Research Participants and the Right to be Informed

Deryck Beyleveld and Roger Brownsword

I Introduction

Introducing *Autonomy, Consent and the Law*,[1] Sheila McLean remarks that if the law is 'to facilitate or protect the capacity of an autonomous person to make an autonomous choice—one that reflects his or her own values—it is necessary to develop standards that can ensure meaningful patient participation in healthcare decisions.'[2] And, the development of such standards, McLean suggests, 'is generally said to be the function of the legal doctrine of consent.'[3] However, having analysed a sweep of English medical law (focusing on end-of-life questions, pregnancy, genetics, and organ transplantation), McLean claims that the jurisprudence of (informed) consent is less than fully congruent with the idea that the autonomy of the patient is focal. Indeed, McLean concludes: 'In building the rules around consent to treatment, courts have stopped short of ensuring that people are fully informed and therefore truly able to weigh their decisions and act in a self-determining manner.'[4]

Following McLean, we would say that, were autonomy to be regarded as focal, it would be for each individual patient, not for clinicians, to decide whether a suitable available treatment should be commenced, modified, or discontinued, and which of such treatments to have. Guided by such an autonomy model, (informed) consent would translate in the following way. If a patient refuses to consent to a procedure (for example, a pregnant woman refuses to consent to a Caesarean section or a person refuses assisted nutrition and hydration[5]), then she should not be subjected to the procedure; conversely, if a person consents to the administration of a drug (for example, a drug that will end her life), then the drug should be administered. McLean's point is that, if consent is to serve the autonomy of a patient, it must be designed to track and reflect that particular patient's will (however seemingly 'irrational' or 'unreasonable') rather than operate in accordance with its own rules.[6]

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1 Sheila A.M. McLean, *Autonomy, Consent and the Law* (Abingdon: Routledge-Cavendish, 2010).

2 McLean, note 1 above, at 3.

3 Ibid.

4 McLean, note 1 above, at 216.

5 Of course, there is a questionmark about whether ANH is appropriately characterised as a form of medical treatment: see Sheila A.M. McLean, 'From *Bland* to *Burke*: The Law and Politics of Assisted Nutrition and Hydration' in Sheila A.M. McLean (ed), *First Do No Harm* (Aldershot: Ashgate, 2006) 431.

6 See McLean, note 1 above, at 98: 'It is generally agreed that the corollary of the right to consent to treatment is the right to refuse it. While choosing to accept recommended therapy can be an affirmation of the patient's autonomy, so too can be his/her decision to avoid or reject it. Both are about self-determination or control over our lives….While rejecting treatment may seem in some cases to be

According to McLean, the autonomy of patients is compromised not only when their consent or refusal of consent is egregiously ignored but also when they make decisions that 'are based on misunderstandings or on overt or covert denial of choice resulting from withholding of information that *would* have been important to that particular patient….'[7] Following up this latter claim, we might inquire how far the foreground 'informational' doctrines of English medical law serve the background idea that the patient's autonomy is fundamental. This prompts McLean to review the well-known common law cases on disclosure of risk.[8] However, we might extend this line of inquiry. For example, in the context of experimental procedures, we might ask whether the law requires clinicians to inform patients in a way that facilitates the latter making their own treatment decisions.[9] If the law permits a clinician to withhold information about a procedure in order to steer the patient towards a treatment decision that health-care professionals would generally endorse, this suggests that a thread of paternalism remains in the law; and, by contrast, if the law permits a clinician to withhold information about a procedure in order to steer the patient towards a treatment decision that health-care professionals would generally regard as far too risky, this raises quite different concerns about the safety of patients. Either way, the autonomy of patients is compromised.

In this paper, our interest is in the analogous question of the responsibilities of *researchers* to inform *participants* in a way that respects the autonomy of the latter. If participation is to be on an informed basis, there are many questions to be answered—for example, questions that relate to the purpose (or purposes) of the study, whether the research processes or products might be patented (and commercialised), whether and how the privacy of participants and the confidentiality of their information will be respected, whether participants will remain identifiable (and linkable to the samples and data that they provide), whether participants have proprietary rights in relation to their samples and data, and so on. Much could be written about each of these questions. However, our present interest is in the responsibilities of researchers to return autonomy-relevant findings to their (identifiable) participants—in short, the question is whether there will be (and should be) any individualised feedback of health-related findings made by the researchers. For example, if a researcher realises that a particular participant has a life-threatening aneurysm, would the law be deviating from an autonomy-centred focus if it did not require the finding to be disclosed—or, at any rate, would this be a deviation if the participant had either already consented to the return of findings or had not indicated that there should be no return of findings?

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irrational…there may be reasons—possibly unknown to healthcare professional—that lead people to make the decision not to accept it.'

7 McLean, note 1 above, at 61.

8 McLean, note 1 above, at 73-86. The leading case in English law is *Sidaway v Bethlem Royal Hospital Governors and Others* (1985) 1 BMLR 132.

9 Compare the Nuffield Council on Bioethics, *Novel Neurotechnologies: Intervening in the Brain* (London, June 2013) 111-113.

