, but also in subsequent commentaries and critiques within the wider scientific community when details of this collaboration between the Royal Free and DeepMind came to light.

This is illustrated by the discussion of the potential role of the HRA's Confidentiality Advisory Group's (CAG) role in relation to the transfer of NHS data by the Royal Free to DeepMind. The science and technology publication, *New Scientist*, which originally broke the Streams data transfer story, noted that no application had been made to the CAG by the Royal Free, but that:

'In situations where consent cannot reasonably be given in practice – in large research projects, for example – the CAG review process allows for sensitive medical data to be shared and processed. Successful applications culminate with *consent for data processing being given on patients' behalf* by the UK Secretary of State for Health.'⁶²⁴

⁶²¹ Wenner (n 246) 28.

⁶²² Wenner (n 246).

⁶²³ DeepMind, 'Scaling Streams with Google' (*Deepmind*, 13 November 2018) </blog/announcements/scaling-streams-google> accessed 27 February 2022.

⁶²⁴ Hodson (n 614).

As is evident from the discussion in Chapter 3, this does not present a wholly accurate account of the CAG's function, which is to advise the HRA (or the Secretary of State for non-research activities) on whether the common law duty of confidence should be temporarily lifted in respect of the transfer of confidential patient data.⁶²⁵ Rather than providing proxy consent 'on patients' behalf', the role of the CAG is better characterised as '...a safeguard through providing reassurance that applications [to use patient confidential information without consent] are independently scrutinised by an impartial group before a final decision is taken.'⁶²⁶ In other words, instead of providing a substituted form of *individual* consent, this scrutiny⁶²⁷ involves broader consideration of matters including '...whether the activity is in the public interest, if it fulfils a medical purpose, and that there is no other reasonable way in which to carry out the activity'.⁶²⁸ In this way the CAG not only considers the individual and public interests in maintaining confidentiality, but also broader public interests that may be engaged by the use or non-use of the data in question. In sum, the point I seek to make here is not in relation to whether or not the CAG *should* have been consulted with regard to the transfer of confidential data for the purposes of testing Streams (indeed Linklaters LLP⁶²⁹ come to the conclusion that the disclosure of data to DeepMind would not come within the scope of the relevant legislation).⁶³⁰ Rather, this analysis highlights the mindset engendered by a focus on individual interests in data protection and privacy (as illustrated by the discussion on consent by proxy), which serves to narrow the debate around the use of data in this context to the protection of the individuals who have contributed their data. In contrast, publicness challenges this narrowing and draws attention to the ways in which collective interests both build on, but also go beyond, such considerations.

Finally, relationality indicates that whether considering individuals, a defined group (for example, of those whose data is being used), or wider publics, publicness draws attention to

⁶²⁵ Health Research Authority, 'Minutes of the Meeting of the Confidentiality Advisory Group' (30 November 2013); Health Research Authority, 'Confidentiality Advisory Group, Frequently Asked Questions, About the Law' <<https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/cag-frequently-asked-questions-1.pdf>> accessed 27 February 2022.

⁶²⁶ Health Research Authority, 'Confidentiality Advisory Group, Frequently Asked Questions, Recommendations and Approval Decisions' <<https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/cag-frequently-asked-questions-3.pdf>> accessed 27 February 2022.

⁶²⁷ Conducted on the basis of the legal framework provided by the Health Service (Control of Patient Information) Regulations 2002. As an aside, even if CAG approval had been sought, this would not have been granted in circumstances where the proposed transfer did not comply with Data Protection Act 2018, as was the case with Streams.

⁶²⁸ Health Research Authority, 'Confidentiality Advisory Group, Frequently Asked Questions, Recommendations and approval decisions' (n 626).

⁶²⁹ Linklaters LLP (n 571).

⁶³⁰ Section 251 of the National Health Act 2006 and the associated Health Service (Control of Patient Information) Regulations 2002.

the potential for data usages to impact unevenly across society over time. An intersectional approach, as examined in Chapter 4, challenges notions of homogeneity, and underlines that people can be members of multiple social categories, and therefore may experience the harms and benefits of data-intensive initiatives differently and in multiple ways.⁶³¹ As outlined above, this moves the regulation of data-intensive innovation beyond a baseline approach, where minimal steps are taken to secure legal compliance, for example through the use of standardised privacy notices⁶³² which help to satisfy the provisions of data protection legislation. Rather this encourages consideration of the potential for wider and differential impacts over the longer term, on a group as well as an individual level, particularly where these may entrench existing inequalities. In this way a publicness-informed approach, which takes relationality seriously, has the advantage of recognising the complexities of a pluralistic society,⁶³³ and responds to calls for notions of ‘public benefit’ (a key driver of acceptable data usages) to be construed in a broad, inclusive and transparent way, throughout the data lifecycle.⁶³⁴ Previous discussion in this thesis has underlined that such an approach may not only be desirable, but also necessary, in circumstances where lawful data use initiatives may nonetheless fail when these do not accord with publics’ expectations, and therefore lack a social licence.⁶³⁵

A further, and closely related, matter that publicness brings to the fore is that of temporality. To recap briefly, as developed in Chapter 4, temporality in the context of publicness is a multi-directional consideration, which requires consideration of both the *time period over which regulation unfolds*, but also of how *processes of regulation can foreground particular periods of time and interests*. Both of these aspects of temporality can be observed in connection with the Streams initiative, though in practice the latter point, in particular, draws out how closely matters of relationality and temporality are intertwined, and so I come to this first.

One ways in which regulation (and, more specifically, data protection legislation) can *foreground individual interests, while overlooking the potential for group and/or collective harms to accrue over time*, is illustrated by the focus on the transfer of records in the early testing phase of Streams, both in the Information Commissioner’s decision⁶³⁶ and in academic commentaries.⁶³⁷ By way of context, while the remit of the Information Commissioner is ‘to

⁶³¹ Hill Collins and Bilge (n 9).

⁶³² Royal Free London NHS Foundation Trust, ‘Privacy Notice’ <<https://www.royalfree.nhs.uk/patients-visitors/privacy-notice/>> accessed 2 April 2022.

⁶³³ Hill Collins and Bilge (n 9).

⁶³⁴ Aitken and others, ‘Who benefits and how?’ (n 168); Hopkins Van Mil (n 490).

⁶³⁵ Carter and others (n 164).

⁶³⁶ Denham (n 572).

