

Testing Times Ahead?

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Please note that this is the accepted version of the paper (with original title).

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Introduction

About twenty years ago, it was discovered that placental cell free DNA can be detected in the blood of pregnant women. Following this discovery, it is now possible to use a simple blood test—so-called ‘non-invasive prenatal testing’ (NIPT)—to ascertain, at a relatively early stage of a pregnancy, genetic information about both the woman and the fetus. On the face of it, NIPT represents a significant addition to the reproductive options that are available to women (and their partners).¹ However, the question raised by the development of NIPT is not whether it is legitimate for women to make their own (informed) reproductive choices, but whether (or which of) the choices now facilitated by NIPT are ‘legitimate’ ones for women to have.²

In this article, our first, and principal, purpose is to review the Nuffield Council on Bioethics’ (NCOB’s) report on *Non-Invasive Prenatal Testing: Ethical Issues* (the Report)³, a report that

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We are grateful for the many helpful comments made by the referees. Needless to say, the usual disclaimers apply.

¹ For the sake of economy, we will not keep repeating ‘and their partners’, but it should be taken to be implicit.

² The initial choice is whether or not to have the test, then whether or not to be informed as to the results, and then which of the post-result options (including further tests and deciding whether or not to terminate the pregnancy) to take.

³ Nuffield Council on Bioethics, *Non-invasive prenatal testing: ethical issues* (London, March 2017); and, for a helpful background paper, see Vardit Ravitsky, ‘Non-Invasive Prenatal Testing (NIPT): Identifying Key Clinical, Ethical, Social, Legal and Policy Issues’: available at

takes a relatively conservative position in relation to the permissible uses of NIPT. Secondly, we introduce two more general questions provoked by the Report, one concerning the nature and extent of the informational interests that are to be recognised in today's 'information societies' and the other concerning the membership of today's 'genetic societies'. Thirdly, at a time when the NCOB is undergoing a process of 'renewal', we ask what kind of bioethics body the Council is and aspires to be.

Our central criticism of the Report is that, while it lays out very clearly a range of competing individual and collective interests that might bear on one's view as to which uses of NIPT are legitimate, it misses the opportunity to put these interests into an order of importance that would explain and justify why the Council takes the particular view that it does. In the light of this criticism, we suggest that the Council should develop such an order of importance (and we sketch how this might be done); or, failing that, we argue that the Council should present its reflections in a way that engages public debate around a number of options rather than making firm recommendations.

We start by sketching the context in which the NCOB has undertaken its work on NIPT. Then, we turn to the Report, focusing on its ethical framework, its recommendations, and its effective implementation. This leads to the two more general questions prompted by the Report. Finally, we consider the methodology and role of the NCOB. We suggest that at every level—for pregnant women, for communities, for the NCOB, and for regulators—there are challenging times ahead.

The Context for the Report

Early in 2016, following a successful trial led by Professor Lyn Chitty at Great Ormond Street Hospital,⁴ the UK National Screening Committee announced that it would recommend the cautious piloting of NIPT within the existing screening programme for Down syndrome.⁵ Stated simply, pregnant women will be initially screened using the so-called combined test⁶; then, those who are identified as being significantly at risk will be offered NIPT. While women who have a negative NIPT result can avoid the more invasive tests for Down syndrome (namely, amniocentesis or chorionic villus sampling), those women with a positive NIPT result will be advised to have one of these tests. If NIPT lives up to its promise, reducing the number of more invasive tests and, concomitantly, the number of babies lost during pregnancy, its advocates will wonder what there is not to like about this new option.

<http://nuffieldbioethics.org/wp-content/uploads/NIPT-background-paper-8-Nov-2015-FINAL.pdf> (last accessed April 27, 2016).

⁴ <http://www.rapid.nhs.uk/about-rapid/evaluation-study-nipt-for-down-syndrome/>.

⁵ See J. Gallagher, 'Safer Down's test backed for NHS use' (<http://www.bbc.co.uk/news/health-35311578>).

⁶ This test combines information from a serum screen with a measurement from an ultrasound scan of the nuchal fold on the back of the neck of the fetus.

Nevertheless, some will oppose NIPT because they see it as exacerbating existing concerns about the ‘medicalisation’ of pregnancy, the ‘commodification’ of life, the ‘trivialisation’ of decisions about abortion, the ‘routinisation’ of prenatal testing, and the ‘stigmatisation of disability’, and so on.⁷ In addition to such concerns, however, there is a new anxiety that stems from the potential use of NIPT to provide information about the fetus that goes beyond Down syndrome and the other trisomies,⁸ even to the point of full genomic profiling, as well as returning information about the mother.⁹ There are also some questions about the accuracy, reliability, and interpretability of the test. While NIPT is extremely reliable in relation to Down syndrome, it is a bit less reliable in relation to Edwards’ and Patau’s syndromes;¹⁰ and, in the case of some chromosomal microdeletions (missing genetic information) and microduplications (additional duplicated genetic information), the results may be equivocal and hard to interpret.

If NIPT were to be available only within the NHS, regulators might be reasonably confident that they could control its availability and application. However, private sector providers of the test already offer a range of information which, in our connected on-line environments, is only an email away. Accordingly, in practice, there are reasons to doubt the ability of national regulators to confine private providers to the particular terms and conditions for use of NIPT that they (the regulators) might specify.¹¹ National regulators might find that they are whistling in the wind.

It was in this context that the Nuffield Council on Bioethics set up a Working Group (chaired by Professor Tom Shakespeare) ‘to consider the ethical, legal and regulatory implications of recent and potential future scientific developments in NIPT, with regard to its use in both NHS and commercial services, including for whole genome/exome sequencing’.¹² Although the Working Group did not treat their remit as an invitation to review the current law on abortion, the relatively permissive legal framework for terminations is central to the context in which NIPT is being discussed. To be sure, some of the points for discussion concern the way in which the information yielded by NIPT might impact on women and future children;

⁷ See (2015) 29:1 *Bioethics* (special issue on NIPT).

⁸ For example, Sequenom’s MaterniT 21 PLUS ‘can tell you if you are having a boy or a girl, and screens for both common and rare chromosomal abnormalities. The test screens for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), trisomy 13 (Patau syndrome), and many others that can affect your baby’s health’: see <https://sequenom.com/tests/reproductive-health/maternit21-plus#patient-overview> (last accessed April 5, 2017).

⁹ See, e.g., K. Oswald, ‘Prenatal blood test detects cancer in mothers-to-be’, *Bionews* 739 (2015) at http://www.bionews.org.uk/page_503998.asp. (last accessed September 25, 2016).

¹⁰ Report (n 3), para 1.18 et seq.

¹¹ Compare, e.g., the experience of the HFEA: see, Shaoni Bhattacharya, ‘HFEA to investigate claims of poor practice in UK fertility sector’ *BioNews* 899 (2017) at http://www.bionews.org.uk/page.asp?obj_id=839506&CView=188645#ULBM-839551 (last accessed February 24, 2018).

¹² Report (n 3), Terms of reference, p. x.

but the core of the debate is about how such information might impact on the pattern of terminations. Indeed, if the law were less permissive, there might be less agitation about NIPT and less pressure to stake out a restrictive position.

That said, even if we believe that the full range of the law relating to reproduction needs to be up for discussion, the Report is likely to be a point of reference in both the bioethical literature and in public debates about NIPT.¹³

The Report

In this part of the article, we will focus on: (i) the values that the Council presents as its ethical starting points; (ii) the application of the values to a range of ‘interested’ parties; (iii) three guiding principles that the Council specifies as a response to the perceived tensions in the ethical values and their application to NIPT; (iv) the Council’s recommendations as to the availability and use of NIPT; and, (v) the effective implementation of these recommendations. We will then undertake a short stock-taking.

To avoid any misunderstanding, we should make it clear that, in this part of our discussion, we are not challenging the Council’s ethical axioms—we are not arguing that the Council has started in the wrong place. Rather, we are trying to clarify its starting points and then to trace out how they help us to engage with the central contested question: namely, which uses of NIPT—from testing simply to be informed through to testing as a precursor to a termination—should be treated as legitimate options?

(i) The Council’s ethical starting points

As we will explain later in the article, the Council does not subscribe to a particular bioethical view. For each report, an operative ethical framework is declared. However, this is not a case of the Council taking, say, a utilitarian approach in one report and then a Kantian or a communitarian approach in another. The Council simply does not relate to professional bioethics in this way. Rather, the ethical framework for each Report is a product of the views expressed by consultees together with the views formed by the particular Working Party. Accordingly, in the Report, which was preceded by extensive consultation, we read that the Council’s ‘ethical starting points’ are given by ‘the values of choice, autonomy and consent; avoidance of harm; and equality, inclusion and fairness.’¹⁴ We might hear echoes in this of Beauchamp and Childress’ principlism¹⁵ but no more than that: the ethics in this Report are bottom-up and bespoke.

