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Medical data donation, consent and the public interest after death

Citation for published version:

Sorbie, A 2019, Medical data donation, consent and the public interest after death: A gateway to posthumous data use. in J Krutzinna & L Floridi (eds), *The Ethics Of Medical Data Donation*. Philosophical Studies Series, vol. 137, Springer, pp. 115-130. https://doi.org/10.1007/978-3-030-04363-6_7

Digital Object Identifier (DOI):

[10.1007/978-3-030-04363-6_7](https://doi.org/10.1007/978-3-030-04363-6_7)

Link:

[Link to publication record in Edinburgh Research Explorer](#)

Document Version:

Publisher's PDF, also known as Version of record

Published In:

The Ethics Of Medical Data Donation

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Chapter 7

Medical Data Donation, Consent and the Public Interest After Death: A Gateway to Posthumous Data Use



Annie Sorbie

Abstract Posthumous medical data donation (PMDD) could deliver a longitudinal dataset that facilitates significant advances in health research. This chapter focuses on a central challenge of PMDD, namely what good governance looks like in circumstances where consent does not provide a ‘single magic bullet’. The central argument is that consent in PMDD must be properly understood as merely one aspect of a holistic governance regime, and that more emphasis ought to be placed on the role of authorisation. This brings to the fore the potential role of the public interest in navigating the various interests in play. As will be demonstrated, this proposed re-orientation of governance could deliver tangible benefits in PMDD and enhance three key elements of good governance: transparency, accountability and engagement with evidence of the views of actual publics. Part I outlines the impetus for the examination of PMDD in the context of the (non)delivery of the ‘data sharing revolution’. Part II considers the pressure that temporal aspects of PMDD exert on traditional notions of consent, and the interests this brings into play. Finally, Part III suggests that authorisation should have a role to play alongside consent.

Keywords Posthumous · Medical · Data · Donation · Consent · Governance · Authorisation

The author thanks Professor Graeme Laurie for his invaluable support and advice on the drafting of this chapter. Thanks also to the Mason Institute’s Work in Progress group, which commented on these nascent ideas, and in particular to Dr Edward Dove. All errors of course remain the author’s own.

A. Sorbie (✉)

School of Law, University of Edinburgh, Edinburgh, UK

Mason Institute for Medicine, Life Sciences and the Law, Edinburgh, UK

e-mail: asorbie@ed.ac.uk

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J. Krutzinna, L. Floridi (eds.), *The Ethics of Medical Data Donation*,

Philosophical Studies Series 137, https://doi.org/10.1007/978-3-030-04363-6_7

115

7.1 Data Governance and the Promise of PMDD

Data use and governance is at a cross roads. Across all sectors, unprecedented quantities of data are being captured and repurposed. This is greatly facilitated by emerging technologies such as machine learning, which have transformed our capacity to analyse data in increasingly sophisticated ways (British Academy and Royal Society 2017; House of Lords Select Committee on Artificial Intelligence 2018). What may appear, at first blush, to be prosaic matters around data usage in fact require us to consider the significant (potential) benefits, and risks, of collecting, curating and sharing information beyond the purposes for which it was originally obtained or generated. As recently articulated by the British Academy and Royal Society, this raises pressing questions for society that go directly to how we live our lives and flourish in the twenty-first century.

These matters are brought into sharp focus in the context of health and the use of medical data. Here there is the very real possibility that proactive data management – whether in the form of data use, re-use or sharing – can deliver improvements in human health. However, this brings with it immediate and legitimate questions about boundaries to open science (The Royal Society 2012) and corollary responsibilities to protect data subjects and ensure good data governance (Laurie et al. 2014). The British Academy and Royal Society also highlight that while health data might tend to flow in silos, research uses might require these flows to be disrupted (and potentially significantly extended), for example where mobile phone data is used to predict the spread of malaria (Buckee et al. 2013). As well as new and varying research uses for health data, new stakeholders – including actors in the public, private and third sectors – raise questions about the public acceptability of data use and sharing initiatives that span the public / private divide (Aitken et al. 2016).