Currently, this line of inquiry is of intense interest because it takes us to one of the most complex and contested issues in the ethics and governance of biobanks. The central question here—a question that Catherine Heeney and Michael Parker rightly single out as '[o]ne of the most hotly debated' in the context of modern biobanking practice—is 'whether there is an obligation to feedback research results to participants.'[10] Suppose, for example, that researchers, who are conducting genetic analysis on biobanked materials, identify a particular mutation for breast cancer in a sample provided by an identifiable participant. Do the researchers have an obligation to inform the participant; or, to turn this round, does the participant have a right to be informed? If it is claimed that the participant does have such a right, a host of further questions need to be addressed, including questions about the scope of the right, its weight in relation to any competing rights, whether researchers owe feedback responsibilities also to third parties (such as relatives of the participant), how the information is to be conveyed to the participant, how the right might be affected by an explicit 'no feedback' policy at the biobank, and whether the right to be informed also implies a right that researchers actively 'look out for' potentially clinically significant findings.[11]

Responding to the headline question of whether researchers have a responsibility to feed back to individual participants those findings that might be clinically significant, we are guided by a rights-based ethic, specifically an ethic that is rooted in the seminal work of Alan Gewirth.[12] According to Gewirthian ethics, in a community of rights, agents are categorically required to respect the generic conditions of agency—for present purposes, particularly the conditions of physical and psychological well-being that are essential before an agent has any prospect of successfully engaging in purposive activity (whatever the agent's purpose, whatever the activity). The generic rights that agents directly hold against one another are both negative (against unwilled acts of interference with the generic conditions) and positive (for acts of assistance in support of their generic conditions provided that this is consistent with the agent's will and does not threaten equally or more important generic rights of those providing assistance). It follows that our blunt—we emphasise that this is extremely blunt—response to the central question is that, where the information in question relates to an agent's generic conditions, then researchers do have feedback responsibilities to their individual participants.

The paper is in three principal parts. First, we sketch the context for the present debate about the informational responsibilities of researchers, particularly analysing the significance of a biobank's 'no feedback' policy and the plausibility of a participant's claim that they have a 'reasonable expectation' that feedback will be provided. Secondly, we outline the key features of the Gewirthian view of positive rights and its justification. Thirdly, we apply this ethic of rights to a number of illustrative scenarios where the question is whether Gewirthian-guided

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10 Catherine Heeney and Michael Parker, 'Ethics and the Governance of Biobanks' in Jane Kaye, Susan M.C. Gibbons, Catherine Heeney, Michael Parker and Andrew Smart, *Governing Biobanks* (Oxford: Hart, 2012) 282, 295.

11 For a recent discussion, see Catherine Gliwa and Benjamin E. Berkman, 'Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings?' (2013) 13 *American Journal of Bioethics* 32-42.

12 Alan Gewirth, *Reason and Morality* (Chicago: University of Chicago Press, 1978).

researchers would do the right thing by giving (or not giving) feedback to a participant; and, at the same time, we draw out the implications for anonymisation (as a strategy to protect participant privacy) if this has the consequence that researchers are thereby disabled from identifying participants who have a right to be informed.

II The Context

Why is it that the question of the informational responsibilities of researchers should have become so 'hot'? It is not that biobanks—broadly speaking, collections of biosamples, personal data, scans and images, and so on—are new. However, large population-wide biobanks, established (much like a library) as a resource to be curated for access and use by the research community are new; and the possibility of undertaking (and understanding the import of) quite detailed genotyping and sequencing is assuming much greater prominence. Moreover, where the studies are of a longitudinal nature, with researchers needing periodically to recontact participants (for example, for further samples or data to be supplied, or for remeasurement, and so on), it is in the nature of the project that clinically significant findings can be returned to individual participants. If feedback can be given by biobanks and their researchers (or researchers who use the resource), the question then is whether it ought to be given.

In many biobanks, the general rule is that 'no feedback' will be given to participants. However, in two respects 'no feedback' is open to misunderstanding. The 'no feedback' notice notwithstanding, there might actually be some findings that are returned to participants.

First, even where the declared policy is one of 'no feedback', this usually refers to the position once participants' samples and data have been 'banked'. Prior to that point, some health-related information might be given to participants. For example, at the point of enrolment, participants might be given their blood pressure or bone density readings, or their BMI score, and so on; and, there might also be some advice about incidental observations as when a participant might be advised to check out a suspicious-looking mole with their doctor. However, once the samples and data have been collected and 'banked' for the use of researchers, the 'no feedback' policy signals that the general rule is that there will be no individual feedback arising from the findings made by researchers (general findings, of course, will be disseminated in the usual way).

The second misunderstanding is more subtle. When a biobank declares that its policy is 'no feedback', this might mean quite literally that there is no feedback, that there is an absolute rule against feedback. Here, 'no feedback' is intended to signify that participants have no right to feedback and that researchers have a duty not to inform; in no circumstances will even clinically significant results of research undertaken on the banked materials be returned to individual participants. However, 'no feedback' might be intended less literally, signalling something more specific, namely that the researchers do not accept any obligation to give feedback. This latter reading is designed to counter participants who assert that they have a right to be informed and that, concomitantly, the researchers have matching obligations. While such a reading is intended to shield researchers against claims for feedback made by participants, it does not preclude the giving of feedback; but, whether or not participants are

informed, is exclusively for the biobanks and their researchers to decide. If the latter is the policy of the biobank, the relevant discretion might be structured in more than one way—for example, by adopting defaults of various kinds, reserving some feedback questions for case-by-case determination, and so on; and, in practice, some feedback (drawing on research on banked materials) might be given.

In the light of these remarks, consider the 'no feedback' policy of ALSPAC, the well-known longitudinal study of parents and their children in the Bristol area. ALSPAC declares its policy on disclosure of biomedical information to participants in the following terms:[13]

> The policy is that information shall not, as a general rule, be disclosed to participants.
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> This general policy should only be set aside when it is reasonably certain that the benefits of disclosure clearly outweigh any possible risks to the participants or their families. This in turn will arise when three conditions are met:
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> 1. That an item of data gives clear, unequivocal information of an existing or future health problem.
> 2. That the health problem identified is amenable to treatment of proven benefit
> 3. That the participant has indicated beforehand that they wish to be informed if such a problem is identified.

