

# Chapter 8

Reflections and  
conclusions

## Chapter 8 – Reflections and conclusions

### Chapter overview

This chapter reviews the state and direction of travel of information technology, data science, research and governance described in the report before drawing together the elements of the ethical argument. It concludes by setting out some practical precepts for professionals involved in data initiatives.

### Introduction

- 8.1 In this final chapter we briefly reflect on the issues we have identified, the ethical argument that runs through this report and some of the conclusions to which our deliberations have led. Our hope is that our approach will prove useful to those proposing to extend the use of data in biomedical research and health care. We therefore conclude by proposing a number of practical precepts for those involved in the establishment or governance of data initiatives.

### The state of the art

- 8.2 We began by setting out a number of propositions, which describe the area of interest and ethical issues that arise within it. The first two of these propositions describe the conditions from which the subsequent propositions follow, namely the accumulation of data from people in health care and biomedical research, and advances in information technology and data science that allow those data to be put to use. We recognise that these underlying technical advances are not specific to the fields of health care and biomedical research, but their impact in healthcare and biomedical research is profound and raise issues of special ethical significance. One reason for this is that the opportunities to which these advances give rise invite us to think about data as a resource with broadly exploitable potential rather than as an output bound to the intentions that motivated its original collection. This way of thinking is, in general terms, very different to the way in which information governance-conscious clinicians and researchers have, until now, been expected to think about data.
- 8.3 The principal ways of realising this new potential involve reframing the data within a novel context, created by a novel ‘research question’ or by linking them with other data, either from a different source or collected especially for the purpose. This led us to observe that the moral significance of data is therefore related to the kinds of questions that the data can help to answer and when or by whom those questions are addressed.
- 8.4 Data collected in health care and biomedical research contexts are not intrinsically more or less ‘sensitive’ than other data relating to individuals, but the medical context in which they are acquired (and in which they may be used) will often mean that they touch important personal interests. On the other hand, we draw attention to the fact that there is a strong public interest in the responsible use of data in research to support the development of knowledge and innovation intended to improve the well-being of all by enabling advances in healthcare. In fact, the use of data can have both beneficial and harmful effects on individuals or groups. These effects may be distributed in different ways: benefits for one group may entail welfare restrictions for another. Furthermore, different people may value different consequences in different

ways: something that might be profoundly troubling for one person might be a matter of indifference for another. It is principally these features – the potential for both beneficial and harmful consequences of data use, the possibility that they may be distributed differently among people, and the diverse ways that different people may value them – that constitute the problematic moral terrain of this report.

- 8.5 Negotiating this terrain is made difficult by the fact that so much about the personal and social consequences of data use is unknown, partly because there is a lack of existing evidence, but mainly because we have to consider an indefinite future in which these data will persist and in which the potential for data use and its impacts could be transformed in unanticipated ways. The digital world of data is growing rapidly and the ways in which datasets can be related and information from them derived are changing constantly. Making decisions about how data are best managed is complicated further by changing and powerful scientific, economic and political interests. In some cases this has led to the terms of publicly significant data initiatives being established the terms for many data initiatives *prior to any wider public debate*. These factors make it reasonable to expect that norms will shift in unpredictable ways over time. It is likely that well-established social norms of privacy and data access that apply today will no longer be applicable even in the near future as the actions of business, major institutions or government seek to *impose* new norms independently of social processes. A possible example is where using patient data offers opportunities meaningfully to inform health care service design, this becomes accepted as ‘necessary’ or is then legally mandated.<sup>481</sup> Meanwhile, the bulwarks that have hitherto protected a satisfactory and workable accommodation of interests, principally, the de-identification of data and the ‘informed’ consent of data ‘subjects’, have been substantially weakened in a hyper-connected (or potentially hyper-connectable) ‘big data’ world.
- 8.6 The morally relevant issues here are not merely to do with the re-identification of individuals: there also are social choices about the terms on which data are used that have moral consequences both because they determine how specific individuals might be treated (they may underwrite discrimination, for example) and because they may have a broader social impact (they may be used to inform political decisions). The challenge recognised in this report is for us as a broader society to get this right, to use data responsibly to promote the public interest, in a way that and best reconciles the morally relevant interests of individuals and groups, and respects their fundamental rights.