While the value and potential of data-driven medical research is well recognised (Knoppers et al. 2014) the jury is out on whether the data reuse revolution has, in fact, been delivered (Pisani and Abou-Zahr 2010). Indeed, various solutions have been proposed to bridge the gap between aspirational policy and pragmatic practice, from facilitating cross-border collaboration, to ensuring that the work invested in curating data sets is appropriately acknowledged. Despite this attention, a persistent stumbling block to progress is not so much the absence of available data, but rather how the potential of existing data might be harnessed and made available to facilitate advances in health research.

A proposal that speaks to this stubborn problem, and has attracted increasing attention in recent years, is the broad notion of data philanthropy. Taddeo (2016) understands this as ‘the donation of data from both individuals and private companies’. The recipients of such data are not specified, but could include international organisations like the UN, actors undertaking research in the public sphere, or those working in industry (Taddeo 2017).

Much of the literature on data philanthropy has focused on the donation of data by private companies (Taddeo 2017). However, the donation of data by individuals

has also been subject to high-profile scrutiny. In January 2018 the late British Labour MP, Baroness Tessa Jowell, delivered a speech to the House of Lords that was extensively covered by the media following her own diagnosis with a brain tumour. She called for ‘...sharing access to more and better data to develop better treatments’ (Hansard 2018) and highlighted the work of the Eliminate Cancer Initiative (ECI). Baroness Jowell was subsequently reported to be the first to donate her medical data to the Universal Cancer Databank (BBC 2018). This kind of ‘altruistic giving’ is typical of many conceptions of data donation, where the language and metaphors of donation are frequently invoked to suggest admirable exercises of autonomy for the sake of the common good.

The ECI was positioned by Jowell as a new initiative, but there are now a range of data sharing schemes and repositories in operation. For example, disease specific registries, which collect information from patients, often without relying on individual consent, are well established in the UK and beyond (Nelson et al. 2016). There are also other projects, such as the Scottish Health Research Register (SHARE), which allows members of the public to voluntarily sign up to allow their coded NHS data to be checked to identify whether they would be suitable for certain health research projects, on the basis they will then be invited to participate if a match is found.¹ These projects operate in different ways, but both speak to the desire to maximise the potential of existing health data, and to harness this to deliver collective improvements in health and social care. This too is an aim of a research project developed by Krutzinna, Taddeo and Floridi of the Digital Ethics Lab at the Oxford Internet Institute, University of Oxford, and funded by Microsoft, to investigate posthumous medical data donation (referred to hereafter as PMDD). An output of this project is to develop an ethical code for PMDD in order to set out the guiding ethical principles for such donations.

By way of context, it is only recently that there has been any sustained consideration of the use of data for research *after death* (Shaw et al. 2016). Although PMDD on a case-by-case basis might, in theory, be possible if an individual were so inclined to anticipate this before their death, there is currently no cogent framework within which such a donation may be offered up, or indeed received, and then the relevant data disseminated for research or other purposes.

To the extent that PMDD on a wider, systemic scale has previously been tentatively explored in scholarly works, this has tended to use organ donation as a comparator. Thus, an example of a potential model is Taylor’s suggestion in *The Lancet* (2000) that card-carrying data donors could volunteer their data for use by brain researchers in the event that the data donor were to succumb to a brain condition. This expression of willingness to provide data would be effective in the event that a brain disorder set in, with the advantage that researchers could access information both before and after the onset of the brain illness or damage. More recently, Shaw et al. (2016) have revisited the question of how data is used after death in more detail, arguing for PMDD as a way to prevent the waste of data which might otherwise be used for valuable research. The authors identify a number of drivers of such

¹ <https://www.nhsresearchanddevelopment.scot.nhs.uk/share/> Accessed 17 August 2018.

a scheme, including: low levels of awareness of how data is used (or not) after death; the thicket of regulations that can make data from the deceased difficult to access; and the significant benefits that such use might yield, as demonstrated through the example of the German National Cohort study.

One of the assumptions of a scheme of PMDD, such as that proposed by Shaw et al. and by Krutzinna et al, is that this would be a widespread undertaking whereby individuals could, for example, opt in as a matter of course at some point in their life. Here the analogy with organ donation holds: the individual might be asked to agree to PMDD at the point where she applies for a driving licence, or perhaps signs up at a GP practice. However, for both practical and principled reasons, the organ donation analogy has significant limitations. These range from the practical matter in PMDD of locating medical records and related (but perhaps dis-located) data that may be held in different formats across multiple sites,² to the potential impact on living family members where shared genetic information is donated (Shaw et al. 2016 and Krutzinna et al. 2018). As will be explored later in this chapter, another divergence is that data is not exhausted by re-use in the same way as a donated organ, nor depleted by repeated use, like a biological specimen. Indeed, the longitudinal value of data potentially increases significantly over time and with increased sharing and re-use. Any effective governance mechanisms must reflect these particular features of data, its protection, and also its value maximisation.