While the function of the 'no feedback' notice at ALSPAC is to scotch any idea that participants have a right to feedback, this does not rule out the possibility of informing individual participants about clinically significant findings. On this view, although participants have no *right* to be informed as such, they might nevertheless be informed if they have signalled this *preference* and provided that the researchers judge that there is a net benefit in giving individual feedback.

One of the points made in support of the ALSPAC policy (and, likewise, biobanks that have a similar policy) is that participants understood when they enrolled that there would be no feedback. In other words, the policy is supported inter alia by the following considerations[14]:

- Individuals have consented to participate in the study on the clear understanding that all measures are for research purposes only and not to inform decisions about their health. To emphasise this, it is often stated explicitly in the information given to participants.
- As a corollary, it is frequently repeated that the tests that participants undergo are not a check on their health, and that if participants are worried they should go to their own doctors.
- The relationship between researcher and participant differs from that between doctor and patient. Crucially the duty of care is different. The primary concern of a researcher is not to the health of a participant but to acquire information for the benefit of humankind.

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13 Available at: www.bristol.ac.uk/alspac/researchers/data-access/ethics/ (last accessed September 14, 2013).

14 Again, drawing on the ALSPAC policy, note 13 above.

There is no doubt that the ALSPAC ethics committee is seeking to do the right thing but the question is whether, from a rights-based perspective, this paternalistic policy is appropriate.

Heeney and Parker come close to answering this question. Noting that one 'no feedback' strategy is, in effect, to manage the expectations of participants, they say:

> One route would be to make it clear to participants and health professionals at the time of consent that there will be no feedback of research results. There are a number of arguments supporting this including its potential for greater clarity about consent and about the distinction between research and clinical care and the fact that feedback assumes some sort of infrastructure in which the connection with participants is maintained to the extent that they can still be contacted and told to seek medical advice, for example.[15]

However, as the authors remark, this approach has fallen out of favour in those cases where research might 'produce very clear evidence of a serious harm which might be avoided by an easily available intervention and where there exists something akin to a duty of easy rescue.'[16] In other words, if our premise is that participants have a positive right to be informed (possibly akin to a positive right to be rescued where this is straightforward and not difficult for the rescuer), we are less likely to judge that biobanks do the right thing by withholding clinically significant findings. Moreover, even if a 'no feedback' policy has been 'communicated' to participants, we might wonder whether its significance has been fully appreciated; and we might judge that, regardless of the biobank's declared policy, participants 'reasonably expect' to be given feedback where a biobank holds clinically significant, serious, and actionable information about a particular individual.[17]

These observations invite two lines of inquiry. First, on what basis might we defend the premise that participants have a positive right to be informed? Secondly, how does the idea of 'reasonable expectation' play in this context? We respond to the first question in the next part of the paper; and we can close the present part of the paper by making some short remarks in response to the second question.

One of the striking features of much of our ethical and regulatory thinking (notably in relation to the interest in privacy) is that the recognition of a right hinges on the question of whether we judge that a person has a 'reasonable expectation' that his or her particular interests will be respected and protected. If a participant's claim to have feedback hinges on whether it is based on a reasonable expectation to have feedback, then the question is: by reference to what standard or practice or to whose authority is the expectation judged to be a reasonable one?

First, the participant might invoke relevant background rules of law. There has been much discussion of whether a participant might succeed against a researcher in a tort claim for

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15 Heeney and Parker, note 10 above, at 296.

16 Ibid.

17 Compare, e.g., Susan Wolf et al 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 *Genetics in Medicine* 361-384; and Bartha M. Knoppers et al, 'Population studies: Return of research results and incidental findings Policy Statement' (2012) *European Journal of Human Genetics* doi: 10.1038/ejhg.2012.152.

wrongful non-disclosure.[18] The consensus is that English law does not clearly support such a claim; and, if the legal test turns on whether it is 'fair, just, and reasonable' to place researchers under a feedback responsibility, this seems merely to restate the original question of whether the claimant's expectation is a reasonable one.

Where a biobank declares a 'no feedback' policy which is clearly notified to participants, if anything, this further weakens the participant's tort claim. However, where 'no feedback' signals that the biobank reserves a discretion to give feedback, a participant might argue in a judicial review that the discretion has been exercised improperly. If successful, the claimant might compel the researchers or biobank to reconsider their decision; but, of course, a claim of this kind would only get off the ground if the policy set by the biobank and its administration were judicially reviewable.

Secondly, the participant might claim that the researchers had formally or informally signalled that feedback would be given. Where a biobank has a well-advertised 'no feedback' policy, this kind of claim would be unlikely to succeed. However, if the policy had not been signalled, then the claim would turn on whether the participant could show on the facts that an undertaking to provide feedback had been given. In principle, unless the background law prohibited researchers from giving feedback, their voluntary assumption of a responsibility to give feedback would be a strong ground for claiming a reasonable expectation of feedback.

Thirdly, the participant might rely on a general attitude that there should be some reciprocity in the relationship with researchers: participants assist researchers in various ways in return for which researchers should assist participants by giving appropriate feedback. There does seem to be evidence that at least some (and, quite possibly, many) participants sign up with the expectation that there will be reciprocation.[19] However, the fact that others share one's own expectation does not make anyone's expectation *reasonable*. Possibly, the claim for reciprocity might be grounded in some other way—for example, in the way that Henry Richardson relies on the relationship of 'entrustment' between participants and researchers[20]; but it is not enough that the de facto expectation is widely held by participants.

Fourthly, the participant might rely on the settled custom and practice at other biobanks or in a certain sector of research (or, indeed, in clinical practice as genetic analysis becomes routine). For example, it might be that researchers who work with MRI scans might consider it best practice to return incidental findings to their participants. Accordingly, where there are such practices and where the claimant participant is dealing with researchers at a biobank with no declared policy on feedback, the unstated assumption (and expectation) that there will be feedback might look perfectly reasonable. However, where 'no feedback' is the declared rule,

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18 Seminally, see Carolyn Johnston and Jane Kaye, 'Does the UK Biobank have a Legal Obligation to Feedback Individual Findings to Participants?' (2004) 12 *Medical Law Review* 239.