⁶³⁷ Powles and Hodson (n 570).

uphold information rights in the public interest⁶³⁸ these powers are not unfettered. Rather, the responsibilities of this role are set out in a number of different pieces of legislation,⁶³⁹ including, in this case, the Data Protection Act 2018.⁶⁴⁰ It follows that the scope of the Information Commissioner's investigation of the Streams collaboration was framed by this legislation, and that the findings therefore focus on the actions of the 'data controller'⁶⁴¹ (i.e. the Royal Free) and the impact on 'data subjects'⁶⁴² (i.e. the identified or identifiable living individuals to whom personal data relates).⁶⁴³ As the Information Commissioner recognised, her decision had '... wide implications for the health care sector',⁶⁴⁴ though these were not detailed in her findings, in circumstances where these go beyond the scope of data protection legislation, as anchored by the concept of the identifiable data subject. This provides an example of a phenomenon that has been recognised elsewhere, whereby '...data protection legislation...implicitly focus on the individual' and therefore '...focuses ethical assessment on harms at the individual level.'⁶⁴⁵ This is problematic in circumstances where the use of large amounts of data also has the potential to lead to collective or group level harms over time. An example of a group harm that has been provided by Mittelstadt and Floridi is where data is used in research that indicates that an ethnic group has a genetic predisposition to particular types of cancer and then is discriminated against as a result.⁶⁴⁶ However, and as suggested by Wenner, arguably the harm in question could also be more diffuse, for example where concerns around data sharing impacts negatively on, for example, the longevity of a data sharing initiative, or the support (financial and social) afforded by stakeholders to similar initiatives in healthcare.⁶⁴⁷ Here the value of an appeal to publicness is not just in respect of its analytical function, but also as a touchstone that brings into focus these wider and potentially longer-term implications of large scale data sharing and usage. This is not only a consideration in the legal domain, but also in relation to the ethical review of such initiatives, where Ienca and colleagues have indicated that: 'While group-level harms are usually considered outside the purview of [ethical review committees], the dangers of ignoring this

⁶³⁸ 'Information Commissioner's Office' (n 237).

⁶³⁹ For full details see Information Commissioner's Office, 'Legislation We Cover' (ICO 20 July 2020) <<https://ico.org.uk/about-the-ico/what-we-do/legislation-we-cover/>> accessed 14 March 2022.

⁶⁴⁰ Data Protection Act 2018.

⁶⁴¹ *ibid* Section 6.

⁶⁴² *ibid* Section 3(2).

⁶⁴³ Denham (n 572).

⁶⁴⁴ *ibid* 10.

⁶⁴⁵ Brent Daniel Mittelstadt and Luciano Floridi, 'The Ethics of Big Data: Current and Foreseeable Issues in Biomedical Contexts' (2016) 22 *Sci Eng Ethics* 303, 326.

⁶⁴⁶ *ibid* 10.

⁶⁴⁷ Wenner (n 246).

type of risk require careful assessment.⁶⁴⁸ Further, they note that: 'Issues of trust, transparency, accountability, dignity compose an even smaller fraction of the current ethical landscape,⁶⁴⁹ and suggest that these should be further explored within the ethical review process. As I have suggested in Chapter 5, publicness specifically draws attention to these wider factors – such as (institutional) trust, transparency, (in)equality and public benefit - that may shape, and be shaped by, people's views on the legitimacy of innovative data usages.

On a second but related point, regulation may also shape *whose* perspective should be used when judging matters such as whether a health professional has breached their duty of confidence to one or more patients. For example, in their 2018 audit report of the Streams collaboration, Linklaters LLP suggested that, legally, whether a breach of confidence has occurred when identifiable patient data is used without consent should be judged '...on the basis of whether a reasonable health professional's conscience would be troubled by the disclosure'.⁶⁵⁰ This approach has been criticised by the National Data Guardian,⁶⁵¹ not only as being out of step with post-Human Rights Act 1998 case law,⁶⁵² but also a broader societal move away from medical paternalism and towards a more collaborative approach to healthcare.⁶⁵³ Rather, it has been proposed that a legal approach based on the 'reasonable expectations of the patient' should be preferred.⁶⁵⁴ Taylor and Wilson have since elaborated on this point and argued that such an approach could '...provide a more sustainable and authentic approach to meeting obligations under the law of confidence than the standard account'.⁶⁵⁵ This potential for the law relating to confidentiality to be interpreted in quite different ways is, of course, not unique to this scenario. Nonetheless this provides an illustration of a point first raised in Chapter 5, in that it is inadequate to fall back on a caricature of the messy subjectivities of publics' views, on the one hand, and the neat approach of the law, on the other. The value of publicness here is to draw attention to the *context* in which this interplay takes place, and the interests that are engaged. Indeed, as noted in Chapter 3: 'If people feel that their information may be used in unexpected ways, for purposes they may not

⁶⁴⁸ Marcello Ienca and others, 'Considerations for Ethics Review of Big Data Health Research: A Scoping Review' (2018) 13 PLOS ONE e0204937, 10.

⁶⁴⁹ *ibid.*

⁶⁵⁰ Linklaters LLP (n 571) 55.

⁶⁵¹ Dame Fiona Caldicott, 'National Data Guardian Letter via Email' (21 August 2018).

⁶⁵² In particular, the NDG points to the case of *Campbell v MGN* [2004] UKHL 22, Lord Hope at [98]: "Where the person is suffering from a condition that is in need of treatment one has to try, in order to assess whether the disclosure would be objectionable, to put oneself into the shoes of a reasonable person who is in need of that treatment. Otherwise the exercise is divorced from its context."

<https://publications.parliament.uk/pa/ld200304/ldjudgmt/jd040506/campbe-1.htm>

⁶⁵³ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

⁶⁵⁴ Caldicott (n 651).

⁶⁵⁵ Mark J Taylor and James Wilson, 'Reasonable Expectations of Privacy and Disclosure of Health Data' (2019) 27 *Med Law Rev* 432.

support, this greatly undermines the fundamental relationship of trust.⁶⁵⁶ I have already used publicness in this thesis to critique the position whereby ‘the public’ is approached as a single and homogenous entity, and, in the previous paragraph, argued that this concept requires that we at least consider the wider and potentially longer-term implications of large scale data sharing and usage. When publicness is used as a lens through which to examine the example above – where a potential breach of confidentiality is framed as solely a matter for the judgement of the ‘reasonable’ health care professional - this serves to highlight the deficiencies of a legal approach which effectively removes patients and publics from the picture altogether.