Returning to Krutzinna et al's model of PMDD, many of the key features of this scheme are detailed elsewhere in this volume, some of which are beyond the scope of this chapter. However, the following bear repetition as they are particularly pertinent to the discussion that will follow:

- The scheme is intended to be user friendly and widespread, to encourage and enable those individuals who wish to participate to easily donate their data posthumously;
- This model of PMDD is designed to facilitate sharing of a comprehensive medical dataset, as included in participants' personal medical records (PMRs);
- Such a scheme should be voluntary and participatory – OII explicitly reject the argument that informed consent is not required for PMDD, though acknowledge the merit in further consideration of how informed consent operates where data is repurposed in ways that *cannot* be anticipated at the point of data collection. (Krutzinna et al. 2018)

This chapter responds to this call for scrutiny of what good governance looks like in circumstances where consent does not, as I will argue, provide a 'single magic bullet' (Laurie et al. 2015). The central argument advanced – that consent in PMDD should be understood as merely one aspect of a holistic governance regime – is wholly consistent with the OII's position that PMDD should enable willing

²This point was made by Kerina Jones of Swansea University at the OII workshop at the University of Oxford on 20th April 2018.

participants to consent to volunteer their data. However, the proposed re-orientation of governance in PMDD will further enhance the transparency and accountability of any such scheme, and support the delivery of a longitudinal dataset that has the potential to facilitate significant advances in health research.

In the sections that follow I will first, in Part II, consider the pressures that PMDD exerts on traditional models of consent. These are analysed with reference to both the temporal regulation of PMDD, and the interests this may bring into play. This discourse serves to delineate the role of consent in PMDD, as well as its limits as a complete governance solution.

Having proposed that consent in PMDD is more properly understood as merely one aspect of a holistic governance regime, Part III suggests that authorisation has a role to play. This is where certain uses of data may be permitted by an access committee, in the absence of consent, and is illustrated by the work of the Confidentiality Advisory Group and the Public Benefit and Privacy Panel, as described further below (Laurie et al. 2015). Consideration of the operationalisation of this re-orientation, in the context of PMDD, brings to the fore the potential role of the public interest in navigating the various interests engaged.

7.2 Timing, Interests and the Limits of Consent

It is trite that issues of consent and autonomy are a central concern of health research regulation (Laurie and Postan 2013) and therefore bear scrutiny in the context of PMDD. Shaw et al. (2016) suggest that participants in PMDD would, prior to their death, be asked to provide consent for the use of their data either for individual projects, or by way of ‘broad consent’. As already indicated, it is a key feature of the governance scheme proposed by OII that PMDD should operate on the basis of ‘informed consent’ (Krutzinna et al. 2018). In order to analyse these proposals a crucial distinction must be made between how data is donated *into* such as scheme (during a donor’s life), and then collected and disseminated *out* of the scheme (once the donor is deceased). This distinction emphasises the temporal aspects of regulating PMDD, and exacerbates a frequent criticism of consent as an ‘up-front, one-off event’ that is unable to account for ‘all interests that are in play’ (Laurie et al. 2015). In the section that follows these criticisms are each examined before turning to specific models of consent.

7.2.1 A Matter of Timing

The criticism of consent as an ‘up-front one-off event’ has particular resonance in the context of PMDD. Here, 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, and as recognised by Krutzinna et al, 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.