¹³ See, e.g., the motion put forward for debate by the Bishop of Carlisle at the Annual Meeting of the General Synod of the Church of England on February 10, 2018: available at <https://www.churchofengland.org/sites/default/files/2018-01/GS%202078%20-%20Agenda%20%28February%202018%29.pdf> (last accessed February 10, 2018).

¹⁴ Report (n 3), para 1.55.

¹⁵ Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (7th ed) (Oxford: Oxford University Press, 2013).

Choice, autonomy and consent

It is not entirely clear how the Council understands each of ‘choice’, ‘autonomy’, and ‘consent’ or the relationship between them. However, following the landmark decision of the UK Supreme Court in *Montgomery v Lanarkshire Health Board*,¹⁶ few will dispute that, in reproductive settings, it is right to take seriously the autonomy of pregnant women, their choices, and their consent.¹⁷ In fact, after *Montgomery*, it is easy to argue that, in reproductive contexts, women should be aware of the clinical options that are available to them and be free to make their own choices. On the face of it, these considerations push in favour of making NIPT available to pregnant women. However, there is still much to clarify about autonomy, choice, and consent.¹⁸

First, if a woman’s choice is to be treated as *autonomous*, it really must be *her own* choice. Although the idea of one person, A, making her own choice is incompatible with another person, B, making the choice for A (unless, of course, A’s choice is to authorise B so to act), or with B coercing A to make a particular choice, the web of relationships in which A finds herself might make it difficult to determine whether B, or other persons, are influencing A’s decision in a way that compromises it being her own choice. Such hard cases notwithstanding, the Council might want to argue that *autonomous* choice is valuable in and of itself, that there are clear cases where women are not making their own choices, and that it is right to do what we can to protect and restore autonomy (both on paper and in practice).¹⁹

Secondly, if the necessary and sufficient conditions for A making an autonomous choice (in relation to some act) are that A chooses on a free and informed basis, then choices can be

¹⁶ [2015] UKSC 11. See, e.g., R. Heywood, ‘R.I.P. *Sidaway*: Patient-Orientated Disclosure—A Standard Worth Waiting For?’ (2015) 23 *Medical Law Review* 455; and Roger Brownsword and Jeff Wale, ‘The Right to Know and the Right Not to Know Revisited’ (2017) 9 *Asian Bioethics Review* 3.

¹⁷ Although, if we take ‘a public health perspective’, matters might be much less straightforward: see Vardit Ravitsky, ‘The Shifting Landscape of Prenatal Testing: *Between Reproductive Autonomy and Public Health*’ (2017) 47 *Hastings Center Report* (Issue Supplement S3) S34-S40. According to Ravitsky, the debate about NIPT has been dominated by a reproductive autonomy rationale; but, there is also a largely unspoken public health rationale which is guided by the societal consequences of reproductive choices and the overall impact of individual decisions on the health of future populations.

¹⁸ See, e.g., Roger Brownsword. ‘Autonomy, Delegation, and Responsibility: Agents in Autonomic Computing Environments’ in Mireille Hildebrandt and Antoinette Rouvroy (eds), *Autonomic Computing and Transformations of Human Agency* (London: Routledge, 2011) 64 (for three conceptions of autonomy with different implications for the relevance of choice); and John Coggon and José Miola, ‘Autonomy, Liberty, and Medical Decision-Making’ (2011) CLJ 523 (particularly for the distinction between autonomy qua self-governance or making one’s own choices and liberty qua freedom to act without third-party interference or having a ‘real’ option).

¹⁹ Compare Emily Jackson and Shelley Day-Sclater, ‘Introduction: Autonomy and Private Life’ in Shelley Day-Sclater, Fatemeh Ebtehaj, Emily Jackson, and Martin Richards (eds), *Regulating Autonomy: Sex, Reproduction and Family* (Oxford: Hart, 2009) 1 at 2: ‘protecting autonomy may not only involve simply an *absence* of state interference, but could require the positive provision of resources to enable someone to have a meaningful set of options.’

autonomous without having to be prudent, rational, reasonable, or moral.²⁰ However, if we want to regulate the choices that are available to women—which the Council clearly does—then the focus of debate about NIPT is not so much on the autonomy of women but on the range of reproductive options that we judge to be permissible. It is the value of choice, or of particular choices, rather than the value of autonomy that is the ‘hot spot’ in this debate.

Thirdly, if we have a background bioethical theory, what we make of consent—like what we make of autonomy and legitimate choices—will be shaped by that theory.²¹ Given, however, that the Council does not subscribe to any particular school of bioethics, this is just the kind of theory that it does not have. Nevertheless, following *Montgomery*, we can take it that, in clinical settings, a consent will not be adequate unless it satisfies conditions relating to freedom, information, capacity, and signalling.²² If we then transpose these conditions to our understanding of *autonomous* choice, we will agree with the Council that autonomous choices are predicated on having relevant information (which, in the case of NIPT, means having access to ‘accurate, balanced and non-directive information’²³ about the test) as well as being free from improper pressure, duress, and the like.²⁴

Summing up, the triplet of choice/autonomy/consent is perhaps best read as supporting the interest of pregnant women in receiving appropriate information about NIPT, as well as the condition for which it is proposed that the test should be used, and then being left to make their own choice about whether or not to have the test. However, this is all subject to the proviso that the options involving the use of NIPT are legitimate. For the Council, *autonomous* choice might be valued but that is not to say that all *choices* are valued.

Avoidance of harm

While it is axiomatic that clinicians should ‘do no harm’,²⁵ the import of the Council’s second starting point is far from self-evident. As the Council itself emphasised in one of its earlier and most reflective reports,

²⁰ We might recall Lord Donaldson’s famous remarks in *Re T* [1992] 4 All ER 649, at 652-653 (to the effect that adult patients, with capacity, have the absolute right to choose, meaning that this right is not limited to making choices that others would regard as sensible or rational).

²¹ For the way in which apparently ‘neutral’ terms such as ‘consent’ are coloured by the particular bioethical background theory that operates them, see Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2008).

²² See, Deryck Beyleveld and Roger Brownsword, *Consent in the Law* (Oxford: Hart, 2007).

²³ Report (n 3), para 1.59.

²⁴ Report (n 3), para 1.62. Coggon and Miola (n 18), referring to *Al Hamwi v Johnston and Another* [2005] EWHC 206, make the important point that the chooser also needs to have an adequate understanding of the information.

²⁵ See, e.g., Sheila McLean (ed), *First, Do No Harm* (Festschrift for Ken Mason) (Aldershot: Ashgate, 2006).

the concepts of ‘benefit’, ‘harm’, ‘better’, ‘poorer’, etc are ambiguous and the nature and likelihoods of different outcomes arising from biotechnologies uncertain, and frequently contested.²⁶

Even if we set aside the notorious vagueness in the concept of harm,²⁷ it is important to know relative to whom or relative to what the harm in question is to be avoided.

The Council indicates that the avoidance of harm might mean ‘restricting access to NIPT in order to protect women from coming to harm’.²⁸ However, it also contemplates that the harm to be avoided might relate to ‘others’ and that this ‘may mean limiting the freedom to access NIPT in some circumstances in order to protect the fetus, or to prevent harm to wider society.’²⁹ If we link this back to the idea that it is right to leave women to make their own reproductive choices, provided that these are legitimate choices; and if we take it that choices that occasion harm to the woman making the choice, or to a fetus or to wider society are not legitimate; then we might wonder just how many options (on paper, let alone in practice³⁰) will be left for women autonomously to choose.

To the extent that the ‘avoidance of harm’ is designed to ensure that women make their own reproductive choices, there is no restriction on the choices that are available. However, if the ‘avoidance of harm’ is designed to ensure that women (with capacity) avoid making choices that others judge to be contrary to their best interests, or that might be harmful to unborn or future human life, or that might be harmful to society, this invites a host of objections (including objections to paternalistic and illiberal restriction on the choices available)³¹ and difficult questions (concerning, for example, the moral status of the fetus,³² the status of

²⁶ Nuffield Council on Bioethics, *Emerging biotechnologies: technology, choice and the public good* (London, 2012), para 10.4(d).

²⁷ Compare, e.g., Roger Brownsword, ‘Cloning, Zoning, and the Harm Principle’, in Sheila McLean (ed) (n 25) 527, and ‘A Simple Regulatory Principle for Performance-Enhancing Technologies: Too Good to be True?’, in Jan Tolleneer, Pieter Bonte, and Sigird Sterckx (eds) *Athletic Enhancement, Human Nature and Ethics: Threats and Opportunities of Doping Technologies* (Heidelberg: Springer, 2012) 291.