Before leaving the theme of temporality, the preceding analysis of Streams (from 2015 to date, and conducted with the benefit of hindsight) also encourages consideration of the *time period over which regulation unfolds*, namely the need to engage with the full research and data lifecycle. For example, this holistic view allows for consideration of the extent to which the anticipated benefits of Streams have been realised over time. One aspect of this is the clinical benefits of the app, which were reviewed in 2019. This evaluation of the impact of Streams on patient care at the Royal Free Hospital pointed to improvements in ‘...the timeliness and reliability of key aspects of AKI care’,⁶⁵⁷ though found that ‘definitive conclusions regarding the clinical impact of the pathway cannot be made at this stage’.⁶⁵⁸ However, these proven efficiencies, as reported in a highly regarded peer-reviewed journal, can be contrasted with the more ambitious statement previously made in 2018 (when the team developing Streams moved from DeepMind to Google Health UK) that:

‘Our vision is for Streams to now become an AI-powered assistant for nurses and doctors everywhere - combining the best algorithms with intuitive design, all backed up by rigorous evidence.’

In further contrast, the current position appears to be that, rather than being used more widely, the Streams app is now due to be decommissioned, and is no longer used by NHS bodies in the UK other than the Royal Free.⁶⁵⁹ Consideration of publicness here therefore provides an example of the non-linear nature of innovation cycle and how the expected benefits may change over time, as discussed in previous Chapters. It further points to the need for ways of learning from the potential for these discrepancies between the expected and actual benefits

⁶⁵⁶ National Data Guardian (n 219).

⁶⁵⁷ Connell and others (n 598) 5.

⁶⁵⁸ *ibid.*

⁶⁵⁹ Lomas (n 593).

of data use to arise, as well as the importance of anticipating how data should be managed at the point that an app is no longer employed.

In this way consideration of temporality is also closely linked to the third facet of publicness, namely accountability. In particular, as an example of an instance of data transfer that was challenged through a formal mechanism – that is, an investigation by the Information Commissioner – the Streams collaboration illustrates the various impacts of this *post-ante* measure. On the one hand, the discussion above illustrates the persistence and severity of the effects on Royal Free (and to a lesser extent on DeepMind) of the data breach which took place in the testing phase of Streams (2015/16). This impact includes matters such as the resourcing costs (financial and otherwise) of dealing with the aftermath of the breach, as well as the potential for reputational damage to the parties and product involved. As noted above, it further appears that a ‘class action’ is currently being brought on behalf of a named person, and the other 1.6 million individuals, whose data were unlawfully transferred. On the other hand, despite these various impacts, there is no way to ‘take back’ the data sharing that took place. Further, the implications for the public purse, at a time when the NHS is already under financial strain, may make this a zero sum game for all of the parties involved. Taken together this illustrates the inadequacies of an approach to the use of data that views this as a closed and linear process. Instead, publicness emphasises the twisting and interlinked nature of consideration of the implications for both individuals and wider publics, and points to the need for review and revision of such matters throughout the data use cycle. For example, in Chapter 5 I indicated the need for the consideration of publicness itself to be ‘done in public’, which accords with the findings of a recent public dialogue on making public benefit assessments when using health and care data, that transparency is a ‘prerequisite for public...throughout the whole data-lifecycle.’⁶⁶⁰ However, the examination of publicness in previous Chapters has further emphasised that transparency alone may not be enough, if this is neither authentic nor demonstrative of meaningful attempts to engage with a variety of viewpoints.⁶⁶¹ Further, when it comes to institutional trustworthiness, this too requires deeper engagement with the core aims of responsible data-intensive innovation, rather than self-interested compliance as a form of regulatory box-ticking.⁶⁶² In DeepMind’s reflection on lessons learned following the Information Commissioner’s findings in 2017, they considered, amongst other matters, their own ‘...improvements to our transparency, oversight and engagement’. One step they highlighted was the appointment of a panel of independent reviewers to scrutinise their work, set up ‘...long before any regulatory or media criticism’, and that this panel would soon report

⁶⁶⁰ Hopkins Van Mil (n 490) 3.

⁶⁶¹ Brown and Michael (n 472); Quiroz-Aitken and others (n 471).

⁶⁶² Kerasidou (n 555).

on their first year.⁶⁶³ This was positioned as an innovative form of oversight and, as set out by the Chair in the Foreword to the panel's first report:

'We are entirely independent, and are not subject to any form of non-disclosure agreement. Indeed, our agreement with DeepMind Health, is explicitly clear that we are not subject to binding secrecy rules, and are free to speak to the press however and whenever we wish. We are self-governing, with our own secretariat and are free to set our own agenda and timetable –our only constraint is to produce an annual report.'⁶⁶⁴

However, the panel appears to have only produced two reports (in 2017, as above, and 2018).⁶⁶⁵ A subsequent newspaper report indicates that this was disbanded in 2018 when DeepMind moved to Google Health UK, noting that:

'The restructure has also resulted in the termination of the review board, which was largely staffed by British experts. The DeepMind spokesperson said: "The independent reviewers panel was a governance structure for DeepMind Health as a UK entity. Now Streams is going to part of a global effort this is unlikely to be the right structure in the future.'⁶⁶⁶

This is in circumstances where there was already criticism from some quarters in relation to this amalgamation. Powles, who had co-authored an early critique of this collaboration,⁶⁶⁷ noted that:

'DeepMind said it would never connect Streams with Google. The whole Streams app is now a Google product. That is an atrocious breach of trust, for an already beleaguered product.'⁶⁶⁸

This independent panel was *prima facie* an example of the transparency and oversight that DeepMind itself had identified was lacking. However, publicness brings into view the complexities and nuance of how transparency is delivered in practice. It also highlights very starkly that mere transparency is in no way a synonym for accountability. In this way, consideration of temporality – *viz.* the short duration of this Independent Review Panel – alongside matters of accountability – including transparency, authenticity and institutional

⁶⁶³ Suleyman and King (n 591).

⁶⁶⁴ 'DeepMind Health Independent Review Panel Annual Report' (July 2017).

⁶⁶⁵ 'DeepMind Health Independent Review Panel Annual Report' (June 2018).

⁶⁶⁶ Alex Hern, 'Google "betrays Patient Trust" with DeepMind Health Move' (*the Guardian*, 14 November 2018) <<http://www.theguardian.com/technology/2018/nov/14/google-betrays-patient-trust-deepmind-healthcare-move>> accessed 21 March 2022.

⁶⁶⁷ Powles and Hodson (n 570).

⁶⁶⁸ Hern (n 666).

trustworthiness as outlined above – provide an illustration of how even well intentioned steps in this respect can fall short.