19 Jasper Bovenberg et al 'Always expect the unexpected: Legal and social aspects of reporting Biobank research results to individual research participants' (Nijmegen: Radboud University, Centre for Society and Genomics, 2009); Laura M. Beskow et al, 'Research Participants' Perspectives on Genotype-Driven Research Recruitment' (2011) 6(4) *Journal of Empirical Research on Human Research Ethics* 3-20; and Wellcome Trust and Medical Research Council, *Assessing Public Attitudes to Health Related Findings in Research* (London, April 2012).

20 Henry S. Richardson, *Moral Entanglements: The Ancillary-Care Obligations of Medical Researchers* (New York: Oxford University Press, 2012).

contrary custom and practice notwithstanding, the argument that there is a reasonable expectation of feedback is seriously weakened.

What these appeals to reasonableness have in common is that they rely on a range of contingent factors being set in the right way. If the law supports a claim to feedback, if researchers voluntarily assume a responsibility to give feedback, if custom and practice supports giving feedback, and the like, then the participant's claim will get to first base; and, other things (such as the notification of the biobank's policy) being equal, the participant's expectation will show as a reasonable one. Where 'reasonable expectation' is the test, then the participant will be judged to be entitled to be informed.

By contrast, a participant might claim to have a reasonable expectation of being given feedback because a right to be informed is grounded in reason—not in contingent legal provisions or promises or custom and practice. Quite simply, if a participant has such a reason-based right to be informed, it would be reasonable (to put the claim at its lowest) to expect to be informed. The question, to which we now turn, is how such a right might be rationally grounded.

III A Rationally-Grounded Right to be Informed

According to Alan Gewirth,[21] agents[22] categorically ought to accept the Principle of Generic Consistency (PGC)─which requires them to grant generic rights (rights to the generic conditions of agency GCAs) to all agents. The reason why the PGC is categorically binding on agents is that it is dialectically necessary for agents to accept it, which is to say that an agent (any agent─call him 'Albert') fails to understand what it is to be an agent (hence implicitly contradicts the idea that he is an agent) if he does not accept it.

In essence, for the PGC to be dialectically necessary it is necessary and sufficient for three propositions to be true, which are:

(1) '"If doing X or having Y is necessary for Albert to pursue or achieve his chosen purpose E, then Albert ought to do X or act to secure Y or else give up pursuit of E", which is to say that the Principle of Hypothetical Imperatives of Instrumental Reason (PHI) is dialectically necessary'.
(2) 'It is possible for there to be GCAs'.
(3) 'If it is dialectically necessary for Albert to accept that he ought to do Z, then it is dialectically necessary, not only for every other agent (say Brenda) to accept that she ought to do Z, but for Albert to accept that he ought to act in accord with the principle that Brenda ought to do Z unless this would prevent Albert from acting in accordance with the principle that Albert ought to do Z'.

From (1) and (2) it follows that it is dialectically necessary for Albert to accept

(4) 'I (Albert) ought defend my possession of the GCAs unless I am willing to accept the generic damage to my ability to pursue or achieve my purposes (generic damage being

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21 See note 12 above.

22 Those capable of acting for reasons. In effect, those who have the capacity to do things voluntarily in order to achieve purposes that they have chosen.

damage to my ability to pursue or achieve every purpose I might have) that will result from my non-possession of the GCAs'.

For the sake of brevity, we will express (4) as the proposition that it is dialectically necessary for Albert to accept that he ought to defend his possession of the GCAs from interference against his will.

If (3) is also true, then it follows from (4) that it is also dialectically necessary for Albert to accept that he ought to defend Brenda's possession of the GCAs from interference that is against her will, provided only that doing so does not prevent him from defending his own possession of the GCAs from interference against his will (and vice versa). But this is equivalent to it being true that the PGC is dialectically necessary for all agents.

We submit that (1) and (2) are clearly true. (1) is true because it is analytic. (2) is true because its truth follows simply from the coherence of the idea that there might be GCAs. The contentious proposition is (3). We will not, here, attempt to explain why we believe (3) to be true also.[23] This is because, for present purposes, it will suffice for us to establish that the English legal system ought to comply with the PGC *on the assumption* that it recognises that all human beings are equal in dignity and rights. This is because the proposition that human beings are equal in dignity and rights is one that the English legal system currently purports to uphold,[24] and when this proposition is combined with propositions (1) and (2) then acceptance of the PGC follows (not as dialectically necessary) but as contingent upon acceptance of the proposition that human beings are equal in dignity and rights.[25]

Now, whether justified as dialectically necessary or as dialectically contingent upon the acceptance of human rights, the generic rights prescribed by the PGC are clearly rights under the will-conception. The duty that Albert has to defend Brenda's GCAs is, by the nature of the right he must recognise she has, one that she may release him from by her will (provided only that doing so will not generically damage other agents against their will). However, if Brenda is to exercise her will in relation to acts or decisions that might affect her possession of the GCAs she clearly needs to know what the effect of these acts might be on this possession and

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[23] See Deryck Beyleveld, *The Dialectical Necessity of Morality: An Analysis and Defense of Alan Gewirth's Argument to the Principle of Generic Consistency* (Chicago: University of Chicago Press, 1991) for a comprehensive defence of the argument for the dialectical necessity of the PGC. For a recent specific defence of (3), see Deryck Beyleveld, 'Williams' False Dilemma: How to Give Categorically Binding Impartial Reasons to Real Agents' (2013) 10 *Journal of Moral Philosophy* 204-226.