²⁸ Report (n 3), para 1.67.

²⁹ Report (n 3), para 1.67.

³⁰ See Roger Brownsword, ‘Law, Liberty and Technology’ in Roger Brownsword, Eloise Scotford, and Karen Yeung (eds), *The Oxford Handbook of Law, Regulation and Technology* (Oxford: Oxford University Press, 2017) 41.

³¹ See, e.g., Stephen Wilkinson, *Choosing Tomorrow’s Children* (Oxford: Clarendon Press, 2010) at 11 (on the standard Millian limiting principle).

³² A question to which, of course, there are several possible answers. See para 5.2 of the Report (n 3).

future generations, the causal link between individual choices and harmful impacts on wider society, and where the burden of justification lies).³³

To pause over just one objection, the avoidance of ‘harm to wider society’ could relate to many different kinds and degrees of harm to human interests. While it is one thing to restrict reproductive autonomy and choice in order to prevent catastrophic harm to the conditions for human existence, it is quite another to restrict it because this is the majority’s preference in a particular community. In due course, we will follow this up by suggesting that, unless some hierarchy is developed within the Council’s ethical starting points, the question of which reproductive options are legitimate will be left to a ‘balancing’ exercise that is more intuitive and pragmatic than principled.³⁴

Equality, fairness and inclusion

Equality, like autonomy, can be conceived of in more than one way³⁵ and, indeed, what one makes of the compatibility of equality with autonomy and choice depends very much on how one understands these concepts. Potentially, the Council’s third ethical starting point, like its second, bears in a restrictive way on the range of reproductive options that should be left available for the autonomous choice of women.

In its introductory remarks, the Council says that equality starts with the idea that the State should respect ‘the equal value of all people’ and this is backed by the aspiration to cultivate ‘a fair and inclusive society.’³⁶ According to the Report, while the equality agenda has been taken forward in relation to gender (and reproductive choice) and the status of disabled people, it remains a cause for concern that ‘disabled people in the UK do not currently have access to the same opportunities as those without disabilities and continue to be discriminated against, excluded and marginalised.’³⁷ The implication is that whatever equality (and other) arguments there might be in support of making NIPT available in the public health service, the State should do nothing to add to the existing failure to treat disabled people in a fair and fully inclusive way.³⁸

³³ On this last point, compare John A. Robertson, *Children of Choice: Freedom and the New Reproductive Technologies* (Princeton, NJ: Princeton University Press, 1994) (presumption in favour of procreative liberty, with the burden on opponents to demonstrate the harmful effects of some particular reproductive technique).

³⁴ See, further, our discussion at pp xxx below.

³⁵ See, e.g., John McMillan and Jeanne Snelling, ‘Equality: Old Debates, New Technologies’ in Brownsword et al (n 30) 69.

³⁶ Report (n 3), paras 1.71-1.73. Even, it seems, to the point of including those who are merely potential future persons.

³⁷ Report (n 3), para 1.77.

³⁸ Compare Erik Parens and Adrienne Asch, ‘The Disability Rights Critique of Prenatal Genetic Testing —Reflections and Recommendations’ (1999) 29 *Hastings Center Report* S1-S24; and Tom Shakespeare, *Disability Rights and Wrongs* (Abingdon: Routledge, 2006).

Pulling these threads together, these starting points suggest that, while it is right to let women make their own legitimate reproductive choices, such choices should not include the use of NIPT where this would be harmful to women, to the fetus or a future child, or to wider society, particularly by compromising the ideals of equality, fairness and inclusivity.

(ii) The impact of NIPT on ‘interested’ parties

As the Council rightly says, what we make of NIPT rather depends upon whose perspective we take—that of ‘pregnant women and couples, future people that fetuses might become, disabled people, [or] wider society.’³⁹ For some, the impact of NIPT will be positive, but for others it will be negative.

The most obvious beneficiaries of NIPT are pregnant women and couples, whose reproductive choices (and equality) promise to be enhanced. However, this is subject to the general proviso that the context supports the making of a free and informed choice (coupled with the choosing agent being able freely to act on their choice)—otherwise there might be more choice but not enhanced *autonomous* choice. It is important, for example, that the information given to pregnant women about NIPT is accurate and reliable (including whether or not the information yielded by the test itself is accurate and reliable); and the Council suggests, too, that reproductive autonomy might be compromised if the information given about the impact of genetic variations on disabled people and their families, as well as information about medical or societal attitudes towards disability, is inaccurate or unreliable.

By contrast, while pregnant women might be harmed by NIPT—at any rate, if the context for free and informed choice is defective in some way, or if the test fails or proves to be inaccurate, unreliable, or inconclusive⁴⁰—the more obvious harm is to both the (terminated) fetus (unless one subscribes to the view that, at the relevant time, the fetus has no moral standing) and the (non-terminated) fetus-that-becomes-a-person (to some extent consequent on the loss of an ‘open future’⁴¹ and infringement of the right not to know but also arising from infringements of that person’s privacy). While disabled persons are not immediately and directly harmed by NIPT, they might suffer incremental and indirect harms, such as psychological harm arising from what they perceive as a negative valuation of them, less research into the genetic conditions that underlie the disabilities, and fewer services for (as well as discrimination against) a now reduced population of disabled persons. Furthermore, if the popular perception of disability changes in a way that leads to people being blamed for

³⁹ Report (n 3), para 5.3.

⁴⁰ Report (n 3), para 5.10.

⁴¹ Report (n 3), para 5.6. Seminally, see Joel Feinberg, ‘The Child’s Right to an Open Future’ in Joel Feinberg (ed), *Freedom and Fulfillment: Philosophical Essays* (Princeton: Princeton University Press, 1992) 76. See, too, Wilkinson (n 31), at 47 (cautioning that talk of a child’s right to an open future ‘is not terribly helpful, both in general and a fortiori when discussing selective reproduction scenarios in which the putative rights bearers do not even exist yet’) and at 47-54 (for the way in which various concerns about the autonomy of a future child might be implicated in such talk).

having a baby with a disability, then this ‘might make disabled people and their families more vulnerable to discrimination, stigma or abuse.’⁴²

Finally—although the Council does not express it in quite these terms—there are perspectives that reflect one’s view of the kind of society to which one wants to belong.⁴³ For example, one might think that it is unfair to expend scarce public health care resources in order to inform pregnant women about non-serious conditions or non-medical traits; or one might object to a change in what is considered to be a healthy pregnancy or a healthy child that is less inclusive; and, for similar reasons, one might oppose any movement towards eugenics.⁴⁴ Beyond such matters, the Council also notes a concern about NIPT being used to facilitate the birth of designer babies, such concern possibly reflecting a positive view of inclusion, but which might also be inspired by the kind of conservative dignitarian ethics that has been so opposed to the commodification or the commercialisation of life.⁴⁵

Given this plurality of perspectives, the key challenge for the Council is to articulate a concept of legitimate reproductive choice in a way that accommodates the interests of pregnant women and couples, the interests of the fetus-that-becomes-a-person, the interests of disabled persons, and the interests of wider society with its collective aspirations for equality, fairness and inclusion.

(iii) Three guiding principles

The Council suggests that policy-making should be guided by the following three principles⁴⁶:

Principle 1 (P1): The wider societal environment in which NIPT is provided and developed should be considered when developing policy relating to NIPT.

Principle 2 (P2): Pregnant women and couples should have access, where appropriate, to NIPT within an environment that enables them to make autonomous, informed choices.

⁴² Report (n 3), para 5.18. Compare Martin B. Delatycki, ‘The Ethics of Screening for Disease’ (2012) 44(2) *Pathology* 63, at 65, where the author notes that ‘when a child is born with trisomy 21, parents have reported being questioned about why the diagnosis was not made during the pregnancy and steps take to prevent the birth of that child.’

⁴³ See Parens and Asch (n 38).

⁴⁴ Compare the cautionary remarks in Ravitsky (n 17); and, see Wilkinson (n 31) Ch 6.

⁴⁵ See, e.g., Roger Brownsword, ‘Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the “Dignitarian Alliance”’ (2003) 17 *University of Notre Dame Journal of Law, Ethics and Public Policy* 15.

⁴⁶ Report (n 3), paras 5.24-5.37.

Principle 3 (P3): Efforts should be made to reduce any risks of significant harms posed by growing use and development of NIPT.

