PERSONALISED MEDICINE, INDIVIDUAL CHOICE AND THE COMMON GOOD

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Presuming the Promotion of the Common Good by Large-Scale Health Research

The Cases of care.data 2.0 and the 100,000 Genomes Project in the UK

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8.1 Introduction[1]

8.1.1 Background

Before World War One (WWI), levels of financial inequality worldwide had reached previously unknown magnitudes,[2] despite forms of democracy having been introduced into many Western countries. WWI was, however, to yield a world 'fit for heroes',[3] one in which the common person had a fair share. Between WWI and World War Two (WWII), little was done to reduce inequality. With WWII's outbreak, the problem of inequality was set to one side. However, after Germany had capitulated, the UK general elections brought in a socialist government whose stated promise was to establish a 'Welfare State', to provide education, health, unemployment benefits and pensions for all, and to nationalise utilities and key infrastructures.

UK citizens and residents are not required to have identity cards or record their domicile with the local authorities. However, the UK government and its agents keep extensive data records, e.g. of births, marriages, deaths, passports, driver's licences, entries into and departures

[1] All information in this chapter is up to date as of 6 November 2017.

[2] Thomas Piketty, *Capital in the Twenty-First Century* (Cambridge, MA: Harvard University Press, 2014).

[3] Politician David Lloyd George promised the British public to undertake major reforms to address education, health, housing and transport inadequacies and to create a land 'fit for heroes to live in'.

from the UK, (un)employment, tax, crime and, not least, healthcare.[4] To some, it may be obvious that it is in the interest of the state to collate these records to give a clearer picture of the population and to improve the allocation of state resources. The records are of particular value in optimising healthcare, crime prevention and education, three of the primary tasks of the UK government. To others, the spectre of Big Brother comes to the fore with fears of a totalitarian state such as those well-known from the last century.

8.1.2 Health Data Collection in the UK

In this chapter, we are concerned with the collection of health-related data in the UK, in particular those deriving from *institutional care* (e.g. care in hospitals – the majority of which are still public institutions), *personal care* (e.g. data held by family physicians, known in the UK as General Practitioners, or GPs, who are not state employees but contractors) and from *specific government initiatives* such as UK Biobank (which holds material and data from about half a million citizens) and the 100,000 Genomes Project (which is to hold information from about 70,000 people with cancers and rare diseases and their relatives, as discussed further in this chapter).

The collation of such health data clearly could improve the efficiency of the UK's National Health Service (NHS),[5] for example, by identifying treatments that are more effective and improving regional allocation of resources. Research using the collated data may help the development of new diagnostic and treatment methods and drugs. This may well fall under the label of 'We Medicine',[6] understood as accessible and publicly funded healthcare aiming to benefit all. However, where commercial players become involved as potential vendors of new products, rather than simply as contractors for the NHS, the benefits may flow to more limited sets of individuals.

[4] Digital Economy Act 2017, www.legislation.gov.uk/ukpga/2017/30/contents/enacted, accessed 6 November 2017.

[5] As Vezyridis and Timmons explain, health data has also become a valuable source of income for the NHS. Paraskevas Vezyridis and Stephen Timmons, 'Understanding the care.data conundrum: New information flows for economic growth' (2017) *Big Data and Society*. Published online.

[6] Donna L. Dickenson, *Me Medicine vs We Medicine – Reclaiming Biotechnology for the Common Good* (New York, NY: Columbia University Press, 2013).

In April 2005, the UK government set up a (publicly owned) company, the 'Health and Social Care Information Centre', which acquired institutional personal health data with at least the aim of making it available for research where the researcher was neither within nor a contracted agent of the NHS. This company (HSCIC-1) went under the names of 'The Information Centre' and the 'NHS Information Centre'. Following the enactment of the Health and Social Care Act 2012,[7] HSCIC-1 was dissolved in March 2013 and its functions were transferred to a new publicly owned company, also called the Health and Social Care Information Centre, which was created on the following day. This new company, which we will refer to as *HSCIC-2*, was empowered to integrate into its health database the *personal health records held by GPs*. The scheme for harvesting GP data was referred to as 'care.data', and, although due to begin in 2014, was suspended that same year. In April 2016, the government announced that, from July 2016, HSCIC-2 would change its name to NHS Digital, and in July 2016 the care.data scheme was officially scrapped.[8] However, although the name has been dropped and the 'consent' model underlying it has been changed, the scheme continues, as we will explain.

In the same year as the Health and Social Care Act 2012, the UK government announced the launch of 'The 100,000 Genomes Project' (hereinafter 100kGP) to 'bring the benefits of personalised medicine to the NHS'.[9] The project involves sequencing the whole genomes of NHS patients with either a rare disease or cancer. Genomics England, a company owned by the Department of Health (DoH), is delivering the project through thirteen Genomic Medicine Centres (GMC) in NHS trusts.

This project has been developing the infrastructure for a national genomic medicine service in which whole-genome sequencing will become a routine and frontline test in cross-cutting areas of medicine. There are plans to 'concentrate all NHS genomic testing into the same

[7] Health and Social Care Act 2012, www.legislation.gov.uk/ukpga/2012/7/contents, accessed 6 November 2017. This Act epitomised the privatisation of the NHS by facilitating the contracting of NHS services to private providers. Allyson M. Pollock, Alison Macfarlane and Sylvia Godden, 'Dismantling the signposts to public health? NHS data under the Health and Social Care Act' (2012) 344 *British Medical Journal* e2364.

[8] George Freeman, 'Written statement to Parliament: Review of health and care data security and consent' (2016), www.gov.uk/government/speeches/review-of-health-and-care-data-security-and-consent, accessed 6 November 2017.

[9] NHS England, 'Genomics' (2012), www.england.nhs.uk/ourwork/qual-clin-lead/personalisedmedicine/genomics, accessed 6 November 2017.

data centre' with 'access to . . . industry for the purpose of developing new knowledge, methods of analysis, medicines, diagnostics and devices'.[10]

8.1.3 Concerns

The collection of residents' health-related data undoubtedly has the potential for public benefit, but is surrounded by concerns regarding privacy, autonomy and justice. While the UK government's schemes do, at least superficially, take these concerns into account, we address in this chapter what we see as a gap – indeed a gaping chasm – between the government's rhetoric and the governance structures they put in place. By taking a closer look at both in the cases of care.data and the 100kGP, we demonstrate that what is presented as 'We Medicine' in fact falls far short. We begin our review with care.data before turning to the 100kGP and the ethical issues we consider to be most pressing.

8.2 Care.data

8.2.1 Current Sharing of Health Data

As David Springate, a biostatistician who works on electronic data base research at the University of Manchester, has noted:

> For a sizeable proportion of the UK population, the sharing of their electronic medical records . . . is already a reality and has been for decades. About a third of UK patients already have their electronic medical records held on the main current UK primary care databases . . . and many have their pseudoanonymised data accessible (for a fee) to both medical researchers . . . [and] private companies, including drug companies . . . In the majority of cases now, patients will not even be aware that their data are being collected, let alone be offered the opportunity to consent.[11]

Physician and science writer Ben Goldacre commented:

> [A] government body handed over parts of my medical records to people I've never met, outside the NHS and medical research community, but it is

[10] Sally Davies, 'Generation Genome. Annual Report of the Chief Medical Officer' (2016) www.gov.uk/government/uploads/system/uploads/attachment_data/file/631043/CMO_annual_report_generation_genome.pdf, accessed 6 November 2017 (chapters 14 and 2).