[24] It does so by the Human Rights Act 1998, which requires English law to be interpreted in conformity with the substantive rights of the European Convention on Human Rights (ECHR) if it is at all possible to do so. The Preamble to the ECHR, states that it is a first step to give effect to the rights declared in the Universal Declaration on Human Rights 1948 (UDHR). Article 1 of the UDHR states that all human beings are equal in dignity and rights. Granted, the Human Rights Act permits departure from the ECHR. On this basis, the acceptance of the principle that human beings are equal in dignity and human rights seems to be a qualified one. However, it is arguable that departure from this principle remains unqualified as acceptance of the substantive rights of the ECHR cannot even be qualified acceptance if Article 1 of the UDHR is not accepted in an unqualified manner. This is because Article 1 UDHR in part defines what it is to be a human right.

[25] For more detail see Deryck Beyleveld 'The Principle of Generic Consistency as the Supreme Principle of Human Rights' (2011) 13 *Human Rights Review* 1-18.

also about the alternatives that are available. In other words she must be granted a right to be informed.

The generic rights are also, clearly, both positive and negative. Albert has a right that Brenda not act to interfere with Albert's possession of the GCAs against his will, and also a right that she assist him to secure his possession of the GCAs when he cannot do so by his own unaided efforts if she can assist without disproportionate risk to her own possession of the GCAs.[26] This is simply because in order to defend his possession of the GCAs, Albert needs to have them; so he needs assistance when he cannot defend his own possession as much as he needs non-interference. He, thus, must have the same attitude towards assistance to secure the GCAs that he needs and desires as he must have to interference with his GCAs that is against his will. So, if Albert ought to defend Brenda's possession of the GCAs from interference against her will, he ought also to assist her to secure that possession when she cannot do so for herself and she so wishes, etc.

IV Applications of a Participant's Right to be Informed

If participants have a (Gewirthian-based) prima facie right that researchers inform them about matters that bear on their GCAs, such as their individual health and well-being, then it is clear why there should be feedback when the information is potentially life-saving, when the burden of informing is low, and when the participant is not otherwise able (or likely) to access the information. However, there are still many questions about the right and about the hard cases that might arise. In this part of the paper, we address five such further questions.

(i) Participant's consent

The first question concerns the relationship between A's right to be informed and whatever consent A may give or withhold to the researchers' proposed arrangements for feedback or 'no feedback'. Clearly, if A has a right to have feedback, and if A wishes to have feedback, then it is not strictly necessary for A to consent to having feedback. That said, in a context where it is possible that A might not wish to have feedback, getting A to confirm consent to feedback leaves no doubt that A does wish to stand on his right.

As controller of the right (such as the right to be informed by B), A has three options in relation to the operation of the right. They are as follows:

(a) A may require B to inform him (A insists on B performing the duty);
(b) A may prohibit B from informing him (A in effect exercises a 'right not to know'[27]); or
(c) A may permit B to inform or not to inform him.

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[26] While non-possession of a GCA has a generic effect on an agent's ability to act, i.e. it negatively affects that ability whatever the agent's purposes, this effect can be more or less immediate, more or less capable of amelioration, and more or less severe. For example to kill someone has an immediate, not ameliorable, effect of maximum severity. It stops the agent from attempting to act, from maintaining the capacity to act and from improving the capacity to act. A disease might eventually kill someone but might be treatable. Ill health might reduce one's ability to act successfully in a generic way but the extent to which it has this effect can vary. (see Gewirth, *Reason and Morality* note 12 above, 48-63). Because this is so, the generic rights are ranked in a hierarchy according to their 'needfulness' for action, and this ranking is to be used to determine when a generic risk is proportionate or disproportionate.

[27] See McLean, note 1 above, at 178-180 (in the context of autonomy and genetic information).

Where A opts for (c), A consents to B not informing him; and where B then acts within the terms of this authorisation, B does no wrong to A (relative to A's right to be informed).[28] Provided that A's agreeing to 'no feedback' is equivalent to A consenting not to be informed, then the position is as in (c).

What about case (b), where A signals that there is to be no feedback? Harking back to Sheila McLean's thesis, if the researchers are to respect A's autonomy, and the particular setting that A has chosen for the operation of the right to be informed, they will give no feedback. If they do so, because they judge (paternalistically) that this is in A's best interests, they (and the law if it supports such action) have failed to keep faith with respect for the agent's autonomy.

While it is tolerably clear what researchers should do when A's position is known, it is much more problematic when the will of a participant is not known. For example, where a research project began before feedback became such a hot topic, participants might not have been asked the right questions. In such a context of uncertainty, how should researchers proceed? It would be easy if the researchers could recontact each of the participants to establish their will in relation to feedback. There might be a few cases where this is possible. However, we assume that there will be many cases where it is simply not possible to establish the participant's position, including cases where this is not possible without giving the game away. Where this is so, how should researchers proceed?

A plausible default position for the research community is to inform a participant if the return of the finding is clinically actionable and possibly life-saving. To give feedback in such circumstances is analogous to treating a person rendered unconscious in an accident when it is not known whether that person wants to be treated but when, at the same time, without the treatment the person will be seriously damaged or will die. Indeed, the default for feedback might be further elaborated according to whether the condition is life-threatening and the treatment low risk. If feedback is given in these circumstances, and if the participant would have wanted feedback (and now welcomes it), then all is well. However, the problem with this particular case of uncertainty is that the researchers do not know what the participant would have wanted and when, following the default, they give feedback, the participant might not welcome it. If so, the researchers have acted in a way that is out of line with the participant's right to be (not) informed. However, there is no easy option. If researchers guess wrong, they either give feedback that is potentially life-saving but not in line with the participant's will, or—and this is hardly an attractive alternative—they withhold feedback in line with the participant's will and do nothing to assist the participant's health.[29]

If a default of the kind just sketched looks defensible where the finding is clinically actionable, what about the case where it is not actionable? In this kind of case, it becomes more plausible for researchers to suppose that the individual participant really might not wish to know. Indeed, even some participants who have signed up for feedback might not wish to know; but, of course, there will be others who value this feedback in order to put their affairs in order or maximise what is left of their lives. Again, researchers are on the horns of an impossible dilemma: if they get it wrong, either they give feedback to a participant who would not have

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28 See Deryck Beyleveld and Roger Brownsword, *Consent in the Law* (Oxford: Hart, 2007).