While P2 is designed to promote an environment for the exercise of free and informed reproductive choices—including ensuring that ‘accurate, balanced and non-directive information is made available to women and couples in both the private and public sectors’⁴⁷—P1 and P3 are intended to set limits on such choices. In P1, the ‘wider societal environment’ stands for the community’s aspiration that its members should be treated equally, fairly, and in an inclusive manner—an aspiration that, in part, militates against the use of NIPT ‘for less significant medical conditions and impairments, non-medical traits, and whole genome and exome sequencing;⁴⁸ and, in P3, the ‘risks of significant harms’ relate to ‘the autonomy, privacy, rights and other interests of future children and people, who should be able to make their own choices regarding information about their genetic makeup, to access the same opportunities and services as those who know nothing about their genetic makeup, and to live a life in which their future is open.’⁴⁹

Applying these principles, a compromise is brokered. On the one hand, autonomy and choice is privileged over inclusivity: for, even with some tilting of the informational environment in which choices about NIPT are being made, a woman might still decide to have NIPT and to act on its results by terminating her pregnancy. On the other hand, the avoidance of harm and the promotion of inclusivity are privileged over autonomy and choice: NIPT should not be used to test for conditions that are not significant (whether minor medical conditions or non-medical traits) or where there is a risk of significant harm to a future person.

However, the fundamental question remains: the compromise recognises only some choices as legitimate but in what sense is this really principled?

(iv) The Council’s recommendations

Broadly speaking, the Council’s overarching conclusions are as we might expect.⁵⁰ They focus on three things: first, supporting the conditions that constitute the context for pregnant women to make autonomous reproductive choices with regard to the use of NIPT; secondly, supporting a social environment where disabled persons are valued as equals, and treated fairly and inclusively; and, thirdly, limiting access to and use of NIPT where the informational interests of pregnant women are relatively insignificant and are outweighed by the interests of future persons.

Although it is recommended that the UK National Screening Committee should take ‘better consideration of the particular psychological, ethical and social consequences, some of which

⁴⁷ Report (n 3), para 5.31.

⁴⁸ Report (n 3), para 5.28.

⁴⁹ Report (n 3), para 5.37.

⁵⁰ Report (n 3), p. 126.

will be unintended, of any prenatal screening programme where termination of pregnancy is an option',⁵¹ the Council supports the piloting of NIPT within the national screening programme for Down syndrome. There is also a clutch of recommendations concerning NIPT in the private sector, including that the 'Committee of Advertising Practice should more closely monitor the marketing activities of NIPT manufacturers and private hospitals and clinics to ensure that they are not misleading or harmful'; that NIPT providers should seek certification from recognised information quality schemes; and that private hospitals and clinics 'should only offer NIPT as part of an inclusive package of care that should include, at a minimum, pre- and post-test counselling and follow-up invasive diagnostic testing if required.'⁵²

The Council, however, recommends two limits on the use of NIPT that invite further discussion: first, that NIPT should be offered only if it provides an accurate prediction of whether the fetus has or does not have the condition being tested for; and, second, that NIPT should 'not normally' be used to check 'whether a fetus has a less significant medical condition or impairment or an adult onset condition; to find out whether the fetus is the carrier of a gene for any kind of medical condition or impairment; [or] to reveal non-medical traits of the fetus, including sex.'⁵³

Accuracy

The first limiting recommendation discourages the return of findings that are difficult to interpret or that cannot be acted on with any confidence. While the Council is not alone in thinking that such findings should not be returned, it is not clear how this view sits with the value of reproductive autonomy or a pregnant woman's right to know. In support of a restriction relating to the return of such findings, the following three justifications might be offered.

First, it might be said that findings that are not reliable, accurate, interpretable and actionable are not worth having. To strike such findings from the list of NIPT options makes no difference to a pregnant woman's *autonomy* and the choices that are not available are not worth having. This, however, ignores the wishes of women who want to know simply for the sake of knowing⁵⁴ or who want to bank the results pending a time when they are more interpretable and actionable (albeit not during their current pregnancy).

Secondly, the argument might be that women might be harmed by irresponsible providers who are willing, without giving fair warning, to return inaccurate or non-interpretable, or non-actionable results, possibly leading to some psychological anxiety and economic loss.

⁵¹ Report (n 3), para 6.33.

⁵² Report (n 3), p. 126.

⁵³ Ibid. The Council also concludes that NIPT should not normally be used for whole genome or exome sequencing of fetuses except in a research environment.

⁵⁴ See, Z. Deans, A.J. Clarke, and A.J. Newson, 'For your interest? The ethical acceptability of using non-invasive prenatal testing to test "purely for information"' (2014) 29 *Bioethics* 19.

Such a consumer protection justification for the restriction might be supplemented by concerns about possible consequential costs to publicly-funded health care.

Thirdly, the second argument might be extended to focus on possible harm to the fetus that becomes a future person. However, those who argue for a robust right to know might wonder why a (current) woman's informational interests should have to yield for the sake of the informational interests of (i) a fetus that might or might not become a future person and (ii) when the results of the test might or might not be ones that, in future, can be relied on.

Although there is some intuitive appeal in the proposition that inaccurate findings should not be returned, the question is whether the option to use NIPT knowing that the results might not be accurate and reliable is a legitimate one. Saying that the results will not be useful is hardly compelling; saying that the results might be harmful to the woman is paternalistic; and saying that the results might harm a fetus that might or might not become a future person invites further analysis and debate.

The type of condition

There is much that might be said in relation to the second limiting recommendation but we will make just four points.

First, the recommendation presupposes that the results obtained by NIPT are likely to be used to inform a woman's choice about the continuation or termination of her pregnancy. While this is not an unreasonable assumption, it presents a danger of losing sight of the question of whether it is legitimate to know simply for its own sake or for the sake of forward planning (but not termination).⁵⁵ For example, in those communities where there is pre-conception genetic testing of teenage children (to inform the latter about their carrier status),⁵⁶ a pregnant woman's use of NIPT to check for carrier status in her child might be viewed as a perfectly legitimate option. Similarly, although late onset conditions can present hard cases for any bioethicist,⁵⁷ it is one thing to want to be aware that a future person has the markers for such a condition and quite another to want to know (as was the case with the claimant in *ABC v St George's Healthcare NHS Trust & Ors*⁵⁸) as a precursor to a possible termination.

⁵⁵ See Deans et al (n 54).

⁵⁶ See Human Genetics Commission, *Increasing options, informing choice: A report on preconception genetic testing and screening* (London, April 2011).

⁵⁷ Compare Deryck Beyleveld, Oliver Quarrell and Stuart Toddington, 'Generic Consistency in the Reproductive Enterprise: Ethical and Legal Implications of Exclusion Testing for Huntington's Disease' (1998) 3 *Medical Law International* 135.

⁵⁸ [2015] EWHC 1394 (QB), [2017] EWCA Civ 336. In the ABC case, the claimant, who was pregnant at the relevant time, sued the defendants, complaining that they had failed to inform her that her father had been diagnosed with Huntington's Disease. Had the claimant been so informed, she would have known that she was at risk of having the disease and, knowing that her child would also be at risk, she would have terminated the pregnancy. In the High Court, the claim was struck out on the ground that, because the defendants obtained the information about the father's health status in

Secondly, there is a sense that the proposed restrictions are made in the shadow of the existing law on abortion. Not only does this shadow obscure the question of whether a woman may legitimately want to know simply for its own sake, but also the Report brackets off the legitimacy of the law (and whatever shadow it casts). So, for example, when it is recommended that NIPT providers should be prohibited from generating or reporting information about the sex of the fetus unless ‘there is concern that the fetus may be showing signs of a significant sex chromosome aneuploidy or is at risk of a sex-linked disorder’⁵⁹, NIPT is being viewed as a precursor to a termination (rather than information pure and simple about the sex of the child) and questions about what the law on social sex selection actually is and what it ought to be are off the table.⁶⁰

Thirdly, the distinction between significant and less significant medical conditions is central to the recommendation. No doubt, there will be plenty of questions about how to draw this distinction, including whether a significant condition is the same as a ‘serious’ condition or a ‘severely disabling’ condition. However, there is once again a danger of losing sight of the distinction between a woman simply wanting to know and her wanting to know in order to decide whether to terminate her pregnancy. Arguably, a woman has a right to use NIPT to detect conditions such as CF or, say, hypertrophic cardiomyopathy⁶¹ regardless of whether they are characterised as significant or less significant medical conditions. Whether or not NIPT should be used to test for such conditions as a precursor to a decision about continuing or terminating a pregnancy is another matter.

Fourthly, if we are to make an adequate assessment of the recommendation, we need to be critically aware not only of the law on abortion but of the full spectrum of the regulatory environment relating to reproductive information and choice. From PGD to NIPT, there needs to be a narrative that both explains and justifies who can be tested for what, how and by whom the test is to be administered, what information is to be returned, and who pays for

confidence, and because the father was emphatic that he did not want his daughter to be told, it would not be fair, just, and reasonable to impose on them a duty to inform the daughter; but, the Court of Appeal reversed this decision and remitted the case for trial.