[11] David Springate, 'Health database could help avoid another pharma scandal' (2014) *The Conversation*, www.theconversation.com/health-database-could-help-avoid-another-pharma-scandal-23730, accessed 6 November 2017.

> refusing to tell me what it handed over, or who it gave it to, and the minister is now incorrectly claiming that it never happened anyway. There are people in my profession who think they can ignore this problem. Some are murmuring that this mess is . . . a public misunderstanding to be corrected with better PR. They are wrong: it's like nuclear power. Medical data, rarefied and condensed, presents huge power to do good, but it also presents huge risks. When leaked, it cannot be unleaked; when lost, public trust will take decades to regain.[12]

Survey results show that only 54 per cent of the public support commercial access to their health data for health research. However, there is a clear desire for the NHS to seek permission before allowing access to companies. Some participants think data access is unacceptable if it is solely for private benefit and do 'not want anyone . . . to be able to co-opt health data for political ends'.[13]

8.2.2 Concerns Regarding the (Im)Possibility of Opting Out from Care.data

In April 2013, nine months before care.data launched, Jeremy Hunt, the UK Secretary of State for Health, gave the public a reassurance that any patient who did not want personal data in their GP records to be shared with HSCIC-2 'would have their objection respected'.[14] On 12 September 2013, he added that 'All they have to do in that case is speak to their GP and their information won't leave the GP surgery'.[15] Objections to information leaving the GP surgery became known as a *'Type 1' objection*. At the same time, for objections to information leaving the HSCIC-2, a '*Type 2' objection*, was proposed.[16]

The option to opt out of care.data is not overseen by the Information Commissioner's Office (the ICO), and is *not* guaranteed by law. Moreover, the Health and Social Care Act 2012 (HSCA), the law that

[12] Ben Goldacre, 'Care.data is in chaos. It breaks my heart' (2014) *The Guardian*, 28 February.

[13] Wellcome Trust/IPSOS Mori, 'The one-way mirror: Public attitudes to commercial access to health data' (2016), www.ipsos.com/sites/default/files/publication/5200–03/sri-wellcome-trust-commercial-access-to-health-data.pdf, accessed 6 November 2017.

[14] Fiona Caldicott, 'Review of data security, consent and opt-outs' (2016), www.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF, accessed 6 November 2017.

[15] Department of Health (DoH), 'Jeremy Hunt confirms commitment to balance patient safety and privacy' (2013), www.gov.uk/government/news/jeremy-hunt-confirms-commitment-to-balance-patient-safety-and-privacy–2, accessed 6 November 2017.

[16] Caldicott, 'Review of data security, consent and opt-outs'.

provided the basis for the care.data scheme, 'trumps' key provisions of the Data Protection Act 1998.[17] Specifically, the HSCA allows all patient data to be used for purposes that extend beyond patient care without consultation, i.e. without the patients' knowledge. Indeed, the HSCA *makes it impossible for patients to prevent their data from being used for research*.

In autumn 2013, NHS England set up a care.data website where citizens could record their views and in January 2014 an information leaflet on care.data was sent to all English households.[18] However, public concern rose, as did concern among General Practitioners. Many patients began to take advantage of the opportunity to opt out that Hunt had offered. Hunt had effectively promised that the data for those who opted out would *not* be harvested from the GPs' records. In reality, the intent was to harvest that data anyway and then 'de-identify' their records.[19]

Amendments to the HSCA in the Care Act 2014[20] went some way towards addressing public concerns regarding confidentiality and inappropriate use of patient health data, not least by allowing data releases only 'for the purposes of the provision of healthcare or adult social care, or the promotion of health'. However, this amendment clearly does not prevent data being made available to drug researchers, pharmaceutical firms and tech giants like Google.

Care.data was not just problematic for patients. As Vezyridis and Timmons[21] observe, the new obligation on GPs to share data with HSCIC-2 created pressure on GPs who are responsible for telling patients about a scheme that they know little about themselves. As data controllers with legal liability for their patients' information, they face conflicting statutory obligations to process patient data fairly and yet disclose

[17] Jamie Grace and Mark J. Taylor, 'Disclosure of confidential patient information and the duty to consult: The role of the health and social care information centre' (2013) 21(3) *Medical Law Review* 415–47; Data Protection Act 1998, www.legislation.gov.uk/ukpga/1998/29/contents, accessed 6 November 2017.

[18] Vezyridis and Timmons point out that the leaflet was sent out without checks, was biased towards the programme's benefits and had little information about the so-called opt-outs. It was later deemed 'unfit for purpose'. (Vezyridis and Timmons, 'Understanding the care.data conundrum').

[19] NHS England, 'Privacy impact assessment: care.data' (2014), www.england.nhs.uk/wp-content/uploads/2014/04/cd-pia.pdf, accessed 6 November 2017.

[20] Care Act 2014, www.legislation.gov.uk/ukpga/2014/23/contents, accessed 6 November 2017.

[21] Paraskevas Vezyridis and Stephen Timmons, 'Dissenting from care.data: an analysis of opt-out forms' (2016) 42(12) *Journal of Medical Ethics* 792–6.

data. Many GP practices provided patients with opt-out forms, but they provided extremely variable information and could have been confusing and unintentionally misleading.

With many GPs showing concern, in February 2014 the government decided to delay GP data harvesting to allow NHS England the opportunity to persuade GPs, healthcare professionals and patients that care.data was necessary and that sufficient safeguards had been put in place. Key elements of the discussions included: appropriate consent mechanisms for data collection and use; the right to object to processing of personal data; the extent of the data collected; and the uses of the data by the NHS or third parties. Citizens also raised several of these concerns.[22]

In September 2015, Hunt bought more time for care.data by commissioning the National Data Guardian, Fiona Caldicott, to review the protection of personal health data and the provision of appropriate opt-outs. The Caldicott Review could then be held out as legitimately dealing with the public's concerns. Shortly thereafter, in November 2015, one concerned GP, Dr Neil Bhatia, made a request under the Freedom of Information Act asking whether the extraction of GP data would still be the same care.data scheme, albeit with an 'updated' dataset, or whether it would be an additional, parallel, extraction for a different project. The following month, NHS England confirmed that 'There will be a single national GP dataset which would therefore replace the dataset as currently defined for the care.data pathfinder stage.'[23]

8.2.3 The Caldicott Review

In July 2016, the UK government issued the long-awaited report on the initiation of the Iraq War, the Chilcot Report. Astonishingly, on the same day, the Caldicott Review[24] was issued, and the UK government announced that the care.data scheme had been scrapped. However, it stated that it remained '*absolutely committed to realising the benefits of sharing information*

[22] Sigrid Sterckx, Vojin Rakic, Julian Cockbain et al., '"You hoped we would sleep walk into accepting the collection of our data": Controversies surrounding the UK care.data scheme and their wider relevance for biomedical research' (2016) 19(2) *Medicine, Health Care and Philosophy* 177–90; Rebecca Hays and Gavin Daker-White, 'The care.data consensus? A qualitative analysis of opinions expressed on Twitter' (2015) 15 *BMC Public Health* 838.