This analysis has obvious implications for how data is donated *into* a scheme of PMDD (during a donor's life) in terms of the practical limitations of the information that can be provided to the donor at the point of consent. However, this also impacts on the operation of the scheme after the donor is deceased, and particularly on how data is disseminated *out* for use in health research. More specifically, any scheme of governance directed to the responsible dissemination of data must be able to respond to changing expectations – including those of research communities and wider publics – about how data can and should be used. The failure of the care.data initiative³ in England provides the paradigmatic example of the perils of assuming public acceptance of new and disruptive data usages which challenge the norms of expected data flows (Carter et al. 2015; Wellcome Trust 2016). Conversely, adopting a conservative position at the point of data dissemination may be equally ethically problematic, in circumstances where participants have donated data on the understanding that this will be utilised for research.⁴ The disjuncture in timing between obtaining consent and the realisation of value in data far beyond what could be anticipated at the time of consent should lead us to question seriously what informed consent could look like in these circumstances.

³This was an initiative in England that was designed to extract information from primary health records for use in secondary purposes, including research.

⁴See OII's first justification for a scheme of PMDD: that 'it is unethical to frustrate the 'will-to-do-it' without proper justification (Krutzinna et al. 2018).

7.2.2 *Interests in PMDD*

Such temporal considerations are compounded by the equally thorny criticism of consent as a governance mechanism that does not account for all of the interests in play in health research. This too calls for a ‘robust assessment of what is at stake’ (Laurie et al. 2015) in PMDD.

First to mind are the interests of data donors who consent (during their lifetime) to PMDD. Although these interests may be presented in different ways, few would dispute that a donor should be able to exercise their rights to self-determination or autonomy in life (Laurie and Postan 2013). On their death donors may leave behind living relatives who could also have an interest in the data that has been donated (Shaw et al. 2016). As noted by Krutzinna et al. (2018), a distinguishing feature of data is that it rarely relates to a single individual, which raises the possibility of harm to others.

At first blush the ‘thicket’ of regulation that applies to data relating to living individuals might appear less dense post-mortem. As was the case for its predecessor legislation, neither the General Data Protection Regulation⁵ nor the Data Protection Act 2018⁶ apply to information about a deceased person. However, the absence of an omnibus legislative framework does not signify a ‘free for all’ in terms of how the data of the deceased may be used, nor does it preclude donors’ interests surviving their death. For example, Sperling (2008) argues that due respect should be given to individuals’ preferences in life about how their data should be used after their death.

A growing body of scholarly work also addresses broader matters of posthumous privacy and informational self-determination (see, in particular, Buitelaar 2017; Edwards and Harbinja 2013). Buitelaar argues that the assumption that privacy rights are extinguished upon death cannot be maintained in our networked society. These matters are often considered in the context of digital assets, but many of the features of this medium, as identified by Edwards and Harbinja – such as its personal and intimate character and shareable nature – might equally be applied to electronic PMRs.

In the medical context, the persistence of obligations post mortem is reflected in guidance issued by the General Medical Council, which has long acknowledged that a doctor has a continuing duty of confidence to a patient after their death (see GMC 2018). With some equivocation, it was also found that such an obligation exists in law in the case of *Lewis v Secretary of State for Health*⁷ (Choong et al. 2014). This case concerned whether documents (including medical records) relating to deceased patients could be disclosed by a GP to an inquiry into human tissue

⁵Regulation (EU) 2016/679 of the European Parliament and of the Council 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, and repealing Directive 95/46/EC (General Data Protection Regulation).

⁶c.12.

⁷[2008] EWHC 2196 (QB).

analysis in UK nuclear facilities. In *Lewis*, disclosure of the records in question turned upon whether to do so was in the public interest.⁸ Here it was recognised that the public interest (which was distinguished from ‘what the public found interesting’)⁹ was multifaceted and could encompass both individual and collective interests including those in: disclosure; maintaining the patient’s confidentiality; and maintaining confidence in the institutions under investigation.¹⁰

This analysis again draws attention to the temporal and varying nature of the interests that may arise in PMDD, both during a donor’s life when their consent is obtained, and after their death when their data is collected and used. However, here the resolution of these interests is crystallised at the point that decisions are made about how data collected by PMDD should be *disseminated out* for use in health research. Herein lies the governance dilemma at the heart of PMDD: if individual consent at the point of donation is constructed *too widely*, then this may not only stray unacceptably far beyond the intentions of the donor, it may also fail to take into account other interests that are in play, such as those of family members. However, should that original consent be construed *too narrowly*, this also risks frustrating the donor’s desire to contribute to sustainable health research, in circumstances where uses go beyond what was anticipated at the time of donation, but are not necessarily unacceptable. Such a restrictive approach may also fail to take into account the full range of interests in play, including collective public interests. This leads one to question whether over-reliance on *any* model of consent is appropriate to legitimise PMDD.