Conclusion

The case study I have considered in this Chapter has provided an example of an innovative, yet highly disputed, use of data in order to test the design of a portable clinical app to detect AKI. Despite the early hype around this app, it did not use artificial intelligence, but rather implemented an NHS decision tree. Although the transfer of data in question was not explicitly for research purposes, this provides an example of a data-intensive initiative where there are multiple and related interests at play, including but, as I have argued, not limited to the 1.6 million patients whose data were shared.

The Royal Free/ Deepmind collaboration has been described as a ‘cautionary tale’,⁶⁶⁹ and a number of shortcomings have been elicited above, not least in relation to the need for more transparency in relation to partnerships between the public and private sectors, and for earlier and better engagement with patients about the use of their data. However, my analysis has also drawn attention to matters such as:

- the mind set engendered by a narrow focus on individual interests in data protection and privacy, to the exclusion of the ways in which collective interests build on, but also go beyond, such considerations.
- *processes of regulation*, and the ways that the law and regulation may serve to foreground some (individual) interests and harms, to the exclusion of others that may exist, for example at a collective or group level, particularly where this has the potential to further entrench existing inequalities.
- the twisting and interlinked nature of the interests at play over time in data-intensive initiatives, which indicates the need for review and revision throughout the data use cycle, as these emerge and become fixed through action.
- the need for deeper scrutiny of matters such as transparency and oversight, and the complexities and nuances of how these are delivered in practice, as well as related concepts such as authenticity and institutional trustworthiness.

⁶⁶⁹ Powles and Hodson (n 570).

Further, the lens of publicness has also provided a new perspective on a number of features that could bear on initiatives that rely upon the use of confidential health data without consent, including for the purposes of research.⁶⁷⁰ So what might the Streams collaboration have looked like if this had used a publicness-informed approach?

First, I suggest that an approach that appeals to the concept of publicness does not, necessarily, present a bar to such a collaboration that involves the transfer of data from a public to a private partner. Indeed, as established earlier in this thesis, there can be a greater or lesser degree of publicness in various data usages, and this is not determined by the status – be that public or private – of the organisation seeking access. This appreciation of shade and nuance better reflects the realities of the research endeavour and public opinion that indicates that data sharing initiatives exist on a sliding scale of acceptability.⁶⁷¹ Nor does publicness require that an individual consent-based approach be adopted, in circumstances where the use of large quantities of data means that this is likely to be impractical, or even impossible.

Nonetheless, publicness does call for greater attention to be paid to the relationship between individual and collective interests engaged by the use of data, and how these build on one another over time. In the case of the Streams collaboration this may have included matters such as:

- From the outset, seeking to take into account the full range of interests that could be engaged by the proposed use of data. As well as engaging with clinicians (who would ultimately use the app), the collaborators should have actively engaged with patients (whose data would be used to test the app), as I come to in more detail below. Further, I have suggested that consideration could also have been given to the potential for the use of data to have wider and differential impacts over the longer term, on a group as well as an individual level. For example, the collaboration appeared to underestimate the level of public concern that would be generated by the transfer of records from the NHS to a private technology company, and the potentially chilling effect that a negative reaction to this might have on future data-driven initiatives.
- On a related point, the collaborators (and the Royal Free, as the data controller, in particular) should, undoubtedly, have taken steps to ensure compliance with the Data Protection Act 2018, the common law duty of confidentiality, and the GDPR. However,

⁶⁷⁰ For another example of where this collaboration has been used to draw out lesson for health research see Ballantyne and Stewart (n 306).

⁶⁷¹ Ipsos Mori, 'The One-Way Mirror' (n 488).

this focus on this legislative framework, which is anchored by the definition of the 'data controller' and 'data subject', would have better been viewed as one consideration, amongst others, when considering the full range of individual and collective interests that were at stake in the project.

- When considering both individual and collective interests the Streams initiative could have taken more explicit account not only of the different types of interests engaged by the initiative (as explored above), but also the heterogeneity of and within these interests. For example, 'patients' appear to have been primarily conceptualised as beneficiaries of the Streams app, and then later, following the Information Commissioner's investigation, as data subjects. As a result other ways that patients (and indeed wider publics) could have potentially added value to the project were overlooked. This could include, for example, contributions with regard to the design and testing process, and the governance of the app and the data flows that facilitated its development and operation.
- Following on from this, a greater role for patients and/or publics in the governance of the Streams project may also have avoided the position whereby the deficiencies of the project only came to light as a result of the investigative journalism of a New Scientist correspondent. At that point the data transfer of 1.6 partial records had taken place and the 'damage', both in terms of the legal and social legitimacy of the project, had already been done. This suggests that future projects should give consideration to incorporating mechanisms to facilitate feedback, ongoing dialogue and transparency throughout the data use cycle.
- Nonetheless, the Streams project further provides an example of the complexities of delivering effective oversight and trustworthy governance in practice. While, along with public benefit, transparency has been shown to be a key driver of the acceptability of data usages, this is unlikely to be secured through stand-alone mechanisms, such as DeepMind's innovative, yet short lived, independent review panel. While the path to institutional trustworthiness is neither linear nor straightforward, this is more likely to be achieved where projects are able to demonstrate authentic and meaningful attempts to grapple with a variety of viewpoints (not just those of an expert elite). Even where the *clinical* benefits of an app such as Streams are articulated, notions of *public benefit* reach beyond this, and encompass not just the outcomes that novel data usages seek to achieve, but also *how* the data are used in this process.

Separately and cumulatively the points above demonstrate, in different ways, how a publicness-informed approach moves the regulation of data-intensive innovation beyond a baseline approach, where minimal steps are taken to secure legal compliance. Instead publicness encourages consideration of the potential for wider and differential impacts on range of stakeholders over the longer term. However, this is not just proposed as a means to enhance or improve projects, though this may well be a positive benefit that accrues. Rather, my proposal responds to the evidence from previous data sharing initiatives considered in this thesis – including *care.data* as well as Streams – which suggest that is more than a ‘nice to have’, and may in fact be crucial to the long-term success of current and future data-intensive innovations. Finally, the deployment of publicness in this Chapter in a real world context emphasises that its threefold facets of relationality, temporality and accountability, as discussed throughout this thesis, do not exist in isolation from one another, but rather overlap and intersect. In these various ways this case study illustrates how publicness delivers a concept that can support the robust review and revision of data-intensive initiatives, where there are multiple and related interests at play, throughout the full research lifecycle.

