

THE UK NATIONAL HEALTH SERVICE'S 'INNOVATION AGENDA': LESSONS ON COMMERCIALISATION AND TRUST

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ABSTRACT

The UK National Health Service (the 'NHS'), encouraged by the 2011 report *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS*, and empowered by the Health and Social Care Act 2012, is in the process of adopting a new agenda for stimulating innovation in healthcare. For this, the bodies, body materials, and confidential health information of NHS patients may be co-opted. We explain why, without refinement, this brings the NHS into a moral conflict with its basic goal of providing a universal healthcare service. To put NHS databases at the disposal of industry, without properly addressing ethical concerns regarding the privacy, autonomy and moral integrity of patients and without requiring a 'kick-back' to enhance the service that the NHS is set up to provide, is inappropriate. As this paper shows, with reference to an example from the commercial arena of direct-to-consumer genetic testing, it is crucial that patient and public trust in the NHS is not eroded in the process.

KEYWORDS: Data; Health and Social Care Act 2012; innovation; NHS; research; trust

In this country we can no longer accept the traditional paternalistic attitude of the NHS, that the benefits of medicine, science and research are somehow self-evident regardless of the wishes of patients or their families¹

The greater the number of patients involved in research, the wider the public benefit²

I. INTRODUCTION

It is a truism to say that biomedical research brings us many benefits; but its further continuance requires the trust of those whose bodies, tissues and data are used in that research, whether commercial, altruistic or merely epidemiological.³ This paper explains

¹ Alan Milburn, Government Health Secretary, 29 January 2001, quoted in: Department of Health, *Building the Information Core: Protecting and Using Confidential Patient Information – A Strategy for the NHS* (DoH: London, 2001), at 8.

² Department of Health, *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS* (DoH: London, 2011), at 17.

³ Caplan, Arthur L. (ed.) (1992) *When medicine went mad: bioethics and the holocaust*, Totowa, NJ: Humana Press. Müller-Hill, Benno (1998) *Murderous science: elimination by scientific selection of Jews, Gypsies, and others in Germany, 1933-1945*, Woodbury, NY: Cold Spring Harbor Laboratory Press. Reverby, Susan M. (ed.) (2000) *Tuskegee's truths:*

how recent developments in the UK risk undermining that trust and thereby threaten to hamper future medical research.

Altruism, confidence in science and medical progress, trust in researchers and trust in research projects are quite common persuaders for people to participate in biobank research.⁴ Various studies⁵ have shown that individuals donating biological samples and

rethinking the Tuskegee syphilis study, Chapel Hill, NC: University of North Carolina Press.

Skloot, Rebecca (2010) *The immortal life of Henrietta Lacks*, London: Macmillan.

Washington, Harriet A. (2006) *Medical apartheid: the dark history of medical experimentation on black Americans from colonial times to the present*, New York, NY: Anchor Books.

⁴ H Nobile and others, 'Why do participants enroll in population biobank studies? A systematic literature review' (2012) 13 (1) Expert Review of Molecular Diagnostics 35-47. For an overview of biobank research issues, see B Elger and others (eds), *Ethical Issues in Governing Biobanks: Global Perspectives* (Ashgate: Aldershot, 2008), and J Kaye and M Stranger (eds), *Principles and Practice in Biobank Governance* (Ashgate: Farnham, 2009). For some problematic examples of biobank research, see: LB Andrews and D Nelkin, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (Crown: New York, 2001); DL Dickenson, *Property in the Body: Feminist Perspectives* (Cambridge University Press: Cambridge, 2007); and K Van Assche, S Gutwirth and S Sterckx, 'Protecting Dignitary Interests of Biobank Research Participants: Lessons from Havasupai Tribe v. Arizona Board of Regents' (2013) 5 (1) Law, Innovation and Technology 55-85.

⁵ See, for example: G Haddow, '"We only did it because he asked us": Gendered accounts of participation in a population genetic data collection' (2009) 69 (7) Social Science &

phenotypic information consider this to be an altruistic act that might help others. Highly relevant in this context is the importance of the donors' trust in the researchers and the research performed. As Graeme Laurie and Emily Postan have argued in this journal, the governance of research relationships depends crucially on trust and that trust 'is self-evidently vital ... to the future viability of all research involving human participants'.⁶ Indeed, the trust of current and future people (both patients and healthy citizens) is essential for the success of health research. Trust in their doctor or a researcher or an institution is a major reason for people to agree to take part in research.⁷ Loss of trust could lead to less public participation in research and thus hamper genetic and, more generally, health research.⁸

The Health and Social Care Act 2012 provided for the creation of a corporate body, the 'Information Centre', which is empowered to collect and collate the hospital and personal

Medicine 1010-1017; AA Lemke and others, 'Public and biobank participant attitudes toward genetic research participation and data sharing' (2010) 13 (6) Public Health Genomics 368-377; and J Allen and B McNamara, 'Reconsidering the value of consent in biobank research' (2011) 25 (3) Bioethics 155-166.

⁶ G Laurie and E Postan, 'Rhetoric or reality: what is the legal status of the consent form in health-related research' (2013) 21 Med L Rev 371-414, at 372.

⁷ G Gaskell and others, 'Publics and biobanks: Pan-European diversity and the challenge of responsible innovation' (2012) 21 European Journal of Human Genetics 14-20.

⁸ J Bussey-Jones and others, 'The role of race and trust in tissue/blood donation for genetic research' (2010) 12 Genetics in Medicine 116-121.

physician (GP, general practitioner, or family doctor) data of all British citizens.⁹ This body has meanwhile been set up and already holds hospital data. It will begin to ‘harvest’ GP data in March 2014. In January 2014, the NHS sent all British households a leaflet describing the data collection,¹⁰ which is to begin in Spring 2014, and offering an ‘opt-out’ option, which requires GPs to amend their records to include two abstruse computer codes. The leaflet, as the present authors and many other citizens (see below) have discovered, arrived together with the usual ‘junk mail’ for take-away pizza restaurants and estate agents, hence many people simply binned it without even noticing it.

The NHS also set up an internet page,¹¹ entitled ‘Better Information Means Better Care’, on which British residents could log their comments, scheduled to be reviewed in Spring 2015, i.e. long after the patients’ data would have been ‘harvested’. As discussed in Section IV below, that blog contains many entries demonstrating the profound discomfort felt by many UK citizens, not least with the opening of the database to commercial researchers from both the pharmaceutical/medical diagnostics industry and the insurance industry.