7.2.3 *Models of Consent*

Questions around what constitutes an optimal model for the consent of health research participants, and the limits of that consent, have been closely and extensively scrutinised in the academic literature. There remains disagreement on terminology as between broad and blanket consents (De Vries et al. 2016) and in particular as to whether broad consent can, or cannot, be sufficiently informed in ethically robust terms (Sheehan 2011; Kaye et al. 2014). A comprehensive review of this ongoing debate falls outside of the scope of this chapter. However, briefly reviewing some potential models of consent, in light of the analysis of PMDD above – which pays close attention the subject / object disconnect and interests at play in PMDD, and also how data received *into* and disseminated *out of* such a scheme – reveals insights that can inform its good governance.

Laurie and Postan identify the ‘many different qualifying adjectives’ that are used to describe consent in the context of health research (2013). However, this

⁸Ibid. Paragraph 58.

⁹Ibid. Paragraph 59.

¹⁰The Judge’s order for disclosure was explicitly subject to proper safeguards being put in place to ensure that the information did not become ‘public’ beyond the inquiry. Ibid. Paragraph 58. I return to further consider the role of the public interest in PMDD at Part III below.

chapter will focus on the proposals outlined by Shaw et al, and developed by Krutzinna et al, which both suggest that some form of ‘broad’ consent will be most appropriate in the context of PMDD, with Krutzinna et al emphasising that this should be ‘informed’.¹¹ In the analysis of this model I will argue that, because of the temporal disconnect inherent in PMDD, and the multiple interests in play, while consent (of any type) might be a basis for signing people up to participate in PMDD, it is not well placed to be the enduring governance tool over time and certainly not after the donor’s death. To the extent that such issues are a reoccurring theme in health research regulation more broadly, this is particularly so in PMDD in circumstances where the subject – the donor – is no more, while the object – the data – not only endures but proliferates over time.

Although not proposed in either of the PMDD models referred to above, I turn first (and briefly) to ‘open’ consent, where a donor passes over data posthumously on the basis that the recipient can ‘do whatever they want with it’. This bears brief scrutiny as it could be said that this is workable *precisely because* the donor is deceased; indeed, in the case of organ donation, the donor is not consulted on exactly how that organ is used and who should be the recipient. While this analogy could appear persuasive, there are, I would argue, good reasons why this does not hold good (Shaw et al. 2016). Despite the data usage occurring post mortem, many of the ethical concerns raised in relation to open-ended consent – such as whether this could ever be meaningful or take account of the multiple interests in PMDD as outlined above – persist and are exacerbated by the multitude of ways in which the data might subsequently be used (Lunshof et al. 2008). Further, robust open consent, as operated in the context of the Personal Genome Project,¹² is a rigorous and onerous process that requires ‘a high degree of ‘information altruism’ ... thereby introducing a strong moral motive’ (Lunshof et al. 2008). This might set the bar too high for many and impact negatively on rates of participation. This would be fatal to a scheme of PMDD that relies on willing data donors and aspires to a streamlined donation procedure.

This brief critique of open consent underlines why a scheme of broad consent is the scheme of choice in both PMDD proposals. For the purposes of this chapter I park the question of whether broad consent can be informed consent (see, for example, Caulfield 2007; Sheehan 2011; Kaye et al. 2014). Further, ‘broad consent’ itself is not an entirely settled term, and so, for expediency, I will use, as my starting point, Sheehan’s (2011) understanding of this as ‘...encapsulat[ing] consent to a range of different conditions’. He sees this primarily as agreement to an arrangement whereby a governing body will make decisions about how data might be used,

¹¹ For the purposes of this chapter, I have discounted the possibility of specific consent and dynamic consent, which are clearly not possible in circumstances where a dead donor cannot be re-consented. See Kaye et al. 2014, for the benefits of dynamic consent in biobanking, as compared to broad consent. For the sake of space, and because it has not been proposed as a solution for PMDD, I have also omitted any consideration of consent by proxy in PMDD, which would occur after the donor’s death. This model raises numerous ethical issues. See, for example, Wrigley (2007).