## Ethical approach

- 8.7 Our ethical approach takes the perspective that the collection and use of data, and the determination of the circumstances in which these take place, are social activities that involve and affect people, individually or as members of groups, through time. Our focus has not been on identifying particular kinds of data as being of special concern (as almost all data can be ‘sensitive’ or ‘personal’, depending on the context), but on the human relationships that variously facilitate or restrict the use of data, or which may be created or affected by particular uses of data, and which change through time. Our

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<sup>481</sup> See, for example, the arguments about the ‘need’ to use patient data to support health care service design and resource allocation that was put forward by NHS England in support of its ‘care.data’ programme, and the legislative action to facilitate data sharing a range of health-related purposes through the Care Act 2014.

aim has been to identify from among the influences and drivers shaping these relationships the values and interests that are *morally relevant* and how they should be respected accordingly.

- 8.8 *Privacy* is important to people for a number of reasons relating to their ability to maintain their identity, relationships and well-being. Respecting people's privacy can be seen as an aspect of showing respect for them as persons. The *public interest* is an interest that people share as members of a society, e.g. the promotion of commonly valued conditions like security, physical and mental health and material prosperity. People are simultaneously both individuals and members of wider groups with shared values and interests: they thus have interests both in allowing other people to access data that relates to them and in guarding against this to preserve their privacy, just as they have interests both in access to data about others and in their privacy. *Private and public interests are fundamentally entwined*: there is both a private and public interest in maintaining acceptable levels of privacy, and a private and public interest in making responsible use of data compatible with this. Data initiatives therefore have to perform a '*double articulation*' that seeks to reconcile the private and public interest in using data, and of the private and public interest in protecting privacy, rather than simply 'balancing' privacy interests *against* public interest.
- 8.9 Recognising the complex interrelation of morally relevant interests at stake leads to a more nuanced ethical approach than simply that of distinguishing the morally acceptable from the morally unacceptable. This is not to ignore that there might be unacceptable outcomes: those that do not respect persons or that violate their human rights are unacceptable, a point reinforced by our first two 'substantive' principles of *respect for persons* and *human rights*.
- Asserting the principle of respect for persons requires that the terms of a data initiative are set as a result of moral reasoning that takes the complex interrelationship of public and private interests into account. Enabling those with morally relevant interests to assert their own interests and offering them a reasoned account of decisions regarding data use that recognises those interests as being morally relevant are ways in which data initiatives may demonstrate respect for persons.
  - Asserting the principle of respect for human rights entails that people should be free to exercise, and that others should respect, rights derived from people's core, morally relevant interests (among which is the right to protection of private and family life and personal correspondence). It also entails that this freedom may only be restricted for weighty reasons, where it is necessary to achieve an end that the person is expected, through their membership of the society, to find reasonable and compelling, and in a way that is proportionate to achieving this aim.
- 8.10 However, the ethical approach also recognises that that job of moral reasoning should not cease once the threshold of acceptability is passed but should continue throughout the process of establishing and governing a data initiative, and permeate it at every point. Opportunities for ethical reflection should therefore be built into data initiatives. Moral reasoning thereby assumes a constructive role: rather than that of the external conscience poised to say 'no' to certain practices that step over a notional line of acceptability, the recognition that there are ethical arguments on both sides of any question about data use allows them to be harnessed in the search of good and better solutions, not merely the delineation of acceptable ones. Hence the notion of what is

*morally reasonable* is not merely about satisfying some formal standard of reasonableness but rather about the outcome of a process of moral reasoning in which values and interests confront and challenge each other in a concrete situation.<sup>482</sup> In the report we offer two further principles to guide this positive search for a set of morally reasonable expectations.