The facts that the UK government is portraying a ‘good news’ message to its public, and yet that the darker shadow of commercial involvement is ever-present, are aptly illustrated by a single issue of one of the UK’s major national newspapers, The Times. On the front page of that newspaper, the good news story was that:

⁹ We will discuss the legal framework pertaining to the Information Centre in Section VI.

¹⁰ NHS (2014) Better information means better care, London: NHS.

¹¹ <http://www.nhs.uk/NHSEngland/thenhs/records/healthrecords/Pages/care-data.aspx>

Millions of patient records ... have been harnessed into a single database to create the biggest cancer registration service in the world. ... It paves the way for highly personalised treatment of each cancer patient.¹²

However, further inside the newspaper, it was reported that:

Jeremy Hunt became the latest minister to be caught out arriving at Cabinet with sensitive papers clearly visible ... The documents, marked “restricted”, revealed plans to create a government-owned company to handle the genetic code of 100,000 NHS patients ... The document also revealed that a quango set up last year to act as a “dating agency” between the NHS and lucrative clients overseas was yet to make great headway.¹³

The primary function of the NHS is to supply top quality medical care at a cost that the UK taxpayer can afford. With spiralling costs and dwindling funding, this is a challenge that was addressed in Sir Ian Carruthers’ 2011 briefing paper *Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS*.¹⁴ In that paper, hidden amongst the management speech, were three specific recommendations relevant to the topic of this paper: introduction of greater efficiencies in practice and scrapping of out-dated, inefficient practices; adoption of new, effective treatment practices; and ‘collaboration’ in the

¹² M Barrow, ‘Personalised cancer files to save thousands of lives’ (2013) *The Times* (London, 12 June 2013) 1.

¹³ C Smyth, ‘Hunt gives a brief look at slow progress of NHS business plan’ (2013) *The Times* (London, 12 June 2013) 4.

¹⁴ Department of Health, above, n 2.

development of new treatments. The first is clearly intended to reduce overall costs. The second threatens to involve increases in costs. As a counterbalance to such increases, the third recommendation, *'collaboration' in the development of new treatments*, is the one we are primarily concerned with here. It could follow a number of pathways, but some of those risk eroding the trust that the public has in the NHS.

Section II of this paper will highlight the most relevant parts of the Carruthers report. In this regard, we consider that the NHS would do well to look to some controversies that have emerged in recent years with regard to the research and intellectual property practices of certain players in the life sciences industry.¹⁵ Hence, in Section III, we will take a close look at one of those controversies, involving the direct-to-consumer genetic testing company 23andMe. The fallout from the company's actions highlights the fragility of trust in the context of health research. We will contextualise the 23andMe case study by discussing the

¹⁵ Not only controversies regarding practices in industry are relevant. The NHS would also do well to give serious consideration, in the further implementation of its innovation agenda, to the UK's experiences with past breaches of trust, such as Alder Hey, the Bristol Inquiry, and more recently the Mid-Staffordshire Inquiries. The Alder Hey, Bristol and Mid-Staffordshire reports are available at http://www.official-documents.gov.uk/document/hc0001/hc00/0012/0012_ii.asp, http://webarchive.nationalarchives.gov.uk/20090811143745/http://www.bristol-inquiry.org.uk/final_report/report/index.htm and <http://www.midstaffspublicinquiry.com/report>. See also the paper by Chris Newdick in this issue.

findings from empirical studies showing that many research participants have a desire to know about the *commercial* aspects of research projects that they (or their data or body material) might be involved in. In Section IV, we will draw attention to some of the comments on trust made on the NHS Care Data blog mentioned above, as these comments are strikingly similar to the ones expressed by many 23andMe customers.

In Section V, we will comment upon the different avenues that the NHS might take to carry out its plan of promoting collaborations with the biomedical industry and, drawing on the observations from Sections III and IV, we will explain why certain of those avenues may undermine public trust in the NHS. Finally, in Section VI, we will comment on the risks posed by the NHS reform to the privacy, autonomy, and moral integrity of NHS patients.

II. THE NEW NHS INNOVATION AGENDA: ‘COLLABORATION’ IN THE DEVELOPMENT OF NEW TREATMENTS

As the healthcare provider for all UK residents, the NHS possesses an immense quantity of genotypic and phenotypic data, and has access to millions of patients’ bodies and tissue samples. The NHS *data* bank is a goldmine for companies seeking to develop drugs or diagnostic tests. Indeed, the bodies of its patients, their body samples, and their data could well be described as the ‘family jewels’ of the NHS.

However, the new NHS policy of fostering collaboration in the development of new practices or treatments raises the spectre that patients’ bodies, body parts or data could be hired out or sold to the biomedical industry for use in research and product development

without due consideration of ethical issues and without a compensating ‘kick-back’ in terms of reduced product-access costs.

In the Carruthers report we find comments such as:

It is a key goal of the NHS for every willing patient to be a research patient... The greater the number of patients involved in research, the wider the public benefit. The NHS could and should do more to explain to patients the benefits both to them and to society at large of their agreement to participate in clinical trials and approved research.¹⁶

The [Academic Health Science Centre] ... is distinguished by its ... competitive approach to the management of [intellectual property], strong track record of productive research collaborations with the life sciences industry and emerging clinical data informatics platforms.¹⁷

The existing Intellectual Property strategy is no longer fit for purpose and needs to be updated.¹⁸

These comments may seem unrelated but they are not. First, the good news – there will be new treatments and so we should all be happy. But then the bad news – the cost that we may have to pay is that monopoly prices are charged.

¹⁶ Department of Health, above, n 2, at 17.

¹⁷ Department of Health, above, n 2, at 19.

¹⁸ Department of Health, above, n 2, at 23.

Given the plans of the NHS and the UK government to ‘foster innovation’, the question arises as to what ethical and legal problems these plans may involve, especially in relation to patient and public trust in the NHS. Since the plans draw the NHS into the commercial sphere, let us first look at the controversy that has arisen with regard to the research and intellectual property practices of one particular company in the life sciences industry.