¹² See: <https://www.personalgenomes.org.uk/sign-up>

but notes that this can also include other matters such as ‘an account of a general program of research, an account of the general goals of research or an account of the institutional values and aspirations’.

Two recent studies, both of which are broadly supportive of broad consent as a governance tool for ethical research, echo the multiple elements that broad consent encompasses. Steinsbekk et al. (2013) see broad consent as signifying acceptance of a framework to review future research, part of which includes ‘strategies to update regularly the [biobank] donor’ and also potentially the option of withdrawal and/or re-consenting. The authors further suggest that this interactive aspect of broad consent may be improved though the use of some of the communication methods used in dynamic consent (see also Kaye et al. 2014 for a description of this model). De Vries et al. (2016) suggest that the challenge in broad consent is to combine ‘transparency about sponsored research together with governance models that assure the donor community and the public that their interests and moral concerns are being respected’. In the case of live donors to biobanks, they note that this can be achieved through access to information – for example by providing up-to-date descriptions of projects. These academic interpretations of broad consent are consistent with the recruitment, retention and access policies for UK Biobank,¹³ which is recognised as operating under a scheme of broad consent. This governance model makes specific provision at the outset for ‘active engagement with participants... in particular regarding the research that is being conducted on [the resource] and the research findings that emerge’ (Summary), as well as incorporating provisions for the re-contact of participants in some circumstances (Section B6) and re-consent (Section B6.2).

When these recognised conditions for obtaining legitimate broad consent are considered in the context of PMDD model – where the donor’s initial consent is held in stasis at the point of their death, and *no form* of ongoing interaction is possible – it could be concluded that consent is redundant in these circumstances. In particular, it fails to resolve the central governance dilemma of PMDD, as delineated above, and results in either an overreach (where this is construed *too widely*) or an under reach (where this is construed *too narrowly*), respecting neither the temporal aspects of PMDD, nor the interests in play.

Returning to the analysis above of how data is donated *into* such as scheme, as well as how it is disseminated *out* for research use, provides a more nuanced interpretation, in light of the foregoing discussion. Taking the OII scheme as our starting point, a key element of this framework is that participation should be both ‘voluntary and participatory’ (Krutzinna et al. 2018). In terms of the voluntariness of the donor, there is a clear role here for a scheme of broad consent as a threshold device to legitimately recruit participants *into* the scheme. For example, the donor can sign up, at the point of consent, to express their ‘willingness to volunteer their data’ (Krutzinna et al. 2018) within a broader governance structure. However, the analysis above also underlines the limitations of consent in the context of PMDD, when this is unable to cope with the temporal aspects of PMDD, nor the multiple interests

¹³ See: http://www.ukbiobank.ac.uk/wp-content/uploads/2011/11/Access_Procedures_Nov_2011.pdf

in play, which crystallise at the point that data is *disseminated out* of such a scheme. It therefore follows that consent in PMDD is better understood as merely one aspect of a holistic governance regime, and that it is necessary to look to a range of approaches to deliver effective and enduring data governance.

So far this chapter has considered the work that different models of consent can do and concluded that, in PMDD, this will not deliver a complete solution. The circumstances of PMDD, as discussed above, preclude the discharge of some elements of broad consent, namely any form of ongoing interaction with the donor. However, some aspects of this approach, such as the review of prospective research projects by a committee to identify whether access requests should be granted to the data resource, are achievable. In the context of broad consent, this mechanism is traditionally framed as part and parcel of the consent process, effectively sitting *behind* the donor's consent. This chapter calls for a re-orientation of governance, such that consent in PMDD is more properly understood as merely one aspect of a holistic governance regime. In the section that follows I consider another potential aspect of such a regime in PMDD, namely the role of authorisation. I propose that this governance mechanism should be seen as sitting *alongside* consent. In considering how this might operate in the context of PMDD, this brings to the fore the potential role of the public interest in navigating the various interests in play.