Chapter 7: Conclusion

Introduction

The preoccupation at the heart of this thesis is the complex and nuanced interrelationship between collective and individual interests in health research, and the implications of this relationship for optimising contemporary HRR. In this final Chapter, I conclude by first briefly revisiting the research problem that I outlined at the start of this thesis. Next, I provide a summary of the key conclusions that I have drawn in Part I and Part II, before recapping the original contributions that these contain. Throughout, I revisit the research questions that I introduced at the start of this thesis, to reflect on how these have been answered in my preceding Chapters. Finally, I consider a number of future directions for research that may follow on from these findings.

The relationship between individual and collective interests in HRR, and why it matters

My interest in the relationship between individual and collective interests began with my work in relation to the concept of the public interest, first as a lawyer in legal practice, and then as a legal academic as part of the Wellcome-funded Liminal Spaces project.⁶⁷² However, while working within varied interdisciplinary teams it became increasingly clear that disciplinary boundaries and semantics had the potential to stymie otherwise productive discussions about how concepts such as the public interest – that sought to capture something about the social side of research – were deployed. Researching and writing this thesis has allowed me temporarily to take a step back from the public interest *per se*, a concept which might fairly be described as coming with significant disciplinary ‘baggage’, in order to consider the more foundational question of why the relationship between individual and collective interests matters, and how this can better be understood. In turn, by exploring the new concept of publicness, and how this is operationalised in data intensive health research, this has provided me with a new perspective on the public interest as a regulatory device in HRR.

My starting point in this thesis has been the changing context of contemporary health research, and its regulation. I have identified fundamental changes in the technoscientific, socio-cultural and institutional domains which have, I argue, individually and cumulatively, had significant implications for the co-construction of biomedical science with society in relation to health

⁶⁷² University of Edinburgh, ‘Liminal Spaces: Driving a Whole Systems Approach to Health Research Regulation’ (2022) <<https://www.law.ed.ac.uk/research/research-projects/liminal-spaces>>.

research and its regulation. These shifts include processes of ‘biomedicalization’,⁶⁷³ that have resulted in health research taking place in ways that are increasingly technical, complex and multidirectional. Developments, such as the advent of electronic health records, which can more easily be accessed, shared, and interrogated, have spurred new advances in human health, but also created new vulnerabilities, which are felt unevenly across society. As I have traced, in Chapters 1 and 2, this more expansive understanding of health research is reflected in the shift of focus from ‘hands on’ clinical research, in the post-World War II era, to the inclusion of large-scale research, by multiple institutions, involving the use and linkage of tissue and data that may not have originally been collected for research purposes. This, in turn, has disrupted the boundaries between patients, participants and publics, and put traditional regulatory mechanisms, such as consent, under strain, in circumstances where there may be little or no contact between those carrying out research, and those whose data is (re)used. Over the same period socio-cultural understandings of this unevenness of impact have also developed. An intersectional approach to matters of law and, more recently, to health research itself, draws attention to sameness and difference, and the simultaneous and interrelated effects of factors including gender, race, class, age, disability, sexual orientation, religion and national identity. In this way, the homogeneity of ‘patients’ or ‘publics’ whose interests may be engaged by the conduct and regulation of health research is challenged. These changes are also reflected in the institutional domain where the terminology of ‘science *and* society’, denoting the divide between these different realms of knowledge and expertise, has been superseded by that of ‘responsible research and innovation’. Thus indicating that societal actors – including researchers, citizens and funders, amongst others – should work together to align research and innovation with societal expectations and needs.

These transformations have impacted on the *type* of health research that is carried out, as epitomised by the increase in health research using big data,⁶⁷⁴ *how and with whom* health research is conducted, including through disruption of the traditional researcher/participant relationship, and asks question about *what* should legitimately be supported as responsible health research, with regard to publics’ expectation of the benefits that this should deliver. In each of these ways contemporary health research challenges traditional regulatory structures that are underpinned by an increasingly outdated approach to individual and collective interests. As such, a new understanding of what is at stake is required in order to optimise HRR, through a deeper understand of the complexities of the relationship between individual

⁶⁷³ Clarke and others (n 3).

⁶⁷⁴ CIOMS (n 26) ix; see extensive discussion in Laurie and Tai (n 26).

and collective interests, and the multiplicity of ways in which decisions about the conduct of health research might impact on our lives.

Part I: an overview

How is the interrelationship between individual and collective interests understood in HRR at present?

Having provided the context for this thesis in Chapter 1, as outlined above, in Chapter 2 I have focused on the way that individual and collective interests have been reflected in HRR, as a persistent and evolving concern since the post-World War II period. This can be observed both in foundational international instruments that have shaped modern health research regulation, such as the Nuremberg Code, and the first and subsequent iterations of the Declaration of Helsinki, as well as in contemporary instruments and guidelines. My analysis has highlighted that while there are collective interests in the goal of advancing knowledge through responsible health research, it is axiomatic that health research also relies on the participation of individuals *qua* individual persons whose rights and interests must be protected. I have argued that, against the backdrop of the growing recognition of the interconnectedness of these dual considerations, *a more radical paradigm shift is required in order to reflect fully the complexities of this interrelationship*. More particularly, I argue that *there is something about the quality of human health research that is focused on realising and promoting collective interests that builds on, but also go beyond, the protection of individuals who contribute to that that research, and that this must be reflected in the way that it is regulated*. In circumstances where individual and collective, or private and public, interests are often pitted against one another I have suggested that the present terminology in HRR is inadequate to the task of capturing this quality. The solution I offer is the concept of ‘publicness’, which I have introduced in Chapter 2, and have explored through the course of this thesis. In essence, publicness is a new concept that reflects the interrelationship between individual and collective interests, thereby drawing attention to the particular context in which this interplay takes place, as well as the implications of this relationship for HRR, both now and in the future. I have identified three interlinked and overlapping facets of publicness which can be summarised as relationality, temporality and accountability.

I have approached the introduction of publicness, as a new concept, with some caution. To justify the use of what might be considered to be ‘yet another neologism’ I have used the threshold concept framework⁶⁷⁵ to further delineate the contours of publicness, as well as the

⁶⁷⁵ Land and others (n 130).

insights that this can elucidate in the context of this thesis, and in HRR more widely. In particular, I have shown how publicness can be transformative, 'probably' irreversible, and integrative, and may potentially be bounded and troublesome. This has highlighted, amongst other matters, the distinction between publicness as a broad concept, and the different ways in which this may be operationalised. In summary, Chapter 2 both sets the scene for how publicness is understood as my thesis unfolds, and demonstrates its transformative capacity to take our understanding beyond that which is routinely accepted in order to help optimise contemporary HRR. Publicness does this by naming the interrelationship between individual and collective interests, and by providing the foundation for a framework of analysis in relation to each of its three facets: relationality, temporality and accountability. However, as well as presenting a potential way forward, this analysis also raises questions about whether, and to what extent, publicness is currently operationalised in HRR?