⁵⁹ Report (n 3), para 6.16.

⁶⁰ On what the law is, see Emily Jackson, ‘The legality of abortion for fetal sex’ in *Britain’s abortion law. What it says, and why* (Stratford-upon-Avon: BPAS, May 2013) 19, available at http://www.reproductivereview.org/images/uploads/Britains_abortion_law.pdf (last accessed February 11, 2018). To the extent that doubts about this matter turn on a lack of DoH guidance, compare Emily Jackson, ‘Abortion, Autonomy and Prenatal Diagnosis’ (2000) 9 *Social and Legal Studies* 467, 470-471, and Jeff Wale, ‘Don’t forget the legal framework: the public provision of non-invasive prenatal testing in England & Wales’ (2015) 15(4) *Medical Law International* 203, 211.

⁶¹ <https://www.bhf.org.uk/heart-health/conditions/cardiomyopathy/hypertrophic-cardiomyopathy> (last accessed July 15, 2017). This condition is a target for the use of the latest gene-editing techniques: see Ian Sample, ‘Deadly gene mutations removed from human embryos in landmark study’ *The Guardian* August 2, 2017 (available at <https://www.theguardian.com/science/2017/aug/02/deadly-gene-mutations-removed-from-human-embryos-in-landmark-study>) (last accessed August 3, 2017).

all of this.⁶² In short, the regulatory environment should be coherent.⁶³ However, this is no easy matter. Once we set the proposed restrictions on NIPT in this larger regulatory context, we soon meet the more general questions about the kind of community that we want to be that we will introduce later in the article.

(v) Effectiveness

In a world designed for regulatory effectiveness, regulators would know exactly what they planned to achieve, they would commit sufficient resources to all phases of the regulatory cycle, there would be no attempt by regulatees to corrupt or capture regulators, there would be no resistance by regulatees, and there would be no external interference. Needless to say, this is not our world, and it is certainly not the world in which the State might act on the Council's recommendations.

Insofar as it is accepted that NIPT should be offered subject to the Council's recommended terms and conditions, there would seem to be better prospects for effective implementation in the public sector than in relation to private sector provision. Even then, we should not assume that there will not be resistance to limited availability and use within the NHS. Already, for example, the UK National Screening Committee (UKNSC) has experienced significant resistance to its unwillingness to introduce routine screening for group B Streptococcus in pregnancy and, concomitantly, to make more use of antibiotics.⁶⁴ If, following its piloting of NIPT, the UKNSC adopts a restrictive policy to which there is significant opposition, it might find that its experience with the group B Strep community is repeated with a new lobbying group for NIPT.

However, with regard to the private sector provision of NIPT, there are additional factors that militate against effective implementation of the Council's recommendations. Most importantly, many private providers will have an online presence. As the Council acknowledges, any attempt to restrict access to NIPT in order to determine the sex of a fetus might be ineffective 'given the possibility of accessing NIPT services in other countries or via the internet'.⁶⁵ It seems that, while we might endlessly debate the rights and wrongs of particular uses of NIPT, we should lower our expectations about the effective implementation

⁶² Nb the seminal critique of the regulatory environment for reproduction in Emily Jackson, 'Conception and the Irrelevance of the Welfare Principle' (2002) 65 MLR 176; and for some important cautions about equating PGD with Prenatal Testing, or an embryo with a fetus, see Rosamund Scott, 'Choosing between Possible Lives: Legal and Ethical Issues in Preimplantation Genetic Diagnosis' (2006) 26 OJLS 153.

⁶³ On which, see Roger Brownsword, 'Regulatory Coherence—A European Challenge' in Kai Purnhagen and Peter Rott (eds), *Varieties of European Economic Law and Regulation: Essays in Honour of Hans Micklitz* (Heidelberg: Springer, 2014) 235.

⁶⁴ See, in particular, the lobbying activities of the Group B Strep Support campaign (<http://gbss.org.uk/campaigning/parliament/contact-your-mp/>) and its response to the latest consultation on the matter by the UK National Screening Committee (<http://gbss.org.uk/latest-news/say-group-b-strep-uk-national-screening-review/>) (both sites last accessed July 13, 2017).

⁶⁵ Report (n 3), para 4.48.

of any policy that impinges on the reproductive choices that pregnant women—or, at any rate, pregnant women with sufficient resources—might want to have.

Significantly, there is already evidence—confirmed by the Council’s own review⁶⁶—that online information about NIPT falls short of what is required for the proper exercise of reproductive autonomy. For instance, there is evidence that commercial test providers are pitching their online communications above the recommended reading age for public health information,⁶⁷ and that some commercial web advertising may contain inadequate or outdated information⁶⁸ (the latter being a particular risk when technology advances so quickly). Whilst the threat of deliberate miss-selling or fraud might be unlikely, it is no surprise that commercial test providers tend to emphasise the benefits rather than the limitations of the technology in their marketing material.⁶⁹ Links to peer reviewed citations are not always present and this can make it difficult to evaluate the nature and currency of the claims made.⁷⁰ Further, private test providers do not always mention the specific abnormalities that can reliably be detected through conventional trimester screening,⁷¹ or the differentials in failure rates between different testing technologies.⁷²

That said, although there are challenges to effective implementation, the position is not completely hopeless.⁷³ After all, NIPT cannot be undertaken without blood being drawn and it might be possible to exert some domestic control over professional health care workers drawing samples for this purpose.⁷⁴ This apart, if regulators in the UK are to exert some

⁶⁶ See Report (n 3) at para 4.22 (for the Council’s own review of the adequacy of ‘information made available on the websites and in patient leaflets of manufacturers, hospitals and clinics’).

⁶⁷ MB Mercer, PK Agatista and RM Farrell, ‘What patients are reading about non-invasive prenatal testing: an evaluation of Internet content and implications for patient-centered care’ (2014) 34(10) *Prenatal Diagnosis* 986; JW Aarts et al., ‘Patient-focused internet interventions in reproductive medicine: a scoping review’ (2012) 18(2) *Hum Reprod Update* 211, at 212; and Heather Skirton et al., ‘Non-invasive prenatal testing for aneuploidy: a systematic review of Internet advertising to potential users by commercial companies and private health providers’ (2015) 35(12) *Prenatal Diagnosis* 1167.

⁶⁸ See Skirton et al (n 67); and Mercer et al (n 67).

⁶⁹ See Skirton et al (n 67) at 1174; and Mercer et al (n 67).

⁷⁰ The ARC website suggests that ‘to be of the highest quality, test performance data should be published in a peer reviewed scientific journal and should report pregnancy outcomes from studies involving 1000s of women.’ Available from: <http://www.arc-uk.org/tests-explained/non-invasive-prenatal-testing-nipt> (last accessed February 16, 2017).

⁷¹ See Mercer et al (n 67).

⁷² Yuval Yaron, ‘The implications of non-invasive prenatal testing failures: a review of an under-discussed phenomenon’ (2016) 36(5) *Prenatal Diagnosis* 391.

⁷³ Generally, see Roger Brownsword and Morag Goodwin, *Law and the Technologies of the Twenty-First Century* (Cambridge: Cambridge University Press, 2012) Ch 14; and Mark Leiser and Andrew Murray, ‘The Role of Non-State Actors in the Governance of New and Emerging Digital Technologies’ in Brownsword et al (n 30) 670.

⁷⁴ Report (n 3), paras 1.43, 6.7, and 6.40.

control over online provision of NIPT by providers who are based outside the jurisdiction, they need to have some leverage over the provider's assets or personnel or reputation within the UK (recall how, in *LICRA v Yahoo!*,⁷⁵ the Paris court managed to exert some influence over Yahoo!); or they need to persuade internet service providers, or other online intermediaries, to act as 'chokepoints', restricting supply of goods, services, or information from target sites;⁷⁶ or, there might be opportunities for various kinds of reciprocal cross-border enforcement or other forms of cooperation between national regulators⁷⁷—for example, there might be opportunities to develop co-operative global state engagement by agreeing guidelines in relation to the leading issues.⁷⁸

Perhaps more controversially, if private provision creates an unacceptable regulatory risk, publicly funded NIPT might be mooted. Potentially this would squeeze the private sector (even without formal abolition) although the extent of the squeeze would depend on the degree of service equivalence. Given that such an initiative would have significant resource implications,⁷⁹ a more realistic solution might be some form of public/private partnership that utilises the Council's proposed system of licensing, certification and professional body regulation/guidance.⁸⁰ The challenge for the State is to determine how far the informational interests of pregnant women are to be recognised and supported,⁸¹ and then to decide on the allocation of costs between the public and private sectors while maintaining a coherent public narrative and regulatory environment.⁸²

(vi) Taking stock

NIPT is new and it merits the kind of ethical attention that it is given by the Council. Nevertheless, seasoned commentators might view the Report as a continuation of old debates—for example, debates about the tension between reproductive autonomy and the

⁷⁵ https://en.wikipedia.org/wiki/LICRA_v._Yahoo! (last accessed February 26, 2017).