[23] NHS England, Letter dated 10 December 2015, responding to a Freedom of Information Request by Dr Neil Bhatia, www.whatdotheyknow.com/request/single_national_gp_dataset_2, accessed 6 November 2017.

[24] Caldicott, 'Review of data security, consent and opt-outs'.

. . . Therefore, *this work will now be taken forward* . . . in order to retain public confidence and to drive better care for patients' (emphasis added).[25]

The Caldicott Review was clear that it had been an exercise in generating public trust in the use of their health data:

> This has been a report about trust. . . . Because of the importance of earning public trust, the Review concluded that people should be able to opt out of their *personal confidential data* being used for purposes beyond their direct care unless there is a mandatory legal requirement or an overriding public interest.[26] (emphasis added)

However, Caldicott recommended that: confidential patient information should nonetheless be collected by HSCIC-2, *irrespective* of any opt-out by individual patients; and that 'data that has been de-identified [by HSCIC-2] according to the [Information Commissioner's Office's] anonymisation code should *not* be subject to the opt-out' (emphasis added).[27] Interestingly, Caldicott noted the government's decision to re-brand HSCIC-2 as NHS Digital saying that '[t]his will provide [HSCIC-2] with a good opportunity to use the NHS brand to make it clear to everyone that it is part of the NHS "family"'.[28]

Since the effects of the opt-outs proposed by Caldicott would conflict with the Type 1 opt-out promised by Hunt in relation to care.data, Caldicott recommended that 'the Government should consider the future of the care.data programme'.[29] More particularly, Caldicott noted that applying the Type 1 opt-out 'to all HSCIC[-2] data collections, including existing data collections from hospitals, would degrade the quality of data currently available to . . . researchers'.[30] It is thus abundantly clear that the function of the Caldicott Review was to advise the government *how to restart the care.data scheme for the same purposes, but without the risk of public outcry* and without Hunt's misleading promise that opting-out would prevent data being harvested from the GP records. We refer to the 'new' scheme as care.data 2.0.

Rhetoric aside, Caldicott proposed that NHS England consider two approaches to opt-outs, and present these to patients on forms with tick-boxes. One approach offers two alternatives (which we will label, for clarity, 'broad' – the default option – and 'narrow'), while the other also adds a third (which we will label 'limited'):

[25] Freeman, 'Written statement to Parliament: Review of health and care data security and consent'.
[26] Caldicott, 'Review of data security, consent and opt-outs'. [27] Ibid., p. 8.
[28] Ibid., p. 7. [29] Ibid., p. 8. [30] Ibid., p. 34.

> ***Broad:*** *'Information about me can be used to run the NHS and social care system and to support research to improve treatment and care for everyone.'*
> ***Limited:*** *'Information about me can be used to run the NHS and social care system, but not for research.'*
> ***Narrow:*** *'Information about me can only be used by the people directly providing my care.'*

This way of representing the opt-outs is problematic for at least three reasons. First, in the wording of each of the options, the patient is told that this relates to 'information about me', while the opt-out applies to 'confidential patient information'. The patient is given no indication that the latter is a term with a specific and narrow legal definition (see below) and that the HSCIC-2 is *free to share de-identified, pseudonymised or anonymised data* (which patients think is also 'information about me'[31]) *with anyone* as long as it is 'for the purposes of the provision of healthcare or adult social care, or the promotion of health'. The information provided also fails to make clear the technical limitations of pseudonymisation as a de-identification technique.[32] Second, in the Limited option, the patient is not offered the choice between research by or for the NHS and research by and for commercial organisations,[33] and hence is 'nudged' away from this option. Third, in the Narrow option, the patient is not advised that persons directly providing their care are not just the physicians and other healthcare professionals with whom they interact.

This misleading nature of the Caldicott opt-outs is also shown in the language used in introducing the proposed opt-outs:

> You are protected by the law. Your *personal confidential information* will only ever be used where allowed by law . . . [Y]ou can ask your health care professional not to pass on particular information *to others involved in providing your care. You have the right to opt out.* You have the right to opt out of your *personal confidential information* being used for these other purposes beyond your *direct care . . . This opt-out will be respected by all*

[31] Wellcome Trust/IPSOS Mori, 'The one-way mirror'.

[32] Kieron O'Hara, *Transparent Government, Not Transparent Citizens: A Report on Privacy and Transparency for the Cabinet Office* (Southampton: University of Southampton, 2011).

[33] Caldicott noted that 'people hold contrasting views about information being used for purposes beyond direct care and some people became concerned when data is shared outside the NHS "family"'. Nevertheless, she took the view that the opt-out model 'should be set around the purpose to which data is put . . . and that dividing up NHS and "non-NHS organisations" without reference to purpose can be artificial and misleading'. This decision is highly problematic, as we will explain in the section on ethical questions. Caldicott, 'Review of data security, consent and opt-outs', p. 23.

> *organisations that use health and social care information* . . . You can change your mind . . .[34] (emphasis added)

In sum, the Caldicott Review makes it clear that the opt-out *only* applies to data from which the patient may be directly identified, and even then *only* to data supplied to those not involved directly with the patient's care, with 'direct care' being defined more broadly than the normal person would understand this term. This is problematic, as a Wellcome Trust/IPSOS Mori[35] report shows that people are already unclear about who can access their data. The obfuscatory language in the Caldicott Review will only exacerbate the confusion.

8.2.4 Has the GDPR Any Effect?

In 2016, the EU enacted the *General Data Protection Regulation* (Regulation (EU) 2016/679, GDPR), a law that came into force in EU member states in May 2018. Under Article 18(1)(d) GDPR, people are given 'the right to obtain . . . *restriction* of processing . . . [of data relating to them] pending the verification whether the legitimate grounds of the [data] controller override those of the data subject' (emphasis added). Article 21(1) GDPR, moreover, states that 'The data subject shall have the right to *object* . . . to processing of personal data . . . unless the [data] controller demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject. . . ' (emphasis added).

However, Article 6(1) GDPR reads, in relevant part, as follows:

> Processing shall be lawful only if and to the extent that [it is necessary]: for *compliance with a legal obligation* to which the [data] controller is subject . . . [or] for the performance of a task *carried out in the public interest* or *in the exercise of official authority* vested in the [data] controller. (emphasis added)

Perhaps not surprisingly, the GDPR thus allows EU member states to override the data subject's rights in certain (if not most) circumstances concerning state use. Until at least March 2019 the UK is covered by EU regulations. Thus it will come as no surprise that the UK government has introduced in the House of Lords the Data Protection Bill,[36] which, when accepted, will be UK law.

[34] Ibid., p. 39. [35] Wellcome Trust/IPSOS Mori, 'The one-way mirror'.
[36] Data Protection Bill [HL], www.publications.parliament.uk/pa/bills/lbill/2017–2019/0066/18066.pdf, accessed 6 November 2017.

In Section 15 of the Data Protection Bill, the relevant government minister is to be given the right to override the GDPR *without* Parliament approval, by issuance of a Rule:

> – to adapt the application of rules of the GDPR . . . *for compliance with a legal obligation*, for the performance of a task *in the public interest* or *in the exercise of official authority*;
> – [under Article 23(1) GDPR to restrict] the scope of the obligations [to] and rights [of the data subject] . . . *to safeguard certain objectives of general public interest*; [and]
> – [under Article 89 GDPR] to provide for derogations from the rights mentioned in paragraphs (2) and (3) of that Article . . . *for scientific . . . research [or] statistical purposes* (emphasis added)[37]

In other words, the Data Protection Bill, when passed, will allow free use of *de-identified* personal health data.