III. THE FRAGILITY OF TRUST: THE 23ANDME CONTROVERSY

23andMe is a Californian direct-to-consumer (DTC) genetic testing company.¹⁹ DTC genetic testing has been held out to consumers as a ‘fun’ way of obtaining information about one’s genetic make-up, for example one’s ancestral heritage. It has also been presented, in particular by 23andMe, as an opportunity to collaborate in a pain- and risk-free manner in medical research that could result in tests and treatments that would benefit mankind.

As DTC genetic testing companies recruit more customers, they can amass increasingly large informational (DNA) ‘biobanks’. In and of themselves, such DNA biobanks are of little value. However, when linked with *phenotypic* information, they become extremely valuable for biomedical research. Accordingly, some DTC genetic testing companies have sought to increase the value of their databases by asking customers to complete questionnaires to provide phenotypic information.

¹⁹ <https://www.23andme.com/>

23andMe provides its customers with the opportunity to consent ‘to the use of their data for research’.²⁰ The company has focused on, for example, Parkinson’s disease (PD) and sarcoma.²¹ The company website states that letting consumers participate in research ‘can produce revolutionary findings that will benefit us all’ and challenges customers to ‘join an effort to translate basic research into improved health care for everyone’.²²

However, these encouragements to advance research *for the public good* stand in contrast with 23andMe’s announcement on 28 May 2012 that it was to be granted a US Patent²³ *on the very next day*. The diagnostic method claims²⁴ in 23andMe’s US patent are similar to patent claims held by Myriad Genetics for assays for BRCA1/2 genetic anomalies correlating to propensity for breast and ovarian cancer, *i.e.* the type of patent claim that might be used to prevent other companies from carrying out a screening test for susceptibility for PD.²⁵

²⁰ CB Do and others, ‘Web-based genome-wide association study identifies two novel loci and a substantial genetic component for Parkinson's disease’ (2011) PLoS Genetics, 7:e1002141.

²¹ 23andMe, ‘23andWe Research’ (2012), available at <https://www.23andme.com/research>.

²² 23andMe, above, n 11.

²³ N Eriksson and C Do, ‘Polymorphisms associated with Parkinson’s Disease’ (2012) US Patent No. 8187811.

²⁴ For a detailed discussion see [REFERENCE BLINDED FOR REVIEW].

²⁵ The validity of such patent claims in the US is severely in doubt following the US Supreme Court’s decision in *Mayo v. Prometheus* from March 2012, *i.e.* after 23andMe’s patent application was accepted but before it was granted. See *Mayo Collaborative Services*,

CEO Anne Wojcicki announced on the company website (*The Spittoon*) that the goal of the patent was to ensure that the underlying research could lead 'towards successful translation

DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc. 566 U.S. ____ (2012), 132 S. Ct. 1289 (2012). The Court found that methods based on 'laws of nature' and consisting of well-understood, routine and conventional steps are not patentable. The possibility of patent claims to the types of DNA actually used in diagnostic tests (*e.g.* probes) or in commercial production of protein drugs (*e.g.* cDNA) is little affected by the 13 June 2013 decision of the US Supreme Court in *AMP v. Myriad* in which the Court unanimously found that isolated human genes are unpatentable. See *Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al.* 569 U.S. _ (2013). The recent history of the 23andMe PD case is convoluted but nonetheless interesting. On 20 April 2012, 23andMe filed a divisional patent application on, *inter alia*, the use of one specific DNA abnormality, rs11755699, referred to by one of the bloggers on *The Spittoon* as the most significant abnormality. On 21 March 2013, 23andMe's patent attorneys *expressly* withdrew the divisional application leaving no further extension of 23andMe's case still pending. This is decidedly unusual – patent attorneys normally allow cases to lapse through *inaction* when the case is of no further interest to their clients (after all, the clients may change their minds). The PD patent, however, has neither been expressly abandoned nor 'dedicated to the public' (*i.e.* made available for use without any licence agreement).

of this discovery’ and that the patent would ‘be important for a biotech or pharmaceutical company to pursue drug development’.²⁶

Patenting is normal practice for any technology-based industry, but in the (bio-) pharmaceutical sector, patents are considered to be vital, for example to raise venture capital or justify further investment. Thus, the mere fact that 23andMe is participating in patenting activities seems quite normal. Yet, although the company has filed various patent applications, until June 2012 it had only drawn the attention of its customers to one patent case, the PD patent. Moreover, the communication was made *the day before* the US Patent was granted – even though the application on which it was based was filed in 2009 and the underlying research results were published in *PLoS Genetics* in 2011²⁷ and then very rapidly drawn to the attention of its user community. The delay in drawing attention to the patent application seems odd, as 23andMe even recently underlined that ‘open dialogue about complicated issues like patents is important’ and that it wanted to be ‘as open as possible about our intentions, including letting people know about our patent and why we have filed it’.²⁸ The announcement immediately sparked controversy amongst various users and research participants of 23andMe, as we will illustrate below.

How likely is it that these events might result in a loss of trust? It is possible that various customers will withdraw their support because they do not consider such activities to be in

²⁶ A Wojcicki, ‘Announcing 23andMe’s First Patent’ (2012), available at

[<http://spittoon.23andme.com/news/announcing-23andmes-first-patent/>.](http://spittoon.23andme.com/news/announcing-23andmes-first-patent/)

²⁷ Do and others, above, n 9.

²⁸ Wojcicki, above, n 14.

line with their altruistic participation in research projects. As one customer wrote on 23andMe's blog after the announcement of the patent: 'this is simply crowd-sourced greed. As a long-time 23andme customer, this patent is extremely disappointing and alarming. Our family is done with your service'. Or, as another contributor put it: 'By the way, I am a 23andMe subscriber ... and it feels good to know that we can, in some small way, contribute to good research. The patent pursuit, however, makes me feel uncomfortable'.

This is *not* a case of 23andMe not meeting the participants' explicit expectations – they did that by finding the biomarkers. It is more a case of suggesting that one will build something with communal resources, building it, and then claiming ownership and (potentially) charging for access. The implied suggestion that the result would be a community good was misleading. An analogy might help: A company in a village by a river says: 'the village needs a bridge – give us the wood and we'll build it'; the wood is given; the bridge is built; but the company then charges a toll. In both cases, the contributors (research participants/ villagers) failed to realize that contribution did not guarantee public ownership. The fault lies not in 23andMe/the builder owning the result, but in the lack of transparency in the appeal for the necessary contributions. The contributors did not understand what was going on until after their contribution was made, and, had they understood, many might not have contributed. Having been misled, contributors may in future be less likely to contribute to the attainment of public goods, fearing that they might not after all be public – which, in turn, might lead to a more morally impoverished community.