- Following the principle of *participation* of those with morally relevant interests in a deliberative procedure can *optimise* the relationship between public and private interests because it allows values and interests to be transformed and reconciled through dynamic interaction (rather than assuming that they are fixed and immutable). This is in contrast to approaches that simply dictate terms of an initiative to fulfil particular interests and invite others to take part. Participation demonstrates respect for persons by involving them in the design of data initiatives (it enables them to engage in forming the conditions of a future in which they have a direct interest rather than merely responding to it) and is more likely to produce outcomes that secure their commitment and build *trust*.
- Following the principle of *accounting for decisions* is a necessary complement to the principle of participation, since not all interests can be represented through participation and not all interests may be satisfied with any outcome. This ensures not only that a decision can be ‘accounted for’ in a community, but also that there is an opportunity to challenge and even to re-evaluate the decisions, through formal structures (e.g. regulation or appeal to a legitimate authority) and broader social processes (e.g. open and continuing debate). It follows that the set of morally reasonable expectations must be a *publicly statable* in a way that allows an account to be given to all those with morally relevant interests of how their interests have been respected. The principle recognises the necessarily provisional nature of decisions about data management and governance, since the horizon of possibilities – and the values and interests invested in them – are constantly changing as the social, political, technological and information environments evolve.

8.11 Together, we believe that these principles offer the best chance of producing, for any particular data initiative, a morally reasonable set of expectations capable of being satisfied in practice. Such a set of expectations must incorporate the principles of respect for persons and human rights; it must include, in other words, expectations about how respect for diverse values and interests will be shown and about how moral conduct of others will be assured, while at the same time resolving the ‘double articulation’ of public and private interests through a process of moral reasoning. We found that there are always three essential elements to the set of morally reasonable expectations, and that the content of these expectations will be strongly interrelated in any data initiative.

- Identifying applicable norms: mere compliance with the law is inadequate to ensure that data use is morally reasonable. This is because law both stands in a broadly derivative relationship with respect to morality and because it provides only a minimal framework for action rather than full determination for moral action. It is therefore important to identify the *moral* norms of privacy and data access applicable in the use context.

<sup>482</sup> The central moral question facing data initiatives, as we formulate it in chapter 3 is: “How may we define a set of morally reasonable expectations about how data will be used in a data initiative...?”

- Respecting individual moral freedoms: similarly, consent is often relied upon as an important way of respecting individual moral agency but it is not sufficient on its own to resolve the morally relevant interests at stake, nor is it always necessary (for example, where the applicable privacy norms do not require it). An appropriate way of respecting individual freedoms must be found in relation to the applicable norms and governance for any particular initiative, which may involve different forms of consent (broad, explicit, etc.) or legitimate authorisation.
- Assuring moral conduct by others: individuals are entitled to have expectations of others using data (particularly professionals involved in data initiatives), including expectations of who these others will be, and how their conduct will be governed. Furthermore, there is a public interest in ensuring that those involved in data initiatives discharge a moral duty of care owed to others, a duty that is not exhausted simply by complying with subjects' consent.

8.12 It is these three elements – the content of expectations, how they were defined and the way in which they relate to each other in the context of specific data initiatives – that we considered when we looked for examples of good practice in specific initiatives in chapters six and seven.

### Some practical precepts for data initiatives

8.13 The key to acting ethically with personal health information in a world of Big Data will be to maintain the engagement of, and oversight by, patients and other affected people not just as a new initiative is being developed, but as it evolves over time. It is natural for the evolution of a system to be driven by its heaviest users, and so an initiative that was initially acceptable to both patients and researchers may within a few years have a quite different balance. The promoters and operators of data initiatives using health and biomedical data must therefore give careful thought not just to how they secure moral acceptability and provide adequate transparency at the beginning, but also how this is to be maintained as the system evolves. Failure to maintain a workable reconciliation of moral, legal, social and professional norms, just as much as a failure to produce it in the first place, can lead to loss of public trust and compromise both the respect for private interests and the attainment of public benefits.