7.3 Authorisation and the Role of the Public Interest

Authorisation is now an established, if under-researched, part of the data sharing landscape in health research (Aitken et al. 2016). Often billed as an 'alternative to consent' (Laurie et al. 2015), some of the most well-known examples that relate to data reuse are the Confidentiality Advisory Group (CAG) in England and the Public Benefit and Privacy Panel (PBPP) in Scotland. To provide some context, CAG is a statutory body¹⁴ that advises the Health Research Authority on requests to access NHS patient records without consent for research purposes.¹⁵ CAG's legislative framework allows the common law duty of confidentiality to be lifted in specified circumstances so that identifiable information may be shared for purposes, including medical research. There are various safeguards within the legislation, one of which is that the activity in question must be in the public interest or in the interests of improving patient care. In Scotland, PBPP has a similar mandate in terms of scrutinising requests to use NHS Scotland-controlled data, and some data controlled by the Registrar General, for research or specified 'other' purposes.¹⁶ In contrast to its English counterpart, PBPP does not operate on a legislative basis, but rather as

¹⁴The CAG discharges its function pursuant to Section 251 of the National Health Services Act 2006, and The Health Service (Control of Patient Information) Regulations 2002.

¹⁵ See: <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/legal-frameworks/>

¹⁶ See: <http://www.informationgovernance.scot.nhs.uk/pbpphsc/>

part of the governance structure of NHS Scotland. The public interest – including that both in protecting individual privacy and in optimising the use of health and social care data – is at the heart of PBPP’s guiding principles. As a result, any request for access to either of these data resources must first show, amongst other matters, that the proposed use is demonstrably in the public interest.

For both CAG and PBPP, authorisation as a governance mechanism is invoked on the basis that neither consent nor anonymisation are appropriate or practicable (Aitken et al. 2016). How, then, might a scheme of authorisation work *alongside* consent to meet some of the governance challenges that are specific to PMDD? There are, as outlined below, tangible benefits this could deliver to PMDD in order to enhance three key elements of good governance: transparency, accountability and engagement with evidence of the views of actual publics.

First, by viewing the authorisation mechanism as sitting *alongside* consent, this will provide donors with a more realistic and informed understanding, at the point of consent, of how their data will be managed in the future, and particularly after their death. This re-orientation of governance, in response to the context of PMDD, explicitly acknowledges the temporal disconnect identified in this chapter as between the subject – being the donor who consents to the data donation in life – and the object – being the multitude of ways that the data may be used after the donor’s death. This shift therefore delivers greater transparency in relation to the work that broad consent *can* do as a threshold device, while acknowledging that, on death, the donor is effectively handing over control of their data to the PMDD scheme and its longitudinal governance mechanism.

Next, such a mechanism, which I propose should regulate the dissemination of data on the basis that access will only be granted where this is in the public interest,¹⁷ would potentially be capable of accounting for the multiple individual and collective interests at play in PMDD (British Academy and The Royal Society 2017). In the course of the preceding discussion, various interests in PMDD have been identified, including those of: donors (both pre and post mortem); family members; funders and researchers in the academic, commercial and third sectors; as well as the collective interests of wider publics in the benefits of responsible health research. As has been acknowledged, consent is able to take into account some of these interests, particularly in relation to the individual interests of the donor, but is inadequate to deliver upon all of the interests that are in play (Laurie et al. 2015).

In proposing demonstrable public interest as the basis on which access to data will, or will not, be granted, it is fair to acknowledge this remains a ‘notoriously uncertain idea’ in health research regulation (Taylor 2011), which requires further intellectual scrutiny (see various commentators in Sorbie 2016). The parameters of

¹⁷Shaw et al. do not go into the detail of such a governance mechanism, while Krutzinna et al. propose that access decisions should be made on the basis of the common good. I favour the public interest as this reflects the practice of established governance mechanisms (e.g. CAG, PBPP and UK Biobank) and reflects ‘the importance of ensuring that data uses align with public interests or preferences’ (Aitken et al. 2016). This scrutiny of the role of the public interest in health research regulation is addressed more specifically in my doctoral research.

this chapter do not allow for this task to be executed in detail, save to tease out the contours of a *holistic* conception of the public interest that might lend itself to the governance challenges of PMDD. In particular, this moves away from a narrow account of the public interest that pits individual interests against collective benefits, and towards an account that is described by Rid as a ‘pluralistic conception of public interest’, i.e. an account that is capable of recognising that multiple interests are in play (in particular, see Rid and Taylor in Sorbie 2016). This approach is evident both in the operation of CAG and PBPP,¹⁸ and is in line with the judicial interpretation of a multifaceted public interest in *Lewis*. The operation of a similar scheme can be seen in the case of the UK Biobank, which uses the public interest to regulate third party access to its resource (Capps 2012). However, PMDD, which only collects and disseminates data in the future once its donors are deceased, can be distinguished from most biobanks, whose aim is to create a more immediate resource, often for use during a donor’s lifetime.