8.2.5 Post-Caldicott: The 'National Data Lake'

Following the issue of the Caldicott Review, but before releasing its response, in July 2017 the government undertook a consultation exercise[38] and in August 2017 a document setting out the proposals for a 'Target Architecture' for care.data 2.0 was leaked to the press.[39]

[37] Article 23(1) GDPR, in relevant part, reads: 'Member State law . . . may restrict . . . the obligations and rights provided for in Articles [18 and 21 GDPR] when such a restriction . . . is a necessary and proportionate measure in a democratic society to safeguard . . . important *objectives of general public interest* of . . . a Member State, in particular . . . an important economic or financial interest of the . . . Member State, including . . . public health' (emphasis added). Likewise, Article 89 GDPR, in relevant part, reads: 'Processing . . .. *in the public interest* [or for] *scientific . . . research* purposes or statistical purposes, shall be subject to appropriate safeguards . . . Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.' (emphasis added). Regulation (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), *Official Journal* L 119/1, 4 May 2016.

[38] Department of Health, 'Your data – Better security, better choice, better care. Government response to the National Data Guardian for Health Care's Review of data security. Consent and opt-outs and the Care Quality Commission's Review "Safe data, safe care"' (2017), www.gov.uk/government/uploads/system/uploads/attachment_data/file/627493/Your_data_better_security_better_choice_better_care_government_response.pdf, accessed 6 November 2017.

[39] NHS England, 'Enabling evidence-based continuous improvement. The Target Architecture. Connecting care settings and improving patient experience' (2017),

The consultation exercise showed the importance of public trust but had also indicated that, while a need for a national data collection existed, the public is 'less willing to share their data when the direct benefit for them and their local population is unclear'.[40] The proposal is thus to harvest data into local pools, each representing the maximum size for which a high degree of public trust can be predicted: about 2–5 million people. With a common architecture in the format of each pool, and with a national spine making the pools interconnectable, a 'National Data Lake' will be created which merely appears to be a set of local pools for local people.

NHS England effectively admits this in the target architecture plan:

> Sensitive personal and confidential data (which is fully identifiable) will almost certainly be required to achieve interoperability and to facilitate precision medicine and case finding. The [Caldicott] Review opt-out will not apply.[41]

Such data, however, obviously remains sensitive. It is 'confidential patient information', a term which is *precisely defined by law and does not mean personal health records in general*, as most people would think. It refers to information[42] which, without a court order, generally cannot be released to parties outside the NHS and its contracted agents without the patient's consent, distinguishing it from information that the NHS *is* permitted to release without the patient's consent, *even if the patient has opted out*.

Care.data 2.0 thus involves NHS Digital collecting confidential patient information, and, by de-identifying it, creating a database of

https://medconfidential.org/wp-content/uploads/2017/09/2017–07-13-Target-Architecture.pdf, accessed 6 November 2017.

[40] NHS England, 'Enabling evidence-based continuous improvement', p. 35.

[41] Ibid., p. 31.

[42] National Health Service Act 2006, www.legislation.gov.uk/ukpga/2006/41/contents, accessed 6 November 2017. Section 251(10) defines 'patient information' as follows: '(a) information (however recorded) which relates to the physical or mental health or condition of an individual, to the diagnosis of his condition or to his care or treatment, and (b) information (however recorded) which is to any extent derived, directly or indirectly, from such information, whether or not the identity of the individual in question is ascertainable from the information.' However, Section 251(11) goes on to make clear that patient information is 'confidential patient information' where: '(a) the identity of the individual in question is ascertainable—(i) from that information, or (ii) from that information and other information which is in the possession of, or is likely to come into the possession of, the person processing that information, and (b) that information was obtained or generated by a person who, in the circumstances, owed an obligation of confidence to that individual.'

'non-confidential' information. The new Caldicott opt-outs have *no effect whatsoever* on the release to *any* party of personal health data which has been 'de-identified', to whatever extent the government sees fit.

The government warmly welcomed and supported Caldicott's recommendations, and HSCIC was duly rebranded as NHS Digital. A national data opt-out is being prepared, i.e. a single opt-out to replace the Type 1 and Type 2 opt-outs (to prevent uploading of GP data to HSCIC-2's database, and to prevent release of identifiable data by HSCIC-2, respectively). This national opt-out is to be available from March 2018. In effect, the only thing the national opt-out will provide is the right to prevent fully identifiable data from being used for research and 'planning'.

The timeline set out in the government's response to the Caldicott Review sets a date of September 2019 for NHS Digital to implement a new mechanism to de-identify data on collection from GP practices, so we can presume that this is likely to be the new start date for care.data 2.0.

8.3 The UK 100,000 Genomes Project

8.3.1 Background, Focus and Patient Recruitment

The 100kGP is a hybrid of a biobank for research (including by industry and commercial actors) and clinical practice (in that participating in the project might lead to a diagnosis or to the identification of a treatment for that patient's presenting condition).

The 100kGP is being delivered and implemented using existing NHS resources. NHS clinicians treating potentially eligible patients identify and refer them to the project. Those who want to take part have a preliminary discussion with a healthcare worker and are sent information documents to read. Genomics England has designed these documents via piloting with public/patient involvement groups and discussion with different advisory committees. Notably, research showed that some patients found the documents too lengthy and complex and they have been revised.[43]

At least 24 hours after receiving the information, patients and family members are seen in a face-to-face consent appointment with NHS staff at a Genomic Medicine Centre. There, they give samples of blood, tissue and saliva which are sent to the sequencing hub. The sequence data are sent for storage to Genomics England's data centre. Genome data

[43] Caroline Benjamin, 'Findings from the National Consent Evaluation' (2016) www.genomicsengland.co.uk/consent-evaluation-findings, accessed 6 November 2017.

are then combined with data about the patient from their hospital or clinic, their GP records, national disease registries, social care records and Public Health England. The data is to be extracted over the patient's whole life into a database built in partnership with NHS Digital. In a bid to protect privacy, the linked dataset is 'de-identified'. The samples are also stored for future research. These sample and data banks are controlled by Genomics England (although what will happen to them once the project is over will be left to the Secretary of State for Health to decide).

The project shares some similarities with the 500,000-participant strong UK Biobank,[44] which also collected biomaterial and detailed health-related information linked to GP and hospital data. The key differences are that UK Biobank had broad recruitment criteria and offered test results such as blood pressure readings and body mass index, while 100kGP recruitment is more tightly linked to the NHS patient 'family' and provides results from tests otherwise unavailable through the NHS (whole-genome sequencing and, eventually, other 'omics'). Many patients and families in the rare diseases arm will be those who have had earlier tests which failed to achieve a diagnosis. Whole genome sequencing is a last hope after a long 'diagnostic odyssey'. Although patients and family members are told that diagnoses are not guaranteed, they *are* told they are possible. In fact, newspaper coverage of the project's pilot phase has shown that several patients in the rare disease arm have been diagnosed.