The trust issue is not only related to the *nature of the goals* the company or research institution is pursuing (profit driven or not), but also to the extent of *transparency* surrounding the company or institution's strategies. We will come back to this in Section V.

As for transparency, the question of whether the 23andMe participants had given truly *informed* consent, is clearly regarded as crucial by various commentators. For example, as noted by another contributor to the 23andMe blog: ‘It would seem that the ethics of one company profiting from the knowledge of others because it patented a gene variant could do with some scrutiny, especially if it turns out that patients, who provided samples ..., were not aware that the results would be patented’.²⁹

²⁹ 23andMe responded as follows to this comment: ‘We make reference to our intent to pursue intellectual property rights for discoveries made from our research in both [our] Terms of Service ... and in our research Consent document ...’. (Wojcicki, above, n 14) The passages in question mention that 23andMe might develop intellectual property and that participants have no right to share in any profits. See ‘Terms of Service’, available at <<https://www.23andme.com/about/tos/>>. The Consent document provides that: ‘If 23andMe develops intellectual property and/or commercializes products or services, directly or indirectly, based on the results of this study, you will not receive any compensation’. (See ‘Consent document’, available at <<https://www.23andme.com/about/consent/>>). However, the word ‘*patent*’ itself is *only* used in the context of *information presented to the users*. As stated in the Terms of Service (*supra*): ‘You agree that 23andMe ... own all legal right ... in and to the Services, including any intellectual property rights which subsist in the Services ... You further acknowledge and agree that the Services ... contain proprietary and confidential information that is protected by applicable intellectual property ... laws. You further acknowledge and agree that information presented to you through the Services ... is protected by ... patents ...’.

The wording used by no means made it clear that patents would be sought *for the research results*. Various users indicated that they were unaware that 23andMe was planning to apply for patents, whereas, as noted by one of the bloggers: ‘everyone coming to [23andMe’s] service, either by paying it or by funded invitation ... needs to know clearly what this is about and make their own informed decision to join or not’.

We *do not* suggest that 23andMe has done their research without consent; moreover we do not suggest that they have ‘hidden’ the results of their research from their public. The issue is rather whether the consent extended to *patenting* of results. Participants in a study may consent to donate biological materials and phenotypic data for the development of clinical applications. However, if they are not aware that this might be happening through commercialization involving patents, this might undermine the original trust.³⁰ Moreover, it

³⁰ The position of intellectual property rights (IPRs) deriving from material and data provided by the public is also relevant to the ‘UK Biobank’, a repository of information and body material from half a million UK citizens. The UK Biobank’s current position is that IPRs deriving from research on biobank materials will belong to the researchers, although it reserves the right to claim a non-exclusive, sublicensable, worldwide, non-terminable licence if such IPRs *unreasonably* block healthcare research or access to healthcare. See UK Biobank, ‘Material Transfer Agreement for data and/or samples, Terms and Conditions’, Section 3.8, available at <<http://www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Material-Transfer-Agreement.pdf>>. The word ‘unreasonable’ needs to be viewed with a degree of suspicion – since UK Biobank accepts that patents may be applied for, and therefore that they may be enforced, ‘unreasonable’ must mean

might show the original consent to be invalid for, if participants were not told clearly ‘what it was about’, they were not able to make ‘their own informed decisions to join or not’. These words, of one of the contributors to the blog reacting to the PD patent, illustrate a core ethical value that is frequently said to underlie consent, *i.e.* that consent serves to respect and promote the *autonomy* of people considering participating.³¹

something more than ‘makes research or healthcare expensive in the way that patents often do’.

³¹ See, for example, *Chester v. Afshar* [2005] 1 AC 134 (HL), where Lord Steyn described consent as protecting ‘respect for autonomy and dignity’. Obviously, informed consent remains an imperfect tool to protect participants from being harmed. See for example: I Huntington and W Robinson, ‘The many ways of saying yes and no: Reflections on the research coordinator’s role in recruiting research participants and obtaining informed consent’ (2007) 29 (3) IRB: Ethics and Human Research 6-10; J Sugarman and others, ‘Empirical research on informed consent. An annotated bibliography’ (1999) 29 (1) Hastings Center Report S1-42; KE Ormond and others, ‘Assessing the understanding of biobank participants’ (2009) 149 (2) American Journal of Medical Genetics Part A 188-198. For example, participants do not always read informed consent forms, and even those who do frequently do not understand them (Huntington and Robinson 2007, *supra*). Moreover, many people decide to participate before the consent process is finalized. See AF Cook and H Hoas, ‘Trading places: What the research participant can tell the investigator about informed consent’ (2011) 2 (8) Journal of Clinical Research and Bioethics 2. Onora O’Neill disagrees with the claim that consent is ethically important because ‘it secures some form of individual autonomy, however conceived’. In her view,

Although it may be impossible to inform people of *all* possible uses of their material or data, the consent document should contain *sufficient and sufficiently clear* information to allow the individual to decide whether the project accords with her moral values and aspirations.³² As argued by bioethicist Julian Savulescu regarding the use of left-over body material:

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.³³

Indeed, the reason why a participant may perceive a research project as conflicting with her moral values may relate *specifically* to its commercial or intellectual property aspects. As observed by a 23andMe user:

the importance of consent is related to the fact that it 'provides reasonable assurance that a patient (research subject, tissue donor) has not been deceived or coerced'. See O O'Neill, 'Some limits of informed consent' (2009) 29 (1) Journal of Medical Ethics 4-7, at 5. We do not have the space to enter this debate here, but we agree with O'Neill that consent, no matter how *necessary* in certain contexts, can never be *sufficient* justification for action in medicine or elsewhere.

³² TL Beauchamp and JF Childress, *Principles of Biomedical Ethics* (Oxford University Press: New York, 7th edn, 2012).

³³ J Savulescu, 'For and Against: No consent should be needed for using leftover body material for scientific purposes. Against' (2000) 325 (7365) *BMJ* 648-651, at 649.

[S]tating that 'it is written in sections ... that people signed' is not close to a decent answer to people you asked for partnering with you to advance research on PD. A company can be for profit or for social profit. You have the right to choose any form you like ..., but please make it clear. If you choose to be for profit only, I don't think you used the right messaging to call for participation of people ... And remember you can only play it once. Trust is not something you can reclaim easily.