⁷⁶ Natasha Tusikov, *Chokepoints: Global Private Regulation on the Internet* (Oakland: University of California Press, 2016).

⁷⁷ See, e.g. Lawrence Lessig, *Code Version 2.0* (New York: Basic Books, 2006) Ch 15.

⁷⁸ See, for e.g., Heather Skirton et al., 'Offering prenatal diagnostic tests: European guidelines for clinical practice guidelines', (2014) 22(5) *Eur J Hum Genet* 580: (available at <http://www.ncbi.nlm.nih.gov/pubmed/?term=24022298>); and the proposed EU IVD Regulation (Report (n 3) at para 1.39).

⁷⁹ For discussion of the practical and financial difficulties of a publicly funded testing regime, see C Munthe, 'A New Ethical Landscape of Prenatal Testing: Individualizing Choice to Serve Autonomy and Promote Public Health: A Radical Proposal', (2015) 29(1) *Bioethics* 43.

⁸⁰ The Report (n 3), Ch 6, envisages a combination of healthcare and disciplinary regulation and agreement with NIPT providers and manufacturers.

⁸¹ Deans et al (n 54).

⁸² For discussion, see Wale (n 60).

interests of the disabled⁸³, or between individual autonomy and the common good,⁸⁴ and so on. After all, it was some years ago that John Robertson wrote:

[S]ociety must decide whether to permit these [new reproductive] techniques to be developed and used. It must identify the circumstances in which use should be restricted or regulated, and devise a framework for respecting individual desires for access while maintaining ethical values, protecting offspring and participants, and preventing injustice and oppression in their use. This is no small task. The deepest needs of individuals must be reconciled with community values in a setting where the rules are still unwritten and subject to change.⁸⁵

In other words, it might be said that the Report adds little to bioethics, recycling familiar arguments and taking a position that represents a relatively conservative compromise between principles and interests that are opposed.

Is this a fair comment? Certainly, one of the striking features of the Report is the double ethical push-back against NIPT. First, in support of the making of *autonomous* choices, the Report recommends that information about the limits of NIPT and about the actualities of disability should be given; and, secondly, the Report recommends that women's choices to use NIPT should be restricted except where the trisomies or other significant medical conditions are the target. This is a relatively conservative position and it will disappoint those who take a more liberal view. However, what is really missing from the Report is any compelling reason for taking such a position. Neither the ethical starting points nor the three guiding principles can do all the work in justifying this position. They can present the arguments, the tensions and the options; but they cannot of themselves determine how the balance of interests should be struck; they cannot tell us why, at the key points of opposition, one interest has more weight than another.

It might also be said that, even if the Council gave compelling ethical arguments for its conservative position, in practice, the use of NIPT will not be so limited. That might or might not prove correct. However, we can scarcely lay this kind of responsibility at the door of the Council. For ethics councils, just as for regulators and lawmakers, there are no guarantees that the standards that are proposed and adopted are actually effective.

Two General Questions: Informational Interests and Genetic Characteristics

Whatever we make of the Council's particular recommendations about the use of NIPT, we should not lose sight of the bigger picture. For, the Report implicates more general questions about the kind of society we want to be. Moreover, it does so at a moment of intense

⁸³ See, e.g., Rosamund Scott, 'Prenatal Testing, Reproductive Autonomy, and Disability Interests' (2005) 14 *Cambridge Quarterly of Healthcare Ethics* 65.

⁸⁴ See, e.g., Day-Sclater et al (n 19).

⁸⁵ Robertson (n 33) at 3.

technological disruption⁸⁶, when we find ourselves living in ‘information societies’ but without a settled sense of the ‘informational interests’⁸⁷ that we should recognise. At the same time, we inhabit ‘genetic societies’—this, as the Chief Medical Officer has put it, is the era of ‘Generation Genome’⁸⁸—but without having a settled sense of how genetics fits with our traditional values. While some of our questions about genetics are informational questions, most vividly captured in our attempts to stabilise and ground the claimed rights to know and not to know⁸⁹—or, as in the ABC case, establishing the circumstances in which A’s duty to respect the confidentiality of medical information obtained from B may legitimately be overridden in order to prevent harm to C⁹⁰—others are of a quite different order, concerning who we are and what we might be. From a potentially long agenda for discussion, we can speak briefly to the question of informational interests and then to the bearing of genetic testing and selection on reproductive policies that aspire to treat all humans equally, fairly and inclusively.

Our informational interests

For some time, it has been clear that our twentieth-century understanding of our informational interests needs to be reassessed.⁹¹ That understanding, developed in the context of a certain state of technological development⁹², centres on our interest in treating some information as private (as no one’s business other than our own) and our having control over the circulation of such information (if and when it is disclosed). However, this interest in individual restriction and control now comes into tension with the general benefits that are to

⁸⁶ See Brownsword et al (n 30).

⁸⁷ Broadly speaking, we can treat our informational interests as relating to the integrity of the informational eco-system as well as to our individual ability to control the outward and inward flows of information that relate directly to ourselves. See, further, Roger Brownsword, ‘Infosoc 2018: Informational Rights, Informational Wrongs, and Regulatory Responsibilities’ Bournemouth University Working Papers in Law, No 1/2018.

⁸⁸ *Annual Report of the Chief Medical Officer 2016: Generation Genome*: available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/624628/CMO_annual_report_generation_genome.pdf (last accessed July 15, 2017).

⁸⁹ See, e.g., R. Chadwick, M. Levitt, and D. Shickle (eds), *The Right to Know and the Right Not to Know* (Cambridge: Cambridge University Press, 2014); Roger Brownsword and Jeff Wale, ‘The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions’ (2016) 24 *Jahrbuch für Recht und Ethik* 31; Roger Brownsword, ‘New Genetic Tests, New Research Findings: Do Patients and Participants Have a Right to Know—and Do They Have a Right Not to Know?’ (2016) 8 *Law, Innovation and Technology* 247; and Brownsword and Wale (n 16).

⁹⁰ (n 58).

⁹¹ See, e.g., Roger Brownsword, ‘Informed Consent in the Information Society’ (2012) *Health and Society Review* 161, and ‘Guidelines for our Genomic Futures’ (2012) 20 *MEDIC (Methodology and Education for Clinical Innovation—New Series)* 179.

⁹² For a fascinating account of the development of information and communication technologies, see James Gleick, *The Information* (London: Fourth Estate, 2011).

be obtained if only information might flow more freely. So, for example, in a recent contribution to the Chief Medical Officer's Annual Report, we read:

The success of genomic medicine will depend on patients having confidence that the way genomic information is generated, held and used will properly protect their interests. This requires re-examining the traditional rules around confidentiality, which focused on secrecy and the keeping of information as separate and private.⁹³

Moving into the present century, however, the main disruptions to privacy and confidentiality were presented, not by genomics, but by the IT infrastructures that support not only health care research but also vast swathes of commerce. While the requirement that the processing of personal data (in these new IT environments) should be fair and lawful, purpose-specific, and proportionate, might sound reasonable enough, there are huge problems in applying this standard in contexts that are as different as health care research and popular entertainment. With the recent developments in machine learning and AI, there are further pressures: it is one thing to turn a blind eye to the lack of proper notice and consent with regard to the collection and processing of data that enables recommender systems to profile consumers, quite another to do so when the Royal Free London NHS Foundation Trust agrees with Google DeepMind to transfer more than a million patient records to the latter in order to facilitate the development of a clinical alert app for acute kidney injury.⁹⁴

Beyond rethinking which informational interests should be recognised, there is a need to rank the importance of particular interests relative to not only non-informational interests but also inter se. For example, if the ABC case⁹⁵ does go to trial, the judge will have to determine whether the claimant's interest in accessing information about her father's medical condition prevails against the defendant's responsibility to respect the confidentiality of the information at issue. The case for prioritising the claimant's interest is not that the information will advance the collective interest in health care research. This is a case about reproductive autonomy and the traditional value of confidentiality. Whichever way we frame it, this is a tough call for any judge and, equally, a tough call for any community.