To what extent is publicness currently operationalised in the HRR ecosystem? What does this tell us, both about existing concepts in HRR, and about publicness itself?

In Chapter 3 I tackle these questions. I do so by deploying the tripartite framework of analysis that operationalises publicness in order to evaluate three existing concepts in HRR, with the aim of identifying areas whether they may manifest certain features of publicness. These are: the use by the law of the *public interest* as a regulatory device; the ethical objective of realising *social value* in research; and the role that notions of *social licence* play in regulation. I have illustrated how each of these approaches capture elements of the social aspect of health research and its regulation. However, as I go on to show, while they are often used interchangeably, or in close proximity, public interest, social value and social licence are not synonyms for each other, and each is grounded in different disciplinary norms. My analysis has therefore used the *diagnostic* value of publicness to reveal the work that existing concepts already do in HRR, individually and in relation to one another, as well as offering an approach that allows further analysis and discussion to transcend these concepts and associated disciplinary limitations.

More particularly, I have pointed to ways in which the public interest carves out a legally legitimate space within which research activities that infringe on individual interests, but have potential public benefits, can be conducted, which otherwise would not be permitted. In contrast to this, social value speaks to the ethical acceptability of health research, and acts as a promise of the societal good that it is expected to deliver. In further contrast, social licence gauges the acceptability to publics of this research. While these are crude distinctions that cannot do justice to the nuance of each approach, this exercise adds value by helping to

articulate the principal functions of the public interest, social value and social licence in HRR, which so often are conflated.

This analysis further helps to develop and support the claim that publicness in HRR captures something broader than is engaged by any one of these concepts alone. In particular, my examination has demonstrated not only the breadth of this -concept, but also how this may be used as a *lingua franca* to facilitate conversations between and across disciplines.

The use of publicness to build a tripartite framework for analysis in this Chapter also supports a further normative claim, that publicness is not only able to tease apart existing concepts, but can also help point to concrete ways in which these can be optimised in HRR. More specifically, consideration of *relationality* reveals that *engagement with diverse publics* that recognises the full range of interests at stake in HRR is not a given in respect of any one of these existing approach. Optimal HRR is also challenged by *temporality* in circumstances where health research is, by definition, designed to lead to new and as yet unknown findings, yet existing regulatory mechanisms do not do enough to facilitate *ongoing robust review and revision throughout the data and research lifecycle*. Finally, in order to secure *accountability* it is necessary to consider how *the regulation of health research can adapt and respond* in order to accommodate these challenges. As developed throughout this thesis and crystallised in the context of the case study examined in Chapter 6, accountability is not, however, a synonym for mere transparency. This is starkly illustrated by the short-lived operation of DeepMind's Independent Review Panel, which shows that even well-intentioned attempts at openness and oversight can fall short of delivering true accountability. My publicness-informed analysis suggests that these weak forms of openness and oversight, that are neither authentic, nor demonstrative of meaningful attempts to engage with a variety of viewpoints, including those that are under or unrepresented, will not fulfil the demands of this richer, publicness-informed conception of accountability. Rather, publicness emphasises that the legitimacy of data-intensive research and innovation may be influenced by a wider range of considerations including, for example, institutional trustworthiness (as argued in Chapter 4). In this way, publicness can help to form new ideas about the optimal operation of HRR. Thus, while transparency can be an important feature of genuine accountability, the latter can never be reduced simply to the former.

I have concluded Part I of this thesis by offering a working definition of publicness, which reflects the diagnostic and normative value this brings to HRR, as captured in **Table 17**.

Table 17: A (revised) working definition of publicness in HRR

Publicness is a concept used to describe the interrelationship between collective and individual interests, thereby drawing attention to the context in which this interplay takes place, as well as the implications of the interrelationship between collective and individual interests for HRR, both now and in the future.

Publicness also provides the foundation for a framework of analysis which directs attention to:

- **Relationality:** the co-existence of (multiple) kinds of overlapping interests in health research and their interconnectedness, therefore moving away from oppositional ways of thinking about the interests at stake;
- **Temporality:** temporal aspects of these interests in health research, including how these may change over time;
- **Accountability:** how these interests can be accounted for when decisions are made about what, whether, how and with whom health research is conducted.

In this way publicness performs a diagnostic and normative role in that it:

- helps us to understand better the nature and role of existing mechanisms within HRR;
- provides a theoretical and practical basis to move beyond what already exists in the sub-optimal HRR ecosystem

This conceptualisation forms the basis of my further exploration of the HRR ecosystem, and specific regulatory devices within this, in Part II.

Part II: an overview

While my focus in Part I was largely on developing the concept of publicness, and beginning to explore its diagnostic and normative value, in Part II I have demonstrated more specifically how publicness can be deployed in HRR in order to form new ideas about how HRR should be viewed and conducted.

In what ways can publicness help us to better understand and to enrich aspects of the HRR ecosystem?

In Chapter 4 I have approached this task by first considering how publicness can flesh out and enrich those aspects of the HRR ecosystem that, in Part I, I have identified that may be lacking. More specifically I have use the normative force of publicness to explore these sub-optimal features more deeply, and to identify how HRR can better account for the full range of interests

in play throughout the research and data lifecycle. As such, I have considered (1) the temporal aspects of HRR when regulating individual and collective interests over time; and (2) regulatory engagement with the mutability and diversity of and within publics in health research.

In respect of the *temporal aspects of regulating individual and collective interests over time*, I have used the lens of publicness to bring into focus the multi-directional interaction of time and context in HRR. This reveals how an *imagined future* is created by the law where research is expected to be of public benefit and/or to have social value which may (or may not) come to pass. This imagined future therefore informs *ex-ante decisions*, which are made on the basis of a homogenised conception of *who* the stakeholders are in in this scenario, and the *multiple perspectives* they may have on what socially legitimate research looks like. While current understandings of HRR recognise the relevance of temporality to HRR in different ways, time is commonly characterised as part of the historical backdrop against which regulation takes place. In contrast, publicness which brings together consideration of temporality *and* relationality, demands further scrutiny of the *multi-directional interaction* of time and interests in HRR and reveals that not only can time and context shape regulation, but that law and regulation are also capable of shaping context and creating horizons of time. Thus, the lens of publicness provides a new perspective on a familiar aspect of HRR. In response to this re-framing, I have explored modes of adaptive governance that can account for the uncertainties that are inherent in the regulation of data intensive health research. However, as well as feedback loops within existing decision-making processes, I have argued that it is also necessary to revisit and revise the regulatory structures within which such decisions are made.