The point is not that there is anything *inherently* wrong in trying to make a profit or creating business revenues, but rather that conflict may be perceived if the research institution is portraying a transparent, altruistic, and common-good image, as 23andMe has clearly been doing and as the NHS is also doing. As expressed by one blogger: 'I would not have talked my mother and others in my support group into participating if I had understood this was going to be a profit driven enterprise. I believe 23andMe has been disingenuous in gathering a free database'.

Research shows that many participants wish to know about commercial aspects of research projects they might participate in.³⁴ Would this information make them change their minds about participating? Cook and Hoas conducted an interview study exploring the decision-making processes that participants use when deciding to participate in research. They found that a relationship of *trust* with a healthcare provider or researcher seems to influence the

³⁴ See, for example: Cook and Hoas, above, n 25; and KP Weinfurt and others, 'Disclosure of financial relationships to participants in clinical research' (2009) 361 *New England Journal of Medicine* 916-921.

decisions.³⁵ Moreover, they found that most participants desired more information about the *commercial context* of the research and that the information they had been given was not sufficient to enable them to realize that some studies have commercial purposes:

Participants thought it was dishonest not to be transparent about ... the full purpose of a study and said that hiding such information would not be acceptable. Most (90%) wanted to know whether a study had such a commercial purpose and the vast majority (80%) reported that disclosure of such information could influence their decisions about participating in research in the future. Said one participant: “[T]he person should know the purpose of the study ... I think the study participant should be told exactly what is going on. It’s coercion otherwise. ...” Said another [participant]: “Patents. Sure... I absolutely want to know” ... Among those who said it would not influence their decisions about participation, they still felt they should be informed about such issues.³⁶

The participants believed that the conduct of and participation in research studies should include some level of altruism or mutuality on the part of both the researcher and the participant.³⁷

IV. PUBLIC TRUST IN THE NHS REFORM: A SIMILAR CONTROVERSY

³⁵ Cook and Hoas, above, n 25.

³⁶ Cook and Hoas, above n 25, at 4-5.

³⁷ Cook and Hoas, above n 25, at 6.

As mentioned in the introduction to this paper, the NHS has set up a blog for citizens wishing to comment on the collection of health-related data by the Information Centre set up by the Health and Social Care Act 2010. In this Section, we will provide a few examples of the many comments that have been posted. These quotes, from five commentators, capture to a large extent the concerns raised by all the commentators:³⁸

Neither the government nor the NHS has the right to sell [my medical records] either for profit or for the advantage of private companies, business interests or political advantage.

A leaflet was pushed through the door the other day with the rest of the pizza, curry and loft insulation bumf ... On reading it, it states the NHS's intention to "share" (they mean sell) all our medical details... [T]he NHS want to sell you intimate medical details to anybody with the money to buy ... [b]ut they aren't asking your permission, oh no, they're going to do it anyway...

It's about disclosing private and personal information to undisclosed third parties. ... [I]t has all the hallmarks of an attempt to privately acquire the "right" to gather private medical data about the majority of the British public without them realising. ... [T]his is a crafty way of maximising the number of those whose data will be harvested either without their knowledge, or through inertia. ... Am I alone in feeling intimidated?

There is no guarantee that my data will be used ethically. ...

³⁸ <http://www.nhs.uk/NHSEngland/thenhs/records/healthrecords/Pages/care-data.aspx>

I think it is good for medical data to be shared, and hence accessible, throughout the NHS. BUT I am not happy with any prospect that this information be shared with any commercial organisation.

The outrage of these NHS patients with the possibility of personal medical data being used for commercial ends that do not tie in with the individuals' values, clearly reflects the outrage felt by many customers of 23andMe. However (un)realistic the concerns reported may be, the point remains the same – 'You are losing my trust'.

Two general questions arise, to which the answer is not yet clear. Is the primary goal of the new policy to profit from the 'family jewels' of the NHS by selling or leasing out access, or by data-mining and patenting the findings? Or is it to get top quality new treatments to all NHS patients who need them at an affordable cost and with minimum delay, to be done by facilitating the discovery and development phases?

Further, several more specific questions arise. Why has the government chosen to communicate the new policy to the population through a junk mail leaflet? As noted by a representative of the public campaign medConfidential:

That your family's medical confidentiality could rest on spotting a single evasively-worded junk mail leaflet makes an absolute mockery of both transparency and of consent.³⁹

³⁹ Phil Booth, quoted in Shah, Sooraj (2014) Patients' data 'can't be used for marketing or selling insurance premiums', says NHS, Computing/share, 21 January 2014. Available at <http://www.computing.co.uk/ctg/news/2324170/patients-data-cant-be-used-for-marketing....>

Why does the leaflet not state clearly that the new policy allows for the health data of NHS patients to be used for commercial benefit? Instead, it contains vague wording, for example that data will be shared with “approved organisations”, without any further specification.

V. WHAT IS THE GOAL OF THE NHS REFORM WITH ITS FOCUS ON INNOVATION?

In this Section we will discuss the possible goals of the NHS reform with its focus on fostering innovation. Top quality healthcare is becoming ever more expensive. The NHS’s new policy of increasing its involvement in innovation can take one or more of a limited set of forms, involving research at the three *stages* of discovery, regulatory clearance, and post-registration, and using the *resources* of patient data, body material, patients, and NHS staff and facilities.

Let us first look at the possible scenarios in each of the three stages of research. For the *discovery phase*, NHS involvement might take the form of state- or industry-funded research *by NHS staff*. This leads to the questions of which party would own the intellectual property rights (IPRs) that result, and whether the NHS, if not the IPR owner, would have a share in any subsequent profits or would have access to the ultimate products at a reduced price. Since NHS staff involved in discovery stage research are frequently also university employees, the problem may arise that those universities may claim full or partial ownership of the IPR. Alternately, discovery stage research could be carried out *by non-NHS entities* but using NHS resources of patient data and/or body material. This could be

research carried out by a Contract Research Organisation (CRO)⁴⁰ but funded by the NHS, or research funded by the non-NHS entity itself. In the first case the IPR owner would probably be the NHS, in the second it will depend on the conditions that the NHS lays down for access to its resources. The NHS could, for example, follow the IPR policy that has been adopted by the UK Biobank of accepting that the IPRs will belong to the entity carrying out the research but requiring a royalty-free, sub-licensable licence when the IPRs are being used ‘unreasonably’ to restrict health-related research and/or access to healthcare.⁴¹ Or it could follow an entirely different policy. The Carruthers report does not make clear what is to be understood by a ‘competitive approach’ to the management of intellectual property or what the planned ‘update’ of the intellectual property strategy will entail.