Currently, we strive to specify our informational rights by asking whether it is a 'reasonable expectation' that the particular benefit or protection that we claim should be enjoyed, employing various reference points (in the positive law, in practice, in inter-personal signals, in accepted concepts and values, and so on) to determine whether or not an expectation is

⁹³ Anneke Lucassen, Jonathan Montgomery, and Michael Parker, 'Ethics and the Social Contract for Genomics in the NHS' in *Annual Report of the Chief Medical Officer 2016: Generation Genome* (n 88) Ch 16, page 3.

⁹⁴ For criticism, see Julia Powles and Hal Hodson, 'Google DeepMind and healthcare in an age of algorithms' *Health Technology* (March 16, 2017) DOI 10.1007/s12553-017-0179-1. The Information Commissioner duly ruled that the agreement did not comply with data protection law: see <https://iconewsblog.wordpress.com/2017/07/03/four-lessons-nhs-trusts-can-learn-from-the-royal-free-case/> (last accessed July 7, 2017).

⁹⁵ (n 58).

‘reasonable’.⁹⁶ However, to recall one of our earlier remarks (in connection with the idea of harm to the wider society), an expectation might be reasonable because it relates to: (i) the preservation or protection of the preconditions for *human* existence or the essential context for *any* form of human *social* existence; or (ii) respect for the values that are fundamental to, and constitutive of, a *particular* form of human social existence;⁹⁷ or (iii) a plausible balancing of the conflicting, but legitimate, interests and preferences of different members of the community. To deny an expectation that relates to (i) would be unreasonable and irrational; to deny an expectation that relates to (ii) would be unreasonable unless an equivalent competing expectation can be advanced; and to contest an expectation that relates to (iii) is to engage in the everyday negotiation of legitimate but conflicting interests. In other words, we need to differentiate explicitly and systematically between expectations that are reasonable relative to the essential pre-conditions for *any* human social existence and expectations that are reasonable relative to positions and practices that already presuppose that these conditions are secured;⁹⁸ and we need to differentiate between expectations that draw on the values that make our particular community the distinctive community that it is and expectations that are argued for as reasonable in the routine processes of accommodating a plurality of interests.

So, the first step is to consider whether there are any informational interests that are implicated in the essential preconditions for any kind of human social existence. Arguably, there are. In particular, if we accept that, as prospective agents, humans need an environment in which they are able to exercise these distinctive capacities, this implies a context in which humans are able, *inter alia*, to freely choose their own purposes, plans, and projects (‘to do their own thing’) and to form a sense of their own identity (‘to be their own person’). The potential implication of informational interests is nicely expressed in a recent paper from the Royal Society and British Academy where, in a discussion of data governance and privacy, we read that:

Future concerns will likely relate to the freedom and capacity to create conditions in which we can flourish as individuals; governance will determine the social, political, legal and moral infrastructure that gives each person a sphere of protection through

⁹⁶ Compare Deryck Beyleveld and Roger Brownsword, ‘Research Participants and the Right to be Informed’, in Pamela R. Ferguson and Graeme T. Laurie (eds), *Inspiring a Medico-Legal Revolution* (Essays in Honour of Sheila McLean) (Farnham: Ashgate, 2015) 173.

⁹⁷ For example, concerning the value of human dignity, on which see Roger Brownsword, ‘Human Dignity from a Legal Perspective’ in Marcus Duwell, Jens Braavig, Roger Brownsword, and Dietmar Mieth (eds), *Cambridge Handbook of Human Dignity* (Cambridge: Cambridge University Press, 2104) 1. See, too, Elizabeth Wicks, *The State and the Body: Legal Regulation of Bodily Autonomy* (Oxford: Hart, 2016).

⁹⁸ See, further, Roger Brownsword, ‘From Erehwon to Alpha Go: For the Sake of Human Dignity Should We Destroy the Machines?’ (2017) 9 *Law, Innovation and Technology* 117; and, for a somewhat similar view, see Nicolas Petit, ‘Law and Regulation of Artificial Intelligence and Robots: Conceptual Framework and Normative Implications’ at 29-30: available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2931339 (last accessed February 17, 2018).

which they can explore who they are, with whom they want to relate and how they want to understand themselves, free from intrusion or limitation of choice.⁹⁹

In this light, we can understand not only why there is such a profound concern about intensive surveillance—whether George Orwell’s *1984*¹⁰⁰, the Chinese social credit system,¹⁰¹ or today’s dataveillance practices¹⁰²—but also about the informational restriction of an agent’s open future. Quite simply, the concern is profound because it goes to the integrity of the critical infrastructure on which human social existence is itself predicated.¹⁰³

Having worked out which informational interests need to be recognised and protected as part of the infrastructure for *any* human community, the debate can move on to consider which, if any, informational interests are to be privileged in our particular community. Here, bioethics becomes more local and potentially pluralistic; the values recognised as fundamental and constitutive by one community might differ from those of another (but, of course, all communities presuppose the same critical infrastructural conditions). Finally, we get to those legitimate interests and preferences that neither touch and concern the critical infrastructure for all human social communities nor the fundamental values of the particular community. Here, bioethics necessarily has to focus on facilitating acceptable compromise and accommodation rather than reminding communities of the preconditions and context for any purposeful activity or recalling the fundamental values to which the particular community has committed itself. None of this means that, in practice, communities will quickly agree on their scheme of informational interests but at least there will be some clarity about which questions should be asked and why one interest might be treated as more important than another.

Our genetic characteristics

How should the genomic generation square its new insights into human disease and, possibly, human behaviour with its approach, on the one hand, to human reproduction and, on the other, to disability, capability and enhancement?¹⁰⁴ Two strands in the Report span and

⁹⁹ The Royal Society and British Academy, *Connecting Debates on the Governance of Data and its Uses* (London, December 2016) 5.

¹⁰⁰ (Penguin Books, 1954) (first published 1949).

¹⁰¹ See, https://en.wikipedia.org/wiki/Social_Credit_System (last accessed July 17, 2017) (but nb the caveats about this entry)

¹⁰² Frank Pasquale, *The Black Box Society* (Harvard University Press, 2015).

¹⁰³ For an insightful commentary on the relationship between privacy and the context for (any kind of) agency, see Maria Brincker, ‘Privacy in Public and the Contextual Conditions of Agency’ in Tjerk Timan, Bryce Clayton Newell, and Bert-Jaap Koops (eds), *Privacy in Public Space* (Cheltenham: Edward Elgar, 2017) 64.

¹⁰⁴ Compare discussions about gene editing: see <https://www.horizondiscovery.com/gene-editing/crispr> (last accessed August 5, 2017); and, for the tension between enhanced reproductive autonomy and public health driven eugenics, see Ravitsky (n 17).

connect these matters. One is the importance attached to the future person having an open future and the other is the aspiration towards an equal, fair and inclusive society.¹⁰⁵

In the light of our preceding remarks, it will be understood that the preconditions for the self-development of agents include leaving a person to make their own life choices. One aspect of this is leaving it to the person to decide how much or how little they themselves wish to know about their genetic pedigree or profile (quite apart from having a view about whether such information should be recorded and stored or available to others); and, another is leaving it to the person to develop their own talents and tastes. If the reproductive process involves gathering genetic information about the fetus-that-is-to-become-a-person—and it is arguable that we have special (heightened) responsibilities to such a fetus, responsibilities that are quite distinct from whatever rights women might have to terminate or to continue with a pregnancy—then there is a concern that the context for the latter’s self-development might be compromised. Similarly, if the reproductive process involves careful selection of genetic features that are associated with particular skills and talents, then there is a concern that the ‘enhancement’ of the fetus will once again compromise the conditions for its subsequent self-development. As Henry Greely has suggested, it might not be too many decades before reproduction takes place in highly controlled conditions.¹⁰⁶ If so, society will need to decide a cascade of questions about how it wishes to reproduce and what kind of human it wishes to reproduce.¹⁰⁷

Open futures, however, are not the Council’s only concern. Quite rightly, the Council argues that new reproductive technologies should be applied in ways that are consistent with the aspiration for equality, fairness and inclusiveness.¹⁰⁸ At one level, that of the essential preconditions for human social existence, we are all in the same position. We all have an equal need for these conditions. However, at another level, once the preconditions are in place, we begin to contest our understanding of what is equal and fair and how far inclusivity should go. At this level, there will be a plurality of views and each community will have its own vision of an equal, fair and inclusive society. In some communities, it might be accepted that there is nothing unfair about permitting enhancement of an agent’s generic capacities; but, in others, where access to the relevant technologies is not equally enjoyed, such enhancement might be prohibited. However, even if the community’s aspirations for equality and fairness are satisfied, how does enhancement stand with its aspiration for inclusivity?

¹⁰⁵ Compare Scott (n 62) at 169-171 (on open futures) and at 172-174 (on minimising offence to the disabled).