In order to examine *the mutability and diversity of and within publics in HRR*, I have outlined the ways in which publicness pushes us to engage with the multiple perspectives that people may have on what socially legitimate research looks like. Here I have not attempted to address these matters wholesale, but rather to explore the ways in which publicness can provide a new perspective on the diversity of and within publics in the regulation of data-intensive research. This provides a modest first step, from a legal and regulatory perspective, towards the complex and interdisciplinary task of bridging the gap between outputs from PE&I activities, and the incorporation of these into HRR frameworks.

My analysis, through the lens of publicness, has underlined various ways that conceptions of publics have been developed in HRR, particularly in the context of PE&I activities, that recognises the value of lay and experiential expertise, the existence of *different types of publics* and, crucially, that these publics are not pre-existing, but tend to be *constructed* in the

course of PE&I activities. However, I have argued that publicness also encourages us to scrutinise the *mutability and diversity within different publics* in relation to the multiple perspectives that people may have on what socially legitimate research looks like. Further it directs us to ask what the quality of publicness looks like as an *attribute* of any given group, and therefore to interrogate the extent to which different types of publics include a range of viewpoints. In this way publicness further draws attention to publics who have not been so constructed. To facilitate scrutiny of publicness as an attribute I have appealed to the literature on intersectionality, which draws attention to (1) *context* and the need to scrutinise the operation and intersections of inequalities in HRR;⁶⁷⁶ (2) the changing social, political and historical contexts that shape, and in turn are shaped by HRR; and (3) the implications this for HRR *throughout the research lifecycle*. Here an intersectional analysis does not prescribe a 'one size fits all' regulatory approach – but rather requires that attention is paid to domains of power and how these might intersect. To illustrate how this may work in practice I have considered some substantive ways of foregrounding the dynamics that are at play in HRR, such as in the choice of modes of PE&I, and in the selection and training of decision makers.

Taken together, this analysis has pointed to ways that publicness can help to optimise HRR and further refined how publicness *per se* is understood. This highlights both the breadth of publicness as a concept, and how this can resist a narrowing of the way in which HRR frames the multiple and overlapping interests that are in play, and how these can change over time. In summary, in Chapter 4 I have proposed that when publicness is made a constant feature of our regulatory concerns, this requires that we take seriously this ever-changing heterogeneity across the lifecycle of HRR. New issues are also raised, such as how existing regulatory devices can operate to flatten conceptions of publics, and therefore require reconsideration.

[How can publicness facilitate an examination of the public interest as a regulatory device in HRR?](#)

In Chapter 5 I have addressed some of the shortcomings of the public interest, as identified in Chapter 3, such as the *prima facie* impasse between a law-internal conception of the public interest and empirical evidence of the views of actual publics. This Chapter also responds to my finding, in Chapter 4, that an appreciation of publicness in HRR suggests that it may be necessary not only to revisit decision-making processes, but also to review the regulatory structures and devices that shape those decisions – in this case the public interest.

⁶⁷⁶ Hill Collins and Bilge (n 9).

I have examined, in particular, the much-vexed intersection between the public interest as a regulatory device, and extra-legal insights provided by empirical evidence. Here I have used publicness and its facets - of relationality, accountability, temporality - as a way of facilitating a cross-disciplinary examination of this neglected regulatory device. My analysis indicates the need for a defensible and holistic conception of the public interest, that relies neither on a 'thin' legal notion of this concept, nor unquestioningly picks up outputs from public engagement exercises and presents these as constituting 'the public interest'. I have shown that the public interest need not remain disconnected from empirical evidence. Indeed the law has a history of using extra-legal insights, albeit in an inconsistent and unprincipled way: a point that until now has not been directly addressed in the context of the public interest in HRR. However, it is the framework provided by publicness that facilitates the extension of this analysis, and offers further insights in relation to this contested device in three key respects. The re-conceptualisation of the public interest I have proposed: (i) explores the notion of 'the public' in the public interest and how context can shape these interests; (ii) points to the ways in which the research path and the public interest overlap and intersect each other throughout the entire life cycle; and (iii) emphasises the nuanced role of transparency in multi-factorial decision-making. In this way, I have proposed an approach to the public interest that is better equipped to meet the realities and challenges of the contemporary health research environment. Publicness does not operate here to define what the public interest 'is' or where it may lie in a given situation. Rather, it provides the parameters within which decisions can be made and robustly defended, and evidence may be deployed or rejected (as thought to be appropriate).

In order to reintegrate the preceding analysis to the contemporary data use landscape, in Chapter 6 I bring this to bear on a high profile collaboration between The Royal Free and Google DeepMind,⁶⁷⁷ in relation to the creation of an application to help to detect and manage acute kidney injury, known as Streams.⁶⁷⁸ This case study elucidates the mind set engendered by a narrow focus on individual interests in data protection and privacy, to the exclusion of the ways in which collective interests build on, but also go beyond, such considerations. It further points to the way in which *processes of law and regulation* may serve to foreground some (individual) interests and harms, to the exclusion of others that may exist, for example at a collective or group level. Finally, the Streams collaboration provides an example of the twisting and interlinked nature of the interests at play over time in data-intensive initiatives, and the complexity and nuance of how transparency and oversight are delivered in practice. This points to the need for the review and revision of projects throughout the data use cycle, as interests emerge and become fixed through action, as well as the relevance of related

⁶⁷⁷ Now Google Health UK

⁶⁷⁸ Linklaters LLP (n 571) 1.

concepts such as authenticity and institutional trustworthiness to the delivery of legitimate HRR. In these ways the concept of publicness has been deployed here to optimise HRR by both elucidating ‘lessons learned’, and also through the identification of positive steps that can support future data-sharing initiatives to better account for publicness. This analysis further emphasises that its threefold facets, as discussed throughout this thesis, do not exist in isolation from one another, but rather overlap and intersect. In these various ways this case study illustrates how publicness delivers a concept that can support the robust review and revision of data-intensive initiatives, where there are multiple and related interests at play, throughout the full research lifecycle.