Third, an authorisation mechanism, which allows access to data gathered by PMDD when this is in the public interest, has the potential to connect the governance of a scheme of PMDD, with the mounting empirical evidence of public attitudes towards data sharing and linkage, thus closing the gap between aspirational policy and pragmatic practice. This chapter has already touched on the perils of disregarding the need for a ‘social licence’ for any such scheme, and the need to tread carefully in the case of new, and potentially disruptive, data flows. This is also illustrated in Wellcome’s recent research, as commissioned from Ipsos MORI, on public attitudes to commercial access to health data for research purposes (Wellcome Trust 2016). This found that, when considering data uses, ‘a strong case for public benefit is the most important factor for many people: without it, data use by any organisation is rarely acceptable’. While these findings did not relate specifically to PMDD, this is particularly relevant in the context of a scheme that relies on a voluntary and participatory model, as without willing data donors, the scheme will fail before it begins.

Given that authorisation schemes are an established part of the data sharing landscape, Aitken et al.’s finding that there is a lack of evidence of public views on this topic is striking. The conclusions of this chapter certainly suggest that further scrutiny of authorisation as a governance mechanism is likely to have wide application, reaching beyond the current modes in which this is deployed. In the case of PMDD, any proposed governance model would be well-advised to undertake a comprehensive public engagement exercise to gauge both understandings of access decisions that are made in the public interest, and also the extent to which this might be tolerated by publics. In shaping the contours of how a consent and authorisation model might work in tandem, this exercise could explore matters such as whether authorisation should always seek to take donors’ early consent into account, the extent to which

¹⁸For example, the Terms of Reference for the PBPP explicitly recognise that: ‘To ensure the right balance is struck between safeguarding the privacy of all people in Scotland and the fiduciary duty of Scottish public bodies to make the best possible use of the health and social care data collected – it is important to note that each is in the public interest’. See: <http://www.informationgovernance.scot.nhs.uk/pbphsc/home/about-the-panel/>

donors should be able to place conditions on the use of their data, and whether there could ever be circumstances, such as the passage of time, that would legitimately allow an authorisation mechanism to allow access to data in the public interest that goes beyond the scope of the original consent.

7.4 Conclusion

PMDD is a proposal that speaks directly to the persistent challenge of harnessing *existing* data in order to facilitate future research, and holds the promise of delivering significant advances in human health. This chapter has scrutinised what good governance looks like in circumstances where, as I have argued, consent does not provide a ‘single magic bullet’ (Laurie et al. 2015).

This central argument – that consent in PMDD must be properly understood as merely one aspect of a holistic governance regime, and that more emphasis ought to be placed on the role of authorisation – has brought to the fore the potential role of the public interest in navigating the various interests in play in the context of PMDD. This chapter has further set out how a re-orientation of governance could deliver tangible benefits to the good governance of PMDD, thus enhancing its transparency, accountability and engagement with evidence of the views of actual publics.

This chapter contributes to the growing literature on PMDD by elucidating the impact of temporal regulation on good governance in this context, 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, it has been highlighted that 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. This analysis has also highlighted the need to account for multiple individual and collective interests at play in PMDD that are likely to change over time. Taken together, this points to the need for an adaptive governance model that is reoriented to meet the specific challenges of PMDD, and thus provides a gateway to posthumous medical data use.

These contributions also have wider application in health research regulation that go beyond PMDD. In particular, this chapter proposes a framework to analyse innovative data governance regimes with reference to how data flows *into*, and is disseminated *out of*, these models. By highlighting temporal considerations in health research regulation, and the multiple individual and collective interests engaged, this underlines the need for novel and bold mechanisms that do not seek to over-play the role of consent, nor that suggest that third party permissions alone can deliver good governance solutions. Dynamic governance that captures the strengths of each of these approaches is required to bring about a crucial step-increase in health research capabilities when it comes to dealing respectfully and effectively with data after death.

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