Tested people can also opt to have their genomes searched against a constantly updated predefined list of 'additional findings' for potentially serious but actionable risks, e.g. familial hypercholesterolemia and familial cancer syndromes. This offer – as Genomics England's Chief Scientific Officer Mark Caulfield suggests – is made on the basis of increasing fairness and trustworthiness: '[patients] have entrusted us with their genomic information, it seems only fair that we can offer . . . options . . . [that] may benefit their future health'.[45] Genomics England sends reports to physicians about their patients, and so any feedback about results is offered as part of clinical consultations.

[44] UK Biobank, 'Participants' (2016) www.ukbiobank.ac.uk/participants, accessed 6 November 2017.

[45] Genomics England, '100,000 Genomes Project gains ethical approval to offer NHS patients further information about their genomic results' (2015) www.genomicsengland.co.uk/100k-genomes-projectp-gains-ethical-approval-to-offer-nhs-patients-further-information-about-their-genomic-results, accessed 6 November 2017.

The focus is on rare diseases since, in 80 per cent of cases, these diseases have a genomic basis. Although individually uncommon, the diseases affect 6–7 per cent of the UK population. Finding the genetic cause can shed light on the nature of the disease, its prognosis and potential treatments, and areas for further research. Half of new cases of such disease are found in children. The list of eligible rare diseases consists of: diseases for which there is a clinical diagnosis but no molecular diagnosis and no readily detectable genetic mutation in known disease-related genes; diseases for which there is a *suspected* clinical diagnosis; and diseases that are 'ultra-rare'. Since comparing sequences can aid interpretation, multiple family members are invited to participate in the project.

In the cancer arm, patients' germline genomes and the genomes of their cancers will be sequenced, because mutations in tumours are a central factor in determining the progression of the cancer and its likely response to therapy. The project's focus on cancer is unsurprising: in the UK, cancer killed 160,000 people in 2014 and over 350,000 new cases were reported that same year. Given that cancer is extremely heterogeneous, even among people with the 'same' diagnosis, the stated aim of the project here is to make diagnoses that are more precise, as well as to find better, more 'personalised', treatment choices – i.e. those that have a better balance of response rate to toxic side effects. Genomics research has already led to success in this respect, showing that HER2 positive breast cancers respond to the drug Herceptin (trastuzumab).

8.3.2 Research and Development

One of the project's aims – enabling new scientific discovery and insight – is said to be possible only through research on the genomic and clinical information. Thus for patients, having their clinical tests and any chance of a diagnosis is presented as being contingent upon giving broad consent to future, unspecified research on their data. Some of this research is to be done by industry and commercial companies. This is said to be because: 'if any new diagnostic tests and treatments are to come from this project, they will need to be developed, as they always have been, by the private sector and not within government or the NHS'.[46]

[46] Chelsea and Westminster Hospital, 'West London Genomic Medicine Centre', www.chelwest.nhs.uk/about-us/research-development/west-london-genomic-medicine-centre, accessed 6 November 2017. This is of course misleading. Many diagnostic tests and pharmaceuticals have been discovered and developed, if not commercially marketed, by

There are strict restrictions about who can access the data for research. Insurers, marketers and other government agencies, such as the police, are disallowed automatic access, although the police and Home Office can seek a court order for access. Researchers can access only de-identified subsets of the data for research purposes approved by the 'access review committee', in a monitored, secure data environment. Priority and royalty-free access to data is given to members of the Genomics England Clinical Interpretation Partnerships (GeCIPs) which are domains of over 2000 researchers, clinicians, trainees and funders from academia, charitable organisations, government or healthcare. GeCIPs will carry out research into particular disease-types or cross-cutting issues (e.g. health economics) and get free access because their research will aid the interpretation of data. Researchers who do not meet the eligibility criteria to join a GeCIP (e.g. private healthcare institutions or commercial companies) will be able to access the dataset for a fee.

Regarding intellectual property and patenting, Genomics England has adopted a relatively standard approach to inventions made by public bodies carrying out research on its data: patents may be sought and may be licensed to commercial entities and academic institutions on favourable terms. Genomics England also states that there may be cases where it decides not to patent an invention for public policy reasons, e.g. if it would serve the public interest to make the invention freely available for use. The key question, of course, is the extent to which patent rights may vest in commercial entities carrying out research on its data.

8.3.3 Funders and Commercial Actors Involved

Genomics England is largely government funded: the UK government committed £250 million as part of its 2016 spending review after an initial investment of £300 million. The Medical Research Council contributed £24 million towards computing power for the analysis and interpretation of data. NHS England agreed to underwrite an NHS contribution of up to £20 million over the duration of the project. The Wellcome Trust contributed £27 million towards a sequencing facility near Cambridge, UK. Illumina, the US biotechnology company carrying out the genome sequencing, is investing £162 million in return for its £78 million sequencing contract.

the public sector. One has only to think of the antibiotic penicillin and the anti-cancer drug paclitaxel.

In 2015, Genomics England granted access to a subset of aggregated data to twelve pharmaceutical, biotechnology and diagnostic companies from the UK and abroad, including GSK, Roche and AstraZeneca, as part of an industry trial. They asked each company to identify areas of improvement in data collection and to invest money (a fee of £250,000) and staff (scientists and bioinformaticians) to aid the storage, security and analysis of data. These companies have been obliged to publish all research from the industry trial 'at the point at which intellectual property for any product is protected, in common with best practice in the pharmaceutical industry'.[47] Notably, intellectual property is only 'protected' once all the relevant patents are granted: something that will normally occur only 5–15 years after the initial invention. Thus this is by no means a promise of rapid publication. As Samuel and Farsides[48] comment, 'little is known about the outcome of this trial . . . [and] how the ethical issues associated with partnering with commercial entities might unfold'. Several other commercial companies, including Illumina, have access to the data centre or data pipelines because they are providing technical services, such as computing infrastructure, data storage or genome analysis.

At its core, 100kGP is a vehicle through which the government can build a database and capabilities to analyse the data that can lead to health benefits and stimulate economic growth. Indeed, when launching the project in 2012, then-Prime Minister David Cameron stated his government's desire 'to see the emergence of genomic platforms in the UK that . . . support the emergence of new companies and innovations' leading to the developments of 'valuable new products that are sold around the world'.[49]

8.4 Ethical Questions

The developments regarding care.data 2.0 and 100kGP validate Donna Dickenson's concern that: '*Me Medicine* is eclipsing what I call *We*

[47] Genomics England, 'FAQs about how we are working with industry' (2014), www.genomicsengland.co.uk/working-with-industry/working-with-industry-faqs, accessed 6 November 2017.

[48] Gabrielle Natalie Samuel and Bobbie Farsides, 'The UK's 100,000 Genomes Project: manifesting policymakers' expectations' (2017) 36(4) *New Genetics and Society* 336–53.

[49] Department of Business, Innovation and Skills (DBIS), 'Industrial strategy: government and industry in partnership. Strategy for UK life sciences. One year on' (2013), www.gov.uk/government/collections/industrial-strategy-government-and-industry-in-partnership, accessed 6 November 2017.

Medicine, so that we're losing sight of the notion that biotechnology can and should serve the common good'.[50] Without pretending to be exhaustive, in this section we will discuss three ethical issues that these schemes highlight.