29 Compare the shape of the analysis in Deryck Beyleveld and Roger Brownsword, 'Emerging Technologies, Extreme Uncertainty, and the Principle of Rational Precautionary Reasoning' (2012) 4 *Law Innovation and Technology* 35.

wanted to know and who derives no benefit from the information given, or they withhold feedback from a participant who would have wished to know and who would have valued the information (bad news though it is).

The lesson to be taken from this seems to be that researchers need to talk participants through the different kinds of feedback that might be given (whether it is actionable, whether treatment would be burdensome, and so on) and then ask participants to indicate how they wish to exercise their right to be informed. No doubt, the indications given at enrolment can be reviewed or refreshed periodically; and, if participants have on-line access to their own password-protected feedback files, then they can edit their files in accordance with their latest wishes.

(ii) Unclear information: genetic markers

'No feedback' policies often are justified by saying that the researchers do not wish to return false positive findings and cause participants unnecessary anxiety and distress. As biobanks facilitate various kinds of genetic analysis, there will be many markers the clinical significance of which is unclear. If the researchers cannot say with confidence what the significance of the marker is, is 'no feedback' the right policy?

Clearly, if participants have a right to be informed, 'no feedback' cannot be the right policy simply because the researchers so decide; it can only be the right policy if this is the will of the participant—and this simply continues the discussion of the previous section. Picking up that discussion, the pertinent question is about the kind of conversation that researchers need to have with their prospective participants.[30] Information needs to be given, in an accessible form, about the best understanding that researchers have about the link between particular genetic markers and their impact on the health of the individuals concerned. This conversation will reveal different levels and degrees of uncertainty, most importantly uncertainties about the nature of the link between the marker and the expression of particular diseases. In all probability, the genetics community (both researchers and clinicians) will rapidly develop guidelines placing each particular marker in one of three categories: for return; to be considered for return; and not for return.[31] Where such a recommended feedback scheme is in place, it might be presented to prospective participants as 'non-negotiable', as applicable subject to 'opt-out', or as an option available by 'opt-in'.

In this vein, the American College of Medical Genetics and Genomics has recently recommended that, in the context of *clinical* exome and genome sequencing, there should be a (reviewable) list of variants that should always be returned to patients.[32] Variants on this minimum list, the College estimates, will be included in about 1% of sequencing reports. Summarising its proposal, the College says:

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30 For some helpful remarks on the rapidly changing context of genomics and its bearing on feedback to participants, see Erik Parens, Paul Appelbaum, and Wendy Chung, '*Incidental Findings* in the Era of Whole Genome Sequencing?' (2013) 43:4 *Hastings Center Report* 16-19.

31 See Wolf et al, note 17 above.

32 Robert C. Green et al, 'ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing' available at http://www.acmg.net/docs/ACMG_Releases_Highly-Anticipated_Recommendations_on_Incidental_Findings_in_Clinical_Exome_and_Genome_Sequencing.pdf (last accessed July 24, 2013). See, too, Parens et al, note 30 above.

> [T]he Working Group has recommended that when a report is issued for clinically indicated exome and genome sequencing, a minimum list of conditions, genes and variants should be routinely evaluated and reported to the ordering clinician who can place them into the context of that patient's medical and family history, physical examination and other laboratory testing. We have recommended that these findings be reported without seeking preferences from the patient and family and without limitation due to the patient's age….The Working Group recognizes that this list should, and will, evolve as further empirical data are collected on the actual penetrance of these variants, and on the health benefits and costs that might follow from their disclosure as incidental findings.[33]

Recognising that its recommendations 'may be seen to violate existing ethical norms regarding the patient's autonomy and "right not to know" genetic risk information',[34] the College defends its position in the following terms:

> [Given that the minimum list] is weighted toward conditions where prevalence may be high and intervention may be possible, we felt that clinicians and laboratory personnel have a fiduciary duty to prevent harm by warning patients and their families about certain incidental findings and that this principle supersedes concerns about autonomy, just as it does in the reporting of incidental findings elsewhere in medical practice.[35]

So long as patient autonomy is reduced to patient *preferences*, the College's position might be justifiable. However, if patients have a Gewirthian based *right* not to know, the College's position, however well-meaning, is irrational.

What if a patient, having been told about the return of incidental findings where variants are on the minimum list, objects and wishes to exercise their right not to know? According to the College, the only options for such a patient (with, as the College would have it, such preferences) are either to 'decline clinical sequencing if they judge the risks of possible discovery of incidental findings to outweigh the benefits of testing'[36] or to agree to the clinical sequencing on the College's standard minimum list terms. If the NHS were to adopt this approach in its 100,000 genomes project[37], we take it that it would not only be Gewirthians who would protest about such a violation of patients' rights to be treated.

Returning to the context of *research*, suppose that the terms and conditions for participation in a particular study were to adopt a non-negotiable feedback policy along the lines of the College's minimum list. For prospective participants, the choice is to participate on these terms or not at all. If a prospective participant, not wishing to have such feedback, was then excluded from the study, would this be a violation of his or her rights? Although concerns are sometimes

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33 Green, note 32 above, at 19-20.