¹⁰⁶ Henry T. Greely, *The End of Sex and the Future of Human Reproduction* (Cambridge, Mass., Harvard University Press, 2016).

¹⁰⁷ For polar opposites on the ethics of human enhancement, see John Harris, *Enhancing Evolution* (Princeton: Princeton University Press, 2007) and Michael Sandel, *The Case Against Perfection* (Cambridge, Mass.: Harvard University Press, 2007).

¹⁰⁸ Similarly, see Nuffield Council on Bioethics, *Cosmetic Procedures: Ethical Issues* (London, 2017).

One view is that it is not contradictory to treat enhancement as permissible or to adopt measures to reduce or even eliminate disabling genetic conditions while, at the same time, maintaining that those who are not enhanced or those born humans who are disabled should be fully respected.¹⁰⁹ Whatever any particular community makes of this view, it already hints at perhaps the most disruptive effect of new technologies, namely to encourage a shift from ex post response (to crime, to illness, to accidents, and so on) to ex ante prevention. In the emergent technocratic mind-set the dominant thought is this: if we have the technology to manage a particular risk, why not use it? Over time, technological management might displace humans from the workplace, even laws as we know them,¹¹⁰ and in reproductive contexts it might deselect those embryos and fetuses that do not conform to the approved standard of quality and fitness, or that are viewed as unacceptable risks. It might seem like a very long way from NIPT to autonomous vehicles and to predictive policing, but the direction of travel towards prevention and preclusion is unmistakable.¹¹¹

Neither the Council in its Report, nor we in this article, can resolve these important questions. These are matters that touch and concern not only the essential conditions for any viable human community but also the distinctive commitments of each particular society. Just as each human must determine what kind of person they aspire to be, it is for each community of humans to debate and determine what kind of society they collectively aspire to be. This a challenge that should be neither underrated nor ignored—the debate about NIPT is, so to speak, merely the tip of an iceberg.

The Role of the Council

For a quarter of a century, the Nuffield Council on Bioethics has played a key role in informing the public about new developments in science and medicine (particularly new developments in human genetics), in highlighting the ethical and regulatory issues to which these developments give rise, and in encouraging rational debate and deliberation about a range of emerging biotechnologies. In a world where trust is at a premium, the Council rightly enjoys an enviable reputation for its independence and its integrity.

Nevertheless, questions have been raised about whether the way that the Council traditionally operates is fully fit for purpose—witness, first, the Firetail evaluation of the Council¹¹² and, secondly, the setting up of a new Governing Board, sitting between the Council and the

¹⁰⁹ Compare Wilkinson (n 31) at 162.

¹¹⁰ See Roger Brownsword, ‘Technological Management and the Rule of Law’ (2016) 8 *Law, Innovation and Technology* 100.

¹¹¹ See Roger Brownsword, ‘In the Year 2061: From Law to Technological Management’ (2015) 7 *Law, Innovation and Technology* 1.

¹¹² See, <https://nuffieldbioethics.org/wp-content/uploads/Nuffield-Council-on-Bioethics-Evaluation-2015.pdf> (last accessed July 16, 2017). The evaluation singles out the Council’s reports as one of its great strengths but also as a source of its perceived weakness. The problem is that the Council takes time to select its topics; and then it often takes a couple of years to produce a report. Some ‘stakeholders’, it seems, would like the Council to be more agile and quicker in its work.

Funders¹¹³, which is tasked with reviewing the Council's 'work, remit and delivery.'¹¹⁴ In this context, we can highlight two major challenges for the Council, one intellectual, the other political.

The intellectual challenge centres on the Council's general adherence to what Harald Schmidt and Jason Schwartz term a 'flexible-focus'—as opposed to a 'rigid-grid'—approach.¹¹⁵ In contrast with the latter, the 'flexible-focus' approach 'does not impose ethical principles or norms in a top-down fashion, but identifies them anew for each topic or report.'¹¹⁶ Underlying this approach is the Council's commitment to inclusiveness (no single view or approach to bioethics should be favoured, and the expression of all views should be encouraged), to rationality (all arguments should be capable of being heard but should be submitted to tests of coherence and rationality) and to rigour (the work of the Council should be based on the best evidence available, and supported by careful and comprehensive analysis).¹¹⁷ The rationality and rigour, however, are engaged only after a range of voices has been inclusively heard.

In the case of the Report on NIPT, the Working Group starts with a set of values which are then systematised by the three guiding Principles. Given its 'flexible-focus' approach, the Council is under no pressure to start from rights or utility rather than duty, or to major on the idea of solidarity,¹¹⁸ or vulnerability, or human dignity, or genetic identity (which is discussed in the mitochondrial DNA report)¹¹⁹ or stewardship (which features prominently in both the report on public health¹²⁰ and the recent report on cosmetic procedures¹²¹), or to cross-refer to the ethics laid out in the contemporaneous report on gene editing.¹²² Taking its

¹¹³ The Nuffield Foundation, the Medical Research Council, and the Wellcome Trust.

¹¹⁴ See <http://www.nuffieldfoundation.org/news/professor-dame-sally-macintyre-appointed-first-chair-governing-board-nuffield-council-bioethics> (last accessed July 16, 2017).

¹¹⁵ Harald Schmidt and Jason L Schwartz, 'The Missions of National Commissions: Mapping the Forms and Functions of Bioethics Advisory Bodies' (2016) 26 *Kennedy Institute of Ethics Journal* 431, at 435. One exception, noted by Schmidt and Schwartz, at 436, is the report on the ethics of genetically modified crops where the Council declares that it is taking a broadly utilitarian approach.

¹¹⁶ Schmidt and Schwartz (n 115), at 443. Cf the 'rigid-grid' approach of the Human Genetics Commission: see Human Genetics Commission, *Inside Information* (London, 2002).

¹¹⁷ Strategic Plan 2012-2016 p 4: see http://nuffieldbioethics.org/wp-content/uploads/2014/06/Strategic_Plan_2012-20161.pdf (last accessed July 16, 2017).

¹¹⁸ See Barbara Prainsack and Alena Buyx, *Solidarity: reflections on an emerging concept in bioethics* (London: Nuffield Council on Bioethics, 2011).

¹¹⁹ Nuffield Council on Bioethics, *Novel techniques for the prevention of mitochondrial DND disorders: an ethical review* (London, 2012), at 55-57.

¹²⁰ Nuffield Council on Bioethics, *Public Health: Ethical Issues* (London, 2008).

¹²¹ Nuffield Council on Bioethics (n 108), e.g. at paras.7.19-7.21.

¹²² Nuffield Council on Bioethics, *Genome editing: an ethical review* (London, 2016). It should be noted, however, that the exercise in this report was somewhat preliminary being designed only to 'uncover the

particular approach, the Council, as Schmidt and Schwartz put it, assumes ‘more the role of an editor or publisher, leaving the question of the extent to which deeper normative issues need to be addressed to the initiative of the working group.’¹²³

Put starkly, the question is whether the Council can take its commitment to rationality any deeper and whether, at the same time, it can develop a greater coherence and consistency across the body of its work. Without such depth, coherence, and consistency, sceptics might wonder why we should take the Council’s bioethical contributions seriously. Moreover, the Council is liable to find itself on the back foot in engaging with those scientists and technologists who think that their sphere of hard facts is where we find the terra firma of rationality. To be sure, the Council adds gravitas and some structure to bioethics, sharpening and organising the views of its consultees; but, so the criticism might go, it looks like one set of opinions is mediated by the working groups before being endorsed by the Council.

Relating this to the balancing of competing interests which is central to the Report on NIPT, there is a problem, as we have said, about advocating a particular balance without offering a view about the ranking and weight of particular interests. If the Council could articulate a defensible tiered scheme of interests, it would have reason to push hard for its views; but, without that kind of rational underpinning, arguably, it should stick to presenting the options.

This leads to the other challenge which is more political in nature. At a time of major developments in the life sciences and their associated technologies, there are important conversations for each community to have. However, there is more than one way in which the Council might relate to these conversations. For example, the Council might follow its own advice in its report on emerging biotechnologies¹²⁴ when, in the context of developing a public discourse ethics (oriented to the public good), it recommended that

expert deliberation and public engagement exercises should report their conclusions not in the form of simple prescriptive findings but as a properly qualified ‘plural and conditional’ advice.¹²⁵

Taking this approach, the Council would see ‘the public’ as its principal audience; where recommendations are made, they would be presented as starting points for public debate—at most as a candidate common position in our pluralistic democracy; and, the impact of the Council’s reports would be measured, not so much by their translation into government policy, but by their contribution to the quality, reflectiveness, and rationality of public debate

grounds of