8.4.1 Obfuscatory Language and Promissory Discourse

NHS England and Genomics England use the contentious terms 'personalised care' and 'personalised medicine'. The terms are often used interchangeably with 'precision medicine' and 'stratified medicine'[51]. Donna Dickenson has observed that:

> [O]ne meaning of personalized medicine that does seem genuinely beneficial [is] drug treatment tailored to the patient on an evidence-based model for better clinical care. Whether that's really personalized in the sense of *individualized*, however, is arguable . . . individuals are classified into *groups* according to which allele (variant) of the relevant gene they have . . . Even the biotechnology industry-linked Personalized Medicine Coalition concedes that pharmacogenetics is about population subgroup response to particular drugs.[52]

However, she also rightly remarks that 'Patients' enthusiasm for pharmacogenetics would take quite a hit if they saw it as a rationale for denying them therapy, but in an era of cost cutting, that's exactly what could happen.'[53]

Indeed, highly targeted 'personalised' drugs (i.e. 'Me Medicine' – helping me and people like me), available at huge mark-ups over the production costs, could reduce the strength of the population-wide 'safety net' ('We Medicine') that is the NHS. What's more, personalised care could lead to an even more fragmented NHS. In an ethnographic study exploring the translation of stratified medicine into a London cancer centre, Day and colleagues found that:

> [S]tratified medicine placed additional strains on the service through its requirement for a highly-skilled workforce and a meticulously integrated patient pathway that, in the context of budget constraints, were difficult to deliver. Highly-skilled staff have moved increasingly to back-office functions such as laboratory analysis [and] replaced in frontline functions by

[50] Dickenson, *Me Medicine vs We Medicine*, p. 2.
[51] Sara Day, R. Charles Coombes and Louise McGrath-Lone, 'Stratified, precision or personalised medicine? Cancer services in the "real world" of a London hospital' (2017) 39 *Sociology of Health and Illness* 143–58.
[52] Dickenson, *Me Medicine vs We Medicine*, p. 8. [53] Ibid., p. 75.

> less qualified staff following the protocols of the new medicine . . . [T]his recalibration of staff roles has enabled hospitals to trim budgets and carry on, but staff and patients alike reported increasing fragmentation and particular difficulties in coordinating the steps along a pathway . . . [M]easures to improve coordination and navigation . . . do not always work, with the result that some patients describe care that is far from personalised.[54]

Echoing Day's findings, Samuel and Farsides highlight 'the pitfalls of unfulfilled promissory genohype' around the 100kGP. They found that staff at, or working with, Genomics England, felt that policymakers driving the project had 'grandiose expectations': implementation brought several organisational tensions, for example, about whether the 'cash-strapped busy' NHS and 'stressed and busy' staff not trained in genomics would be capable of delivering the project. Other participants felt that the political rhetoric surrounding the project, and the fact that an 'entrepreneurial company' was responsible for the project, was a positive force – mobilising the project and overcoming so-called clinical inertia. As one participant said, 'The objective was . . . to drive this fast . . . and not to give people time to downgrade it'.[55] Along similar, but less positive, lines, a *Lancet* editorial from 2017 about the UK Chief Medical Officer's report cites research that whole-genome sequencing is unlikely to benefit day-to-day care and argues that the NHS might not be the right place to mainstream genomic medicine because it is struggling to deliver even basic services.[56]

The promissory discourse that is so prevalent in relation to both care. data and 100kGP is particularly problematic in view of the multiple unanswered questions and epistemological challenges that surround Big Data projects in biomedicine. These challenges imply fundamental questions regarding the scientific utility and validity of these types of projects, and each of the epistemological problems also has ethical implications.[57] All these problems simply remain unmentioned, so as not to threaten the hype, it would seem.

[54] Day, Coombes and McGrath-Lone, 'Stratified, precision or personalised medicine?', p. 154.

[55] Samuel and Farsides, 'The UK's 100,000 Genomes Project'.

[56] Editorial, 'Public genomes: the future of the NHS?' (2017) 390 *The Lancet* 203.

[57] We do not have the space here to elaborate on this, but for particularly interesting discussions of the problems involved, see, for example, John Ioannidis, 'Informed consent, big data, and the oxymoron of research that is not research' (2013) 13(4) *American Journal of Bioethics* 40–2; Wendy Lipworth, Paul Mason, Ian Kerridge et al., 'Ethics and epistemology in big data research' (2017) 14(4) *Journal of Bioethical Inquiry* 489–500;

8.4.2 The Ethical (In)Defensibility of the Consent Models

As we have hinted at above, the 'consent' model for care.data 2.0 is hugely problematic. The consent model in 100kGP has some shortcomings, but the project is much more limited in scope.

8.4.2.1 The Opt-Out Model Recommended by the Caldicott Review

The Privacy Impact Assessment of care.data undertaken by NHS England (NHS England 2014) made it clear that the GP data of those registering an opt-out *would* be passed to the HSCIC and would most likely be used in research to which those patients have not consented:

> Where patients have objected to the flow of their personal confidential data from the general practice record, the HSCIC will receive clinical data without any identifiers attached . . . If a patient is (a) content for personal confidential data from their GP record to be extracted into the secure environment of the HSCIC but (b) objects to flows of personal confidential data from the HSCIC . . . then the HSCIC will extract the fact of the objection, the date of the objection and the individual's NHS number. The NHS number will be used internally within the HSCIC to match these data to other data held for that patient *so that the data can be anonymised before release.*[58] (emphasis added)

In this context, 'anonymisation' actually meant 'pseudonymisation', a 'technique that replaces identifiers with a pseudonym that uniquely identifies a person', i.e. what is frequently called 'coding' of health data. Astoundingly, what is being said here is that a patient's wish that their confidential information is *not* extracted or used, is respected by extracting and using the data anyway, but in pseudonymised form. This is not what the average person understands by 'opting out' – arguably, people understand this as meaning that their data *will not be used in any way*. Little has changed in the wake of the Caldicott Report since the recommended opt-outs relate only to 'confidential patient information', and, as mentioned in Section 8.2.4 ('Has the GDPR Any Effect?'), data collected by NHS Digital and de-identified is not considered to be confidential patient information. In other words, the opt-out is not actually an opt-out. This scheme is simply care.data 2.0.

Brent Mittelstadt and Luciano Floridi, 'The ethics of big data: Current and foreseeable issues in biomedical contexts' (2016) 22 *Science and Engineering Ethics* 303–41.

[58] NHS England, 'Privacy impact assessment: care.data', pp. 9–10.

This is ethically problematic. As argued by bioethicist Julian Savulescu:

> Each [mature] person has values, plans, aspirations, and feelings about how that life should go. People have values which may collide with research goals . . . To ask a person's permission to do something to that person is to involve her actively and to give her the opportunity to make the project a part of her plans. When we involve people in our projects without their consent we use them as a means to our own ends.[59]

This illustrates why the care.data consent model amounts to a violation of people's autonomy. The principle of respect for autonomy is based on the principle of respect for persons.[60] Respecting people implies that they should be offered ethically appropriate and clearly understandable ways to consent (or not) to have their health records included in central databases. Except for purely privacy-related concerns, de-identification of health data *cannot* overcome any of the important ethical concerns that many people have about the creation and use of databases and/or tissue banks for research purposes.[61] For example, various studies indicate that people may consider commercial uses to be at odds with their original motivation to participate in research *even* when they explicitly agreed to take part in research.[62]

[59] Julian Savulescu, 'For and Against: No consent should be needed for using leftover body material for scientific purposes. Against' (2000) 325 *British Medical Journal* 648–9, p. 649.