34 Green, note 32 above, at 11.

35 Ibid.

36 Ibid.

37 http://www.guardian.co.uk/science/2012/dec/10/1000000-peoples-dna-mapped (last accessed July 25, 2013).

expressed about willing participants being unfairly excluded, and although exclusion would frustrate one of the would-be participant's projects, there would be no violation of the agent's generic rights. Whether there was some violation of a contingent right would depend on the context, on what was reasonably expected, and the like.

(iii) Informing third parties

In the context of third-party interests, McLean observes quite correctly that '[j]ust as genetic information may devastate those who willingly seek it out, so too it may harm those who did not search for it but who are provided with it nonetheless in their purported interests.'[38] This prompts the following question: Do researchers have a responsibility to inform third parties (for example, genetically-related members of a participant's family) where they have findings that bear on the health and well-being of the latter? If the question were put to an English court, it is quite likely that, even if the liability of researchers to participants had been recognised, liability to third parties would be denied—judges would simply be too nervous about over-extending liability and burdening researchers. Moreover, liability would probably be denied on the ground that the relationship between researchers and third parties, unlike that between researchers and participants, lacked sufficient proximity. However, from a Gewirthian perspective, there is no obvious reason to deny third parties positive rights against researchers, including a right to have individual feedback arising from the research project—whatever a lack of 'proximity' might mean to common lawyers, it does not resonate in the same way for Gewirthians. Nevertheless, as McLean's remarks foreshadow, even from this perspective there are some complex issues of principle and practice.

To start with one of the issues of principle: what is the position if the participant has exercised their right not to know? Clearly, the participant (unless specially authorised to act for third parties) has no right to exercise the rights of third parties: if the participant elects to have no feedback, this cannot entail that there is no feedback for third parties. Therefore, it is perfectly possible that, while a participant elects to have no feedback, a third party might have elected to have feedback if they had been asked. This gives rise to two questions: first, what is the right thing for researchers to do where they cannot give feedback to a third party (whose position on feedback is not known) without informing a participant who has elected to have no feedback; and, secondly, if the views of third parties are registered when participants are enrolled, does this mean that some prospective participants might be unfairly excluded because they cannot accept the feedback policy in relation to third parties?

The first question returns us to our discussion on consent. There, we suggested that a defensible default for researchers might be to give feedback to a participant whose will is not known where the condition is clinically actionable. Other things being equal, this might also be a plausible default in relation to a third party. However, we are now assuming two complicating factors: one is that researchers cannot give feedback to the third party without violating the participant's rights (the participant having elected not to be informed)[39]; and the other is that, without

38 McLean, note 1 above, at 222.

39 This has the makings of a question of competing or conflicting rights of the kind that we discuss in the next sub-section below. If the participant and the third party each rely on a 'right to be informed' (one not wanting to be informed, the other wanting to be informed), the question is one of competing rights; if, however, we characterise the participant's right as a different 'right not to be informed', the question is one of conflicting rights—a case of the participant's 'right not to be informed' coming into conflict with the third party's 'right to be informed'.

knowing the position of the third party, giving feedback might or might not be in line with the will of the third party. At best, researchers would violate the rights of the participant and inform the third party in a way that is in line with the latter's will. At worst, they would act in a way that was in line with neither the will of the participant rights-holder nor that of the third-party rights-holder. On balance, respecting the rights and the known will of the participant seems like the more defensible default.

The second question, concerning the exclusion of prospective participants, takes us back to our recent discussion about genetics and the minimum list. There, we suggested that there is no generic right to participate; but there might be context-dependent contingent rights. Here, there is no reason to change that view.

(iv) Conflicting and competing rights

Rights theories are commonly rejected on the ground that they cannot handle questions of conflicting or competing rights. We should note that there is a difference between competing rights (where each agent, A and B, pleads the same right R, for example, in relation to a scarce resource) and conflicting rights (where agents A and B each plead a different right); but critics maintain that rights theory collapses when presented with either kind of case. Certainly, unless a rights theory holds that conceptually rights cannot conflict (in which case rights are recognised rather sparingly and then specified very precisely) there has to be a strategy for dealing with conflicts. Briefly, where rights compete, the spirit of Gewirthian ethics is to try to give priority to the agent whose need (as expressed by the right) is the greater; and, where rights conflict, the strategy is to try to give priority to the right that ranks as more important relative the generic needs of agents.

To start with competing rights, consider again a hypothetical case in which a participant has exercised her right to be informed by indicating that she does not wish to have feedback (for example, about a predisposition to cancer) but a related third-party has exercised the same right by registering a wish to have feedback. Where it is not possible to inform the third-party without also informing the participant, it is not at all obvious which right should prevail. Possibly the context will indicate that the generic needs of one agent are greater than those of the other; but, on the face of it, their needs are much the same. If there really is nothing to choose between the parties, it might be necessary to resort to some secondary and contingent considerations—for example, the view in the community might be that, because the participant is actually assisting the researchers, it is only fair that the researchers should tip the balance in her favour.

Moving on to conflicting rights, those who favour a 'no feedback' policy often point out, quite correctly, that giving feedback involves opportunity costs for the researchers. The more time that researchers spend on feedback, the less time that they will spend on the research project and the longer it will take for, say, a new drug or diagnostic test to be developed. Suppose that this is presented as a conflicting rights issue, with the participant's right to have feedback opposed by the rights of agents generally to have beneficial health-related research come to fruition. However, barring some exceptional circumstances, agents surely do not have a *generic* right that others undertake health-care research, let alone research that is tailored to their particular needs. If this is correct, the generic right to be informed prevails. Granted, if we examine the way in which a particular research study is funded, we might detect certain expectations about the delivery of health-care benefits. Even so, these contingent expectations cannot overcome generic rights unless the rights-holders have consented. It seems likely,

therefore, that the generic right to be informed is going to be difficult to overcome when supposedly conflicting rights are set against it.