As regards the second stage, i.e. regulatory clearance, one of the questions that arise is whether the attitude to regulatory clearance data exclusivity will be as tough as it usually is in industry.⁴² Data exclusivity is commonly used as a means to delay market entry by generic

⁴⁰ See, for example: JE Winter and J Baguley (Eds), *Outsourcing Clinical Development*.

Strategies for working with CROs and other partners (Gower Publishing: Aldershot, 2006); and J Fisher, *Medical Research for Hire. The political economy of pharmaceutical clinical trials* (Rutgers University Press: Piscataway, 2009). We do not have space here to comment on the broader trend of out-sourcing clinical research, which has given rise to international markets with strong competition for clinical trial revenues, a trend which risks erosion of research ethics.

⁴¹ UK Biobank, above, n 24.

⁴² See, for example, N Tuominen, ‘An IP perspective on defensive patenting strategies of the EU pharma industry’ (2012) 34(8) *European Intellectual Property Review* 541-551.

competitors once a pharmaceutical patent expires. The suggestion has been made by Jerome Reichman that clinical trials should be performed wholly or partially at state expense, with the data then being open to others to use. The argument goes that by transferring the major expense of bringing a new drug to market onto the state, pharma might then launch new products at more affordable prices. With the continuing existence of patents, this seems like a pipedream as far as *initial* prices after launch are concerned – however, should the NHS choose to sponsor trials in fields where the cost of existing drugs is prohibitive, it could, perhaps, encourage new entrants to develop new drugs not covered by existing patents, and to request NHS funding of regulatory clearance trials. One effect might be to introduce competition in the marketplace and to push prices downwards. A further effect, one to be hoped for, could be that drugs might be developed for diseases which do not occur so frequently in developed countries that the manufacturer could otherwise hope to recoup research and regulatory clearance costs solely by monopoly-pricing in a patent-bound market.⁴³ The NHS could, of course, choose to carry out clinical trials on selected drugs at its own expense so as to achieve this longer term goal of introducing price competition, and hence of lowering its expenditure on drugs, where such competition seems likely to occur and where current overinflated prices make it desirable to reduce costs over time.

⁴³ JH Reichman, 'Rethinking the role of clinical trial data in international intellectual property law: the case for a public goods approach' (2009) 13 (1) Marquette Intellectual Property Law Review 1-68. See also P Andanda, 'Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health' (2013) 44(2) International Review of Intellectual Property and Competition Law 140-177.

Research in the *regulatory clearance* phase, *e.g.* clinical trials, could be carried out on NHS patients, for example within NHS hospitals, and involve the participation of NHS staff. This could be funded *by the NHS itself*, for example where the treatment has been discovered by or for the NHS and where the NHS is the IPR owner. Alternatively, it could be *industry-funded* (*i.e.* as has been normal practice up to now). Where research is NHS-funded, the question arises as to what the NHS's role would be when the regulatory clearance is gained, *e.g. would the NHS become a licensor of industry or a competitor to industry?*

Where research aimed at regulatory clearance is *industry-funded*, the question arises as to whether the fee paid to the NHS or its staff is sufficient or, if not, whether the NHS would subsequently take a share in the profits or have access to the resultant product at a reduced price. Alternatively, the view might merely be that industry-funded research facilitates the emergence of new treatments and that *this alone* is sufficient to justify the emphasis in the Carruthers report on encouraging all NHS patients to become research subjects.

What about research in the third stage, the post-registration stage? For existing treatments, *i.e.* post-registration, patient data could be analysed to determine whether specific treatments might be 'retired' or to determine which of various alternative treatments should be selected and under which conditions. The example of using GP (family doctor) data to determine which of the available statins should be prescribed is given by Ben Goldacre. As he points out,⁴⁴ after a drug has reached the market, the patient data that is *then* collected may be particularly useful since it goes far beyond the data collected during regulatory clearance.

⁴⁴ B Goldacre, *Bad Pharma – How drug companies mislead doctors and harm patients*, (Fourth Estate: London, 2012), at 231-2.

The position concerning possible NHS research involvement explained above can be visualised more clearly if seen as an array, much like a Rubik's cube. Thus, for the purposes of this paper, *the different forms that research can take* under the NHS innovation agenda can be set out along three dimensions: the level of *transparency*; the *goal* of the research; and the *subjects* used for the research.

The *subjects* used can be: (i) patient data; (ii) patient body material (*e.g.* tissue samples); or (iii) living patients' bodies (*e.g.* in the case of clinical trials), or some combination of these.

Obviously, different legal and ethical questions may be at issue in each case. Below we will comment on some of the problems arising with regard to research involving patient data.

We cannot elaborate here on the specific problems involved in research on human body material or in clinical trials. Concerning the latter, the question obviously arises as to whether the new NHS policy of regarding every patient as a potential trial subject poses a risk of undue influence being exerted,⁴⁵ given that the NHS provides free healthcare and any UK patient without private health insurance is entirely dependent upon the NHS for that healthcare and might, as a result, be reluctant to refuse to join clinical trials. Moreover, this raises a particular conflict for the NHS in cases where it would benefit financially from the outcome of trials or where it would make a profit from performing trials.

As to *transparency*, three scenarios are conceivable, namely where the research (whether on patient data, body material, or patients themselves) is done:

⁴⁵ Laurie and Postan (above, n 20, at 401) talk of 'a power imbalance which belies the putatively empowering nature of the consent process.'

scenario 1: with the informed consent of the patients (or at least after consultation, see the following Section);

scenario 2: with the participants having been *incorrectly* led to believe that the research only aims to benefit patients, *i.e.* with invalid consent; or

scenario 3: *without* the participants having been advised that research is taking place, *i.e.* without any consultation, let alone consent.

Finally, as to the *goal* of the research, this may be to: (a) develop or improve treatments; (b) reduce access prices for new treatments; or (c) make a profit for the NHS in order to reduce its demands on the taxpayer.