[60] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979) www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html, accessed 6 November 2017.

[61] NBAC, 'Research Involving Human Biological Materials: Ethical Issues and Policy Guidance (Executive Summary)' (1999) https://bioethicsarchive.georgetown.edu/nbac/hbm_exec.pdf, accessed 6 November 2017; Kristof Van Assche, Serge Gutwirth and Sigrid Sterckx, 'Protecting dignitary interests of biobank research participants: lessons from *Havasupai Tribe* v. *Arizona Board of Regents*' (2013) 5 (1) *Law, Innovation and Technology* 54–84. At most, anonymisation might offer protection with regard to privacy, although various studies suggest that even this cannot be guaranteed. Genome data pose a high risk of re-identification. This is doubly problematic since genome data have implications for the patient *and* her family members. Melissa Gymrek, Amy L. McGuire, David Golan et al., 'Identifying personal genomes by surname inference' (2013) 6117 *Science* 321–4.

[62] Tore Nilstun and Göran Herméren, 'Human tissue samples and ethics–attitudes of the general public in Sweden to biobank research' (2006) 9(1) *Medicine Health Care and Philosophy* 81–6; John Arne Skolbekken, Lars Ø. Ursin, Berge Solberg et al., 'Not worth the paper it's written on? Informed consent and biobank research in a Norwegian context' (2005) 15 *Critical Public Health* 335–47.

8.4.2.2 The Consent Model Underlying 100kGP

Policymakers are using the 100kGP model as a starting point to design an appropriate approach to consent for NHS genomic medicine services. At the time of writing, this approach was still in development.[63] It remains to be seen whether broad consent, i.e. consent for unspecified and unknown research, and the entwinement of consent for the clinical aspect (e.g. a primary diagnosis) and research will be carried forward. Broad consent could be argued to be morally justified in the name of 'We Medicine': seeking consent for individual studies could slow down research of potential social value. However, the question arises as to how the potential for benefit to the common good of any research project can be assessed. Without an answer to this question, it is difficult to justify the use of broad consent on the grounds of the common good. Further questions arise, such as how public and individual interests can be balanced and who should carry out these balancing exercises. In 100kGP, Genomics England's Access Review Committee[64] takes on this role. It is up to NHS England to decide whether such a committee should continue to exist post-100kGP.

As we will discuss next, notions of altruism and solidarity are sometimes invoked in arguments supporting broad consent. Caulfield and Kaye have pointed out that there is a danger of conflating the idea that people want to participate in a project 'altruistically' – in the name of the common good – with the idea that the ethical and legal norm (i.e. consent) should be altered in its service.[65] Interestingly, some research suggests that the public and patients *do not* see broad consent as acceptable. A systematic review of studies from the USA showed that participants preferred tiered or specific forms of consent, and were less supportive when data could be shared with pharmaceutical companies.[66] Moreover, one survey of over 1000 participants found that initial support for broad consent diminished once specific types of controversial research (e.g. including research into safer abortion methods,

[63] Becki Bennett, 'What does consent mean for Generation Genome?' (2017) *BioNews*, 18 September, www.bionews.org.uk/page_886840.asp, accessed 6 November 2017.

[64] Chaired by Professor Jonathan Knowles, who is also chairman of the board of Adappimunne Ltd and Immunocore Ltd, two UK-based biotechnology companies.

[65] Tim Caulfield and Jane Kaye, 'Broad consent in biobanking: reflections on seemingly insurmountable dilemmas' (2009) 10 *Medical Law International* 85–100.

[66] Nanibaa' A. Garrison, Nila A. Sathe, Armand H. Matheny Antommaria et al., 'A systematic literature review of individuals' perspectives on broad consent and data sharing in the United States' (2016) 18(7) *Genetics in Medicine* 663–71.

xenotransplantation and, notably, research that would lead to patents) were raised as a possibility.[67]

Other research has shown that the general public is generally positive towards medical research and is usually willing to participate without expecting any personal benefit.[68] However, the willingness to participate decreases if the benefits to society are unclear or if private profits might be derived.[69]

8.4.3 Appealing to Altruism: Furthering a Neoliberal Political Agenda?

Donna Dickenson identifies corporate interests and political neoliberalism as one of the key drivers of 'Me Medicine'. Neoliberalism includes making significant cuts in public spending while at the same time increasing the involvement of private corporations in areas such as healthcare, education and scientific research (and outsourcing from the public to the private sector of an increasing number of services).[70] With regard to biomedicine and healthcare, the neoliberal nature of the political agenda is very clear.

For health services, the agenda translates into the following stratification:

(a) to keep the voters happy, a basic, low-level service should be paid for by the state;
(b) a higher-level service should be available to those who pay, directly or via insurance;

[67] Raymond G. De Vries, Tom Tomlinson, H. Myra Kim et al., 'The moral concerns of biobank donors: the effect of non-welfare interests on willingness to donate' (2016) 12 *Life Sciences, Society and Policy* 3.

[68] Dianne Nicol and Christine R. Critchley, 'Benefit sharing and biobanking in Australia' (2012) 21(5) *Public Understanding of Science* 534–55.

[69] Christine R. Critchley, Dianne Nichol, Margaret F. A. Otlowski et al., 'Predicting intention to biobank: a national survey' (2012) 22 *European Journal of Public Health* 139–44; Åsa Kettis-Lindblad, Lena Ring, Eva Viberth et al., 'Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think?' (2006) 16(4) *European Journal of Public Health* 433–40; Saskia C. Sanderson, Michael A. Diefenbach, Randi Zinberg et al., 'Willingness to participate in genomics research and desire for personal results among underrepresented minority patients: a structured interview study' (2013) 4(4) *Journal of community genetics* 469–82; Wellcome Trust/IPSOS Mori, 'The One-Way Mirror'.

[70] Damien Cahill and Martijn Konings, *Neoliberalism* (Cambridge: Polity Press, 2017); Owen Jones, *The Establishment: And How They Get Away With It* (London: Allan Lane, 2014).

(c) extremely expensive services should be paid for by the state, but on a rationed basis;
(d) expensive infrastructure, for whatever purpose, should be paid for by the state; and
(e) value from the services provided by and infrastructure generated by the state should, as far as is possible, be channelled into the private arena.

Indeed, as Donna Dickenson observes, 'at the highest governmental levels, public backing has been solicited to underpin private-sector profit making from biotechnology'.[71] Moreover, '[the] public sector, as the entrepreneurial state, is being asked to sponsor the growth and shoulder the risks for the private sector'.[72]

Interestingly, two simultaneous trends can be observed in the UK: while healthcare and social care data are *centralised* for research purposes, the provision of healthcare itself is being *decentralised*. Indeed, accompanied by a narrative about building healthcare services 'around the needs of local populations', the UK government has announced the 'restructuring' of the NHS through so-called 'Sustainability and Transformation Plans' (STPs). A total of 44 geographical areas ('footprints') are created that need to develop strategic plans to rationalise services. This is arguably a further step in the process of dismantling the NHS as a *national* health service. The STPs, like care.data, suggest that 'sustainability' and economic growth have become the de facto social values. Moreover, 'Individuals, rather than organisations or public institutions, are forced to deal with the healthcare, social and financial consequences of ever-increasing and ambiguous data dissemination practices among entities they are not always aware of'.[73]

Yet, as we have hinted at in our discussion about broad consent, the neoliberal political agenda is veiled with references to benefits for all and altruism. For example, care.data was promoted by the UK government as a scheme that would 'improve the quality of care for all'.[74] In the case of the 100kGP, the message is that the project enhances altruism and that people who take part are altruistic. As Woods[75] has pointed out,

[71] Dickenson, *Me Medicine vs We Medicine*, p. 21. [72] Ibid., p. 180.
[73] Vezyridis and Timmons, 'Dissenting from care.data'.
[74] NHS England webpage previously available at: www.england.nhs.uk/ourwork/tsd/care-data/better-care.
[75] Simon Woods, 'Big Data governance: solidarity and the patient voice' in Brent Mittelstadt and Luciano Floridi (eds.), *The Ethics of Biomedical Big Data* (Springer International, 2016), pp. 221–38.