(v) Relationship with privacy and anonymisation

Article 1 of Directive 95/46/EC, to which the UK gives effect via the Data Protection Act 1998, requires the processing of personal data to be consistent with fundamental rights and freedoms of data subjects (those whose personal data is being processed), especially the right to privacy. Recital 26 of the Directive states that the principles of data protection do not apply to data rendered anonymous, by which it means data rendered so that the data subject cannot be identified from it directly or indirectly (e.g., by use of a code) by anyone without disproportionate effort. Article 8 of the Directive prohibits the processing of sensitive personal data (which includes data on the health of the data subject), unless certain conditions are satisfied. Now, according to the jurisprudence of the European Court of Human Rights, Article 8 of the European Convention on Human Rights (ECHR) (the privacy right) is engaged whenever data on a person's health is processed without the explicit consent of the data subject.[40] This means, though this is not clear from either the Directive or the Data Protection Act, that data on a person's health may not be processed without the explicit consent of the data subject unless conditions laid down in Article 8.2 ECHR are satisfied if the instruments in question are to be compatible with the ECHR.

Recital 26 of the Directive has, however, led many, including the UK's Information Commissioner,[41] to consider that privacy is fully protected by rendering personal data anonymous and that doing so places the data outside of the remit of the Directive. However, there are circumstances in which rendering personal data anonymous (in the way that Recital 26 of the Directive specifies) will violate the right to privacy, or if not that, then some other fundamental right, unless the consent of the data subject is obtained.[42] From what we have argued in this paper, this is fully in line with what the PGC requires, and will include cases where the data, if it can still be connected to the patient, could be used to treat the patient, or warn the patient of a serious health-threatening risk, while rendering the data anonymous renders this impossible.

In relation to this, it should be noted that rendering data anonymous is itself, per both the Directive and the UK Act, a process performed on personal data, which means that it is something that needs the consent of the patient, in relation to which, where anonymisation is

40 See the case of *M.S. v. Sweden* (1997) 28 EHRR 313, paragraphs 34–35.

41 See the Information Commissioner's guidance of 2012 'Data Protection: Anonymisation: managing data protection risk code of practice ' especially at page 11 (available at http:/www.ico.org.uk/for_organisation/data_protection/topic_guides/) (last accessed September 14, 2013).

42 To be sure, the Information Commissioner recognises that, especially in medical research the use of personal data might be necessary (see ibid. 13). But the Information Commissioner confuses matters by asserting in the summary to the guidance (also available at http:/www.ico.org.uk/for_organisation/data_protection/topic_guides/) that while there are circumstances in which the ECHR will render it inappropriate to use anonymised data, these do not affect the Data Protection Act. This is false because the Data Protection Directive (see Article 1.1), and, therefore the UK Act (if properly implemented) exist to protect the rights of individuals under the Convention in relation to the processing of personal data. Processing that violates the ECHR will also violate the Directive.

contemplated, the patient needs to be informed of the consequences of anonymisation (including whatever consequences this might have in relation to the right to be informed).

V Conclusion

To return to our starting point, in an important contribution to the jurisprudence of medical law, Sheila McLean charts the failure to bring informed consent into alignment with the requirements of autonomy. We take it to be implicit in McLean's critique, first, that respecting the autonomy of persons (whether patients or research participants) is fundamentally right and, secondly, that it would not be appropriate to remedy the legal pathology by weakening our valuation of autonomy.

Reading McLean's critique from our Gewirthian perspective, we share her vision of flourishing agency—that is, the vision of agents acting autonomously in the sense that they freely choose and pursue their own projects and purposes. However, none of this is possible without the generic conditions of agency being secured and respected. Accordingly, the moral imperative for the law is to ensure that, in all its articulations—in its primary respect for autonomy and well-being as well as in its treatment of informed consent—it is compatible with the generic needs of agency.

The question of whether researchers should give clinically significant feedback to their participants brings into focus the positive (informational) rights of agents in relation to their generic needs.[43] If the law is to keep faith, not only with the autonomy of agents, but more fundamentally with the protection of the generic conditions that are presupposed by the myriad autonomous choices made by agents, it cannot routinely accept that 'no feedback'[44] is a legitimate position for researchers to specify in their protocols. If a failure to give a participant feedback is also a failure to respond to the generic needs of the agent in question, then the law should require the withholding of feedback to be justified by reference to one or more of three kinds of reasons: (i) that the right to be informed is not engaged—for example, because giving feedback is 'disproportionate' relative to the researcher's own generic needs, or the participant is in a position to gain the information without any acts of assistance; (ii) that giving feedback would be contrary to the will (consent) of the participant; or (iii) that giving feedback to the participant would be to infringe an even more important right of another agent. The law has good reasons to take seriously the claim that researchers have a responsibility to give feedback; but there can also be good reasons for judging that, in a particular case, the giving of feedback is not required or even permitted.[45]

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43 Throughout *Autonomy, Consent and the Law*, McLean maintains that there is no deep opposition between individual and relational conceptions of autonomy, that agents might freely choose to act in a way that recognises their responsibilities to, so to speak, 'connected' others. From a Gewirthian view, it is clearly the case that agents might freely choose to act in this way. However, the optionality of such 'relational' action should not be taken out of context: where the generic rights (both negative and positive) of other agents are engaged, autonomy is necessarily circumscribed by agency responsibilities.

44 In either of the senses that we identified in Part II.

45 Roger Brownsword wishes to make it absolutely clear that this chapter, exploring the implications of Gewirthian ethics for giving feedback to research participants, is co-authored in his personal capacity and in no sense represents the views of the Ethics and Governance Council of UK Biobank.