Original contributions

I suggest that the analysis summarised above supports four original and interrelated contributions:

- I have proposed, and developed throughout this thesis, the new concept of ‘publicness’ to better reflect the interrelationship between collective and individual interests and to draw attention to the context in which this interplay takes place over time, as well as the implications of this relationship for HRR. I have proposed that publicness can help to optimise HRR by naming and foregrounding this relationship, and by providing the foundation for a framework of analysis in relation to each of its three facets: relationality, temporality and accountability.
- I have demonstrated how publicness helps to provide a new understanding of what is at stake in health research and its regulation, and to support its optimal operation in a number of ways. More particularly, I have argued that publicness serves two core purposes: it has *diagnostic* value in that it helps us to understand better what is the nature and role of existing mechanisms within HRR; and, secondly, it has *normative* value in that it provides a basis to move beyond what already exists in the sub-optimal ecosystem.
- In Part I have used the *diagnostic* value of publicness in order to:
 - tease apart and reveal the work that existing concepts that capture something about the social side of research (namely, the public interest, social value and social licence) already do in health research regulation, individually and in relation to one another.
 - identify some of the ways in which the conduct of contemporary health research challenges existing regulatory structures, including the conceptualisation of and

engagement with diverse publics, the facilitation of robust review and revision of health research throughout the research or data lifecycle, and the need for HRR to adapt and respond to these challenges.

- In Part II I have used the *normative* value of publicness to:
 - outline concrete ways in which publicness delivers a concept that can flesh out and enrich the HRR ecosystem through consideration of (1) the temporal aspects of regulating individual and collective interests over time, and (2) the mutability and diversity of and within publics in HRR.
 - offer a reconceptualisation of the public interest as a regulatory device, which (i) explores the notion of ‘the public’ in the public interest and how context can shape these interests; (ii) points to the ways in which the research path and the public interest overlap and intersect each other throughout the entire life cycle; and (iii) emphasises the role of transparency in multi-factorial decision making. This directs attention not only to the public interest in terms of how this may be realised from the (expected) findings from research, but also to the ways in which this may be manifested in processes of research and regulation in relation to data use.
 - move the regulation of data-intensive innovation beyond a baseline approach, where minimal steps are taken to secure legal compliance, and towards an approach that encourages consideration of the potential for wider and differential impacts on a range of stakeholders over the longer term.

Future directions for research

As described at the start of this Chapter, a key aim of this thesis has been to grapple with the fundamental question of why the relationship between individual and collective interests matters and how this can better be understood in order to optimise contemporary HRR. I have responded to this question in a number of ways, as outlined above, but inevitably I have had to make a number of choices as my research progressed. In particular, I have prioritised the consideration of fewer concepts and more targeted issues, in greater depth, over broad coverage. As a result there are a number of directions that I would like to explore further going forwards, either independently or as part as a multi-disciplinary team. In particular, these include the following:

- In Chapter 3 I have explained why I have chosen the concepts of the public interest, social value and social licence to explore, and noted that there are others that could similarly be viewed through the lens of publicness. In particular, solidarity is also often considered alongside the public interest and, I believe, could be explored further using publicness. In this thesis I have also shown how intersectional approaches to the *conduct* of health research might be deployed in relation to its *regulation*. I have not claimed an original contribution in this respect but would like to develop the ideas that have been seeded in this thesis further in relation to intersectional HRR.
- As well as engaging with other concepts, there are also further sites of study that I would like to engage with in more detail. More specifically, in Chapter 6, I have restricted myself to the consideration of one case study (the development of the Streams app by the Royal Free/ DeepMind) in order that, as is fitting for a publicness-informed approach, this can be examined over time (from 2015 to date), and from a number of angles. However, in the course of drafting this thesis I have also considered another, ongoing example of a high profile data sharing initiative in England that has stumbled prior to implementation, namely the General Practice Data for Planning and Research (GPDPR) scheme.⁶⁷⁹ This new approach to collecting information from GP practices by NHS Digital has currently been paused in order to allow more time to engage with stakeholders, including clinicians and patients, prior to its implementation.⁶⁸⁰ I decided not to use this case study in the course of this work as it is still unfolding at the time of writing. However, I consider that this could form the basis for a future article, which uses publicness as the foundation for a framework for analysis.
- In Chapter 5 I have subsequently chosen the public interest, as a regulatory device, to examine more deeply in a stand-alone Chapter. This reflects my longstanding interest in this concept, and the way that this is framed by the law. In particular, I have examined the intersection between empirical outputs, on the one hand, and law and policy, on the other, and advanced thinking in HRR in relation to the conditions under which these can inform one another. To further develop this work on the public

⁶⁷⁹ NHS Digital, 'GP Data for Planning and Research' (24 August 2021) <<https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/general-practice-data-for-planning-and-research/secretary-of-state-letter-to-general-practice>> accessed 16 February 2022.

⁶⁸⁰ Letter from Jo Churchill, 'GP Data for Planning and Research: Letter from Parliamentary Under Secretary of State for Health and Social Care to General Practices in England' (19 July 2021).

interest I would like to undertake empirical work in this area. In particular, I am interested in the ways that the public interest is framed, understood and instantiated by bodies such as the well-established CAG in England, the Public Benefit and Privacy Panel in Scotland (PBPP) and the newly formed Health Research Consent Declaration Committee (HRCDC) in Ireland, which was established as part of the Health Research Regulations made under Ireland's Data Protection Act 2018.⁶⁸¹ These bodies publish their decisions and explicitly consider the public interest as part of their deliberations. There has been, to my knowledge, only one study that has looked at CAG decisions,⁶⁸² but, as I have flagged in Chapter 3, this did not take the public interest as its focus, and as a result the public interest was largely approached as being equivalent to compliance with the relevant data protection legislation. I consider that the work on publicness in this Chapter could provide a framework for analysis across these jurisdictions, which could identify similarities and differences in approach, and ways that each may be optimised. As some of the immediate pressures of the Covid-19 pandemic ease, I am optimistic that this will be possible in the near future, and that this work could be of benefit to these organisations. For example, I presented to the HRCDC in Dublin on the topic of the public interest in May 2022. I would anticipate that this work could be carried out either independently, or as a small team with the assistance of a research assistant.

- I am also interested in developing the use of publicness further through collaborative work. As I have identified and acknowledged at a number of junctions within this thesis, while I have used PE&I literature to develop my ideas from a legal and regulatory perspective, there are limitations to this approach. For example, while I have identified synergies between a power-explicit approach to democratic modes of public participation and to intersectional regulation, these could be explored further, including through empirical research. I would envisage that this could best be advanced in the context of a larger, international group of researchers, given that the complex intersection between outputs from engagement activities, and the incorporation of these into governance, requires a multi-disciplinary response.

⁶⁸¹ Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 S I No 314 of 2018 (IR).

⁶⁸² Cross and others (n 226).

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