Genomics England has used this rhetoric to rally the public to a common cause and to implicitly call upon their civic duty to endorse the project. In this way, 100kGP appeals to the best of 'We Medicine' (i.e. the production of wide social goods through the coming together of rare disease and cancer communities), and 'Me Medicine' (i.e. the chance of a precise diagnosis and treatments). It draws on the language of 'We Medicine', with the ultimate promise of (and hopes for immediate) 'Me Medicine'.

The frequent invoking of the principle of altruism echoes the discourses that have surrounded older healthcare and research ventures, such as National Blood Donation and UK Biobank. The form of altruism applied in such discourses was Richard Titmuss's (1970) 'gift relationship'. An altruistic act within a gift relationship is one that is voluntary and that has no expectation of return. 100kGP is purported to promote altruism and the people taking part are doing so because, at least in part, they are altruistic. Speaking to the *Financial Times*, Professor Mark Caulfield (Chief Scientific Officer) has assumed that the participants are well aware that few will see pharmaceutical benefits themselves: '[T]hey've enrolled on the principle that this is altruistic, and they don't expect any personal benefit. They're doing it because they want someone else to have a better chance than they did.'[76]

However, as we have said, the 100kGP does offer (although does not promise) clinical benefit. So is it accurate to say that people are participating to benefit others? It is likely that at least some are participating to get a diagnosis. Caulfield's assumption, and the references to altruism, thus seem inappropriate.

What function is this rhetoric about common good, civic duty and altruism serving? As others have argued with regard to the biobanks that came before 100kGP, it detracts from the role of industry and from concerns that participants might have about injustice in the research enterprise.[77] It also deflects from the glimmer of hope that there *will* be a diagnosis or a treatment (the 'Me Medicine' aspect). It masks the question as to whether, if new drugs come out of the project, the NHS will even be able to afford them if it is privatised further. This would be a clear

[76] Richard Hodson and Clive Cookson, 'NHS launches genetic sequencing centres to develop treatments' (2014) *Financial Times*, 22 December.

[77] Richard Tutton and Barbara Prainsack, 'Enterprising or altruistic selves? Making up research subjects in genetics research' (2011) 33(7) *Sociology of Health and Illness* 1081–95; Lars Ø. Ursin, 'Biobank research and the welfare state project: the HUNT story' (2010) 20(4) *Critical Public Health* 453–63.

loss for 'We Medicine' as a whole, and a win for 'Me Medicine' but only for those who can afford expensive treatments.

While the two schemes we discuss in this chapter purport to promote the common good, we would submit that fairness requires real benefit-sharing and not just rhetoric. The HSCIC reassures people that it will not make a profit from providing data to other organisations, but will only charge an access fee to cover its costs. While this may look unproblematic, what it means is that commercial companies are provided access to assets they have not themselves bought or created and are thus being given a quasi-free commercial boost by the UK government. However, to put NHS databases at the disposal of industry, without requiring a 'kick-back' to enhance the service that the NHS is set up to provide, is inappropriate. The mere fact that a new drug might reach the market is not sufficient to count as benefit-sharing with UK citizens, since this benefit (the new drugs) is then also available for citizens in other countries, whose health data has not been mined by the companies in question. Instead, the companies seeking access should be required to provide the NHS with reduced access costs for the resulting drugs or other health-related products. With data being collected from the UK population at the expense of the UK state, we are talking about a concealed Public Private Initiative: something which should not be entered into unless the benefits to the private party are at least balanced by the benefits to the public as a whole.

8.5 Concluding Remarks: Trust versus Trustworthiness

The huge controversy surrounding the care.data scheme clearly showed that the various misleading elements of the scheme undermined citizens' trust. The Caldicott Review[78] and the UK Chief Medical Officer's report[79] rightly mention repeatedly that trust is essential for making any such scheme work. However, we should emphasise that there is a difference between *being trusted* and *meriting trust (i.e. being trustworthy)*. In order to merit any trust, those who acquire health data ought to make sure that they respect the autonomy of individuals whom they expect to *entrust* them with their health data.

Does the 'architecture' proposed by the Caldicott Review and the Chief Medical Officer's report represent a scheme that is trustworthy?

[78] Caldicott, 'Review of Data Security, Consent and Opt-outs'.
[79] Davies, 'Generation Genome'.

Transparency is a crucial prerequisite, both for trust and trustworthiness. Regarding care.data 2.0, unfortunately, the misleading and obfuscation continue. In spite of all the Caldicott Review's talk about opt-outs, it is clear that the scheme *is not in fact based on an opt-out regime*, since, as explained above, a patient's wish that their confidential information is *not* extracted or used, is met by extracting and using the data in de-identified form. This makes a mockery of the claim that people can opt out. If somebody opts out, that should mean that their data are simply *not extracted and used*, i.e. HSCIC should receive no data, not even in 'de-identified' form.

It is clear from NHS England's response to Caldicott and from NHS Digital's draft target architecture from July 2017 that NHS England is intent on pressing ahead with care.data 2.0 with a fig-leaf of a national opt-out and the illusory regional fragmentation of the National Data Lake it so desperately wants to create. Health data is to be conscripted regardless.

The consent model underlying the 100kGP arguably might be ethically defensible, on the grounds that the research might promote the common good. However, it is not clear how 'common good' will be defined by policymakers and how the involvement of industry will affect the nature and the extent of any benefits to society. As we have discussed, appeals to altruism can be a thin veil for the neoliberal drive behind 'Me Medicine' schemes and the drastic impact they could have for the NHS and its users. As Dickenson points out, there is a danger that, eventually, people will 'perceive that their altruism is being exploited by commercialisation'.[80] Those who feel exploited will have little recourse, as a commenter on *The Times* newspaper's coverage of the NHS 'National Data Lake' has pointed out:

> [O]nly the very wealthy have a choice as to whether they want a relationship with the NHS . . . however much someone may dislike or distrust the NHS, they cannot seek medical treatment elsewhere. The NHS may want to appear to encourage people to be altruistic . . . but they come very close to compelling rather than promoting the altruism. We are being asked to sign up to the rules of a club that most of us cannot leave.[81]

[80] Dickenson, *Me Medicine vs We Medicine*, p. 199.
[81] R. Moss, Comment on article by Kat Lay, 'NHS to share opt-out patients' data' (2017) *The Times*, 19 September.

Clearly, care.data 2.0 and the 100kGP are using the NHS 'brand' to generate trust in a health service that looks very different to the one set up after WWII. However, trust should be merited and not manufactured for the sake of generating support for whatever projects the government wishes to implement.