In scenarios (2) and (3) mentioned above, the NHS seriously risks the loss of patient and public trust when the truth comes out. However, if a profit motive is present, the erosion of trust is likely to be vastly greater, as is illustrated by the case of 23andMe and the comments on the NHS Care Data webpage discussed earlier. In general, it seems that the *most problematic scenarios, i.e.* those where trust is most likely to be eroded, would be those with no transparency, a profit motive present, and involving a clinical trial. The *least problematic (but not necessarily unproblematic) scenarios* would be those where transparency is provided, the goal is new and improved therapies, and the research is carried out only on data or body material.

VI. RISKS TO THE PRIVACY, AUTONOMY AND MORAL INTEGRITY OF NHS PATIENTS

Where patients cannot prevent their data or body material from being used for research, this represents an erosion of their autonomy.⁴⁶ We will come back to the relevance of autonomy later in this section. However, in addition to autonomy, two other fundamental ethical values are at stake here: *privacy* (the right to a personal sphere free from public attention and intrusion); and *moral integrity* (as persons, patients deserve respect for who they are and for the values, preferences, and commitments they subscribe to). These values, and the ways in which they intersect, will be briefly touched upon in this section.

As to privacy, Part 9, Chapter 2 of the Health and Social Care Act 2012 establishes a *company*, the 'Information Centre', to which essentially all confidential patient information from UK health care professionals will be provided, thereby creating the (data) goldmine mentioned earlier. In an impressive analysis published in this journal,⁴⁷ Jamie Grace and Mark Taylor explain that the 2012 Act allows this data to be used for purposes that extend beyond patient care (*e.g.* for research) without any consultation, *i.e.* without the patients' knowledge. Thus, *the 2012 Act makes it impossible for patients to prevent their data from being used for research.*

⁴⁶ SL Tobin and others, 'Customers or research participants? Guidance for research practices in commercialization of personal genomics' (2012) 14 (10) *Genetics in Medicine* 833-835.

⁴⁷ J Grace and MJ Taylor, 'Disclosure of Confidential Patient Information and the Duty to Consult: the Role of the Health and Social Care Information Centre' (2013) 21 (3) *Med L Rev* 415-447.

Under the Data Protection Act 1998,⁴⁸ any health professional gathering personal information directly from a patient has a responsibility to advise the patient of the intended uses of the information, unless this would be impracticable. However, as Grace and Taylor point out,⁴⁹ in this regard the Data Protection Act may be overridden by the Health and Social Care Act 2012, since the direct recipient of the information from the patient, the patient's physician, is obliged to forward such information to the new 'Information Centre' which itself is *not* obliged to inform the patient of the use of such data once 'anonymised'.⁵⁰ This has far-reaching consequences:

⁴⁸ S 2(1)(a), Part II, Schedule 1.

⁴⁹ Grace and Taylor, above, n 43.

⁵⁰ Interestingly, a number of commentators draw attention to the impossibility of anonymising or de-identifying patient data. See, for example: AL McGuire and RA Gibbs, 'No Longer De-Identified' (2006) 312 Science 370-371; WW Lowrance and FS Collins, 'Identifiability in Genomic Research' (2007) 317 (5838) Science 600-602; D Greenbaum, J Du and M Gerstein, 'Genomic Anonymity: Have We Already Lost It?' (2008) 8 (10) American Journal of Bioethics 71-74; M Wjst, 'Caught You: Threats to Confidentiality Due to the Public Release of Large-Scale Genetic Data Sets' (2010) 11 (21) BMC Medical Ethics 1-4. Greenbaum and colleagues noted that the distinction between identifiable and non-identifiable genomic information is becoming increasingly less meaningful: 'Particularly as industries such as personal genomics expand—flooding both private and public databases with readily identifiable genomic data—they will effectively prevent an ever-growing number of individuals from remaining genetically anonymous ... In fact, recent research has already shown that individual genomes can be readily identified out of

[T]he Information Centre will have the power, under section 259 [of the Health and Social Care Act 2012], to *require* confidential patient information (and other information) from health and social care bodies ...⁵¹ [A] disclosure to the Information Centre, in response to a *requirement* that it be provided, ... will not constitute a breach of the common law duty of confidence and will satisfy the requirement that there is a lawful basis for the processing of sensitive personal data under Schedule 3 of the Data Protection Act 1998.⁵²

Consequently, as observed by Grace and Taylor, the *right of a patient to object* to processing of his personal data on the basis that it would be likely to cause ‘substantial damage or substantial distress to him or to another, and that damage or distress is or would be unwarranted’ (*cf.* Section 10 of the Data Protection Act 1998) is simply removed as a result of the Health and Social Care Act 2012:

larger mixed groups of publicly available data from genome wide association studies using only a small subset of one’s genome’. *Supra*, at 71 (reference omitted). Wjst points out that: ‘[I]t seems necessary to increase public awareness of genetic privacy and to inform probands [*i.e.* patients] continuously about the use of their samples and data ... The risks of re-identification of anonymized data should be included in informed consent procedures, and any data sharing needs to be explicitly approved by the DNA donor. ... data sets with more than 100 SNP markers should be removed from public web servers if not explicitly endorsed by the donor. ... data access should be restricted to scientific collaborations under confidentiality agreements only’. *Supra*, at 3-4 (references omitted).

⁵¹ Grace and Taylor, above, n 43, at 430.

⁵² Grace and Taylor, above, n 43, at 432 (footnotes omitted).

[T]he responsibility to consult the patient and provide her with the opportunity to object] is lifted in relation to *both* the Information Centre *and* health professionals *if disclosure of the information has been required by the Information Centre*.⁵³

This clearly represents an erosion of patient *autonomy*. We should like once again to quote bioethicist Savulescu:

Each mature person should be the author of his or her own life. Each person has values, plans, aspirations, and feelings about how that life should go. People have values which may collide with research goals ... When we involve people in our projects without their consent we use them as a means to our own ends.⁵⁴

This comment was regarding the use of body materials, but applies equally to the use of personal data for research purposes. Indeed, people can only exercise their autonomy as regards uses of their data and/or body material if they have received sufficient information; thus *the right to be informed* about intended uses of one's data (or body material) *is a precondition to the protection of the fundamental rights to autonomy and personal respect*. Grace and Taylor explain how the relationship between these rights is clear from the Data Protection Act 1998:

One of the ... rights of data subjects (which cannot be exercised if they are in ignorance of the [data] processing) is the right, contained within section 10 of the

⁵³ Grace and Taylor, above, n 43, at 435-436, emphasis added.