8.14 How, then, does our ethical approach translate into practical actions? What steps might someone approaching a data initiative take, perhaps as a principal investigator in a research project, a lead policy official or a commissioner of services? Clearly, the appropriate measures that may be taken will vary according to a number of factors including with the nature and size of the initiative. Nevertheless, from our examination of this area we might distil a number of useful precepts.

- **Identify prospectively the morally relevant values and interests** in any data initiative. Some process of stakeholder mapping and reflection on this will be essential as an initial step to understand where these interests are located and what informs them.<sup>483</sup> These will include private interests but may also include economic and political interests, for example. Explicating their moral content may allow them to be set in the same light as other moral interests. This critical reflection may very often reveal that what appear to be 'hard constraints' or 'strategic imperatives' rest on moral assumptions or prior value commitments that ought themselves to be brought into question.

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<sup>483</sup> See recommendation 2 at paragraph 2.50 above (regarding mapping data flows) although the interests in a data initiative are not only those of people and groups at the terminal points of data flows.

- **Take special care to identify those interests that may be especially at risk or that arise from diverse values.** Identifying situational vulnerabilities (i.e. why the consequences of a particular data initiative might disproportionately affect certain individuals or groups) and understanding how different people value the potential benefits and hazards of data initiatives is essential to explore what forms of respect for individual freedoms (e.g. consent) and forms of governance may be required.
- **Do not rely simply on compliance with the law to secure that data use is morally appropriate,** particularly where it does not fully reflect moral norms. The norms enshrined in legal instruments, while they determine how data *may* be used (and, in certain cases, how it must be used) are insufficient to determine how they *should* be used. It should never be assumed that compliance with the requirements of law will be sufficient to ensure that a particular use of data is morally reasonable.
- **Establish what existing privacy norms are engaged** by the contemplated uses of data. These will have a number of different sources, including social conventions, value and belief systems, and needs of individuals, groups and communities. This might include, for example, norms of professional confidentiality, of data sharing within families or social groups, or of wider acceptance of data use. Findings from consultation or public opinion research will be informative at this stage (but caution should be exercised when relying on existing research as the circumstances, values and interests may differ from one data initiative to another). Resistance among the public to the involvement of profit-seeking commercial actors may be an important phenomenon in this context. If private sector organisations are going to play a role in the delivery of public services and public goods, this must be engaged with in formulating reasonable expectations. Attempts to shift norms or impose new norms without engagement risks undermining trust and therefore the objectives of the initiative.
- **Involve a range of those with morally relevant interests in the design of data initiatives** in order to arrive at a publicly statable set of expectations about how data will be used.<sup>484</sup> Participation helps to ensure both that different values and interests may be represented and that expectations are statable in a way that is intelligible from different perspectives. It also helps ensure that an account is given of how morally relevant values and interests are respected. Structured public dialogue or other forms of deliberative engagement, including direct participation of representatives in the initiative, will often be valuable.
- **State explicitly the set of morally reasonable expectations** about the use of data in the initiative. These are likely to include who will have access to data and for what purposes, the way in which disclosures will be authorised (including the form of any relevant consent procedures) and how the conduct of those with access to data will be regulated or accounted for.<sup>485</sup> This statement might take the form, for example, of a written and published ethics and governance framework document that can be accessed easily, with explicit arrangements for it to be reviewed.
- **Involve a range of those with morally relevant interests in the continuing governance and review of data initiatives.** What constitutes morally reasonable expectations may alter over time as new opportunities and threats emerge and as norms shift. Measures such as monitoring relevant social research, periodic consultation or a standing reference panel of participants are desirable.<sup>486</sup>

<sup>484</sup> See recommendations 6 and 7 (which are specifically relevant to the HSCIC)

<sup>485</sup> See recommendation 7 (which is specifically relevant to the HSCIC but covers the publication of data sharing agreements) and recommendations 11 and 13 (with regard to research using broad consent models).

<sup>486</sup> See recommendation 10 (with specific relevance to biobanks).