⁵⁴ Savulescu, above, n 27. See also R Rhodes, 'Rethinking Research Ethics' (2005) 5 (1) American Journal of Bioethics 7-28.

Data Protection Act, to prevent processing likely to cause him or her substantial damage or distress.⁵⁵

They argue for a duty to consult, which, their analysis shows, can be found in current UK law but is at risk of being undermined by the Health and Social Care Act 2012. The implications of such a duty are the following:

We suggest that if someone has been 'consulted' over an intended use of information, then he or she will have received 'sufficient reasons' for the intended processing, have had 'adequate time' to consider those reasons, and will have had an opportunity to offer a response which will be 'conscientiously taken into account' prior to a decision being made.⁵⁶

According to Grace and Taylor, the Data Protection Act 1998, in conjunction with the common law duty of confidence, grounds a responsibility to take conscientious account of

⁵⁵ Grace and Taylor, above, n 43, at 419, referring to s 10(2) of the Data Protection Act 1998.

⁵⁶ Grace and Taylor, above, n 43, at 419-410, referring to *R v Brent London Borough Council ex parte Gunning* [1985] 84 LGR 168 at 169. Grace and Taylor, rightly in our view, emphasise that this is not equivalent to seeking consent: '[M]ost crucially, consent is something that can be withheld by an individual for any reason at all. If consent is a necessity, then dissent effects a prohibition. If instead the requirement is only that those affected have an 'opportunity to comment' and for their views to be 'duly taken into account', then an obligation to consult may be discharged without individual consent'.

Grace and Taylor, above, n 43, at 443.

any response given by the data subject as well as a responsibility to respect any 'reasonable objection' expressed by the data subject against the intended research use.⁵⁷

This highlights the interrelatedness between, on the one hand, the value of autonomy and, on the other hand, *the value of respect for persons and their moral integrity*. As to the latter, it is clear that having personal data or body material used for purposes one is morally opposed to may make one feel morally complicit, which may cause substantial damage and distress. 'Moral complicity' refers to the idea that one can do wrong by being associated in

⁵⁷ Grace and Taylor, above, n 43, at 420. The common law duty of confidence entails that: "[C]onfidential *patient* information may not be used for any purpose outside the reasonable expectation of a patient confiding personal information in a health professional. This includes use by third parties if they receive the information from a health professional". Grace and Taylor, above, n 43, at 421 (footnote omitted). They note that there are at least two circumstances in which the responsibility to consult, inherent to the common law, might be limited: uses of 'de-identified' data and uses of identifiable data in the public interest. As to the former, see note 46 above. With regard to uses 'in the public interest', it is clear that this cannot be invoked as a general exception ('health research by definition is in the public interest'), for this exception only applies if failure to disclose data would risk serious harm (*e.g.* if national security would be breached or if there would be a medical danger to the public). See Grace and Taylor, above, n 43, at 427-428. In sum, the only circumstances in which disclosure of confidential patient data can be justified 'without notification and despite objection' are where 'disclosure is intended to address a serious crime or a risk to the health, safety and well-being of others'. Grace and Taylor, above, n 43, at 446.

some way with wrongdoing by others, for example by causally contributing to others' wrongdoing in a certain way or by increasing the likelihood of the wrongdoing occurring *even without causing it in any way*.⁵⁸ Allowing people to avoid moral complicity is an additional reason for ensuring that people have the right to be informed about and to object to uses of their data or body material.

VII. CONCLUDING REMARKS

We are *not* arguing that, prior to the NHS reform, no potentially problematic research was taking place within the NHS or under instructions from the NHS, but rather that the NHS innovation agenda and the Health and Social Care Act 2012 *permit and even actively encourage 'drift' towards types of research that are more likely to erode the public's trust in the NHS, i.e.* towards the most problematic types of research we described in Section V.

Is the NHS's new policy intended primarily to enhance healthcare or is it to raise funds with enhanced healthcare being merely secondary? If, as seems likely in view of the language used in the Carruthers report and the NHS Care Data webpages, the primary purpose is to raise money, then it is especially important to ensure that the NHS's policy be transparent and that the patients, on whose bodies, tissues and data the success of the policy depends, be fully informed and provided with an easy way to decline to participate.

⁵⁸ For readings on moral complicity, see C Kutz, *Complicity: Ethics and Law for a Collective Age* (Cambridge University Press: Cambridge, 2000); RM Green, 'Benefiting from 'Evil': An Incipient Moral Problem in Human Stem Cell Research' (2002) 16 (6) *Bioethics* 544-556; J Gardner, 'Complicity and Causality' (2007) 1 (2) *Criminal Law and Philosophy* 127-141.

The importance of this is underlined by the paucity of avenues by which NHS patients (or 23andMe customers) may obtain legal redress should their data or body samples, or even their bodies, be used for purposes which they are not informed of and not in agreement with.⁵⁹

The main lesson to be drawn for the NHS seems to be that *any* organization involved in research that relies on human participation, whether through clinical trials or by providing information or body material or both, needs to be transparent, not only about its *research goals* but also about its *strategies and policies regarding commercialization*, including patenting and licensing policies. Such transparency is crucial to enable potential participants to make their own decisions as to whether those goals and policies are in line with their moral values, and, if so, whether they want to contribute to those goals. In the absence of such transparency, any talk, no matter how repeated, of ‘patient autonomy’ and ‘no decision about me, without me’ (one of the key phrases in *Equity and excellence: Liberating the NHS*, the 2010 report on NHS reforms planned by the coalition government),⁶⁰ will continue to sound hollow. That 2010 report promised that patients will have increasing control over their care records:

We will enable patients to have control of their health records. This will start with access to the records held by their GP and over time this will extend to health

⁵⁹ Laurie and Postan, above, n 20, at 393.

⁶⁰ Available

at <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213823/dh_117794.pdf>,, see section 2.11, page 14.

records held by all providers. The patient will determine who else can access their records...

Yet Grace and Taylor's analysis convincingly shows that the Health and Social Care Act 2012 has the opposite effect: patients now have *less* control over who can access and use their healthcare data. The 2012 Act and the NHS innovation agenda pose risks, not only to the privacy of NHS patients, but also to their autonomy and moral integrity.

Trust, once lost, is not easily regained. It is to be hoped that those who are in the process of 'liberating' the NHS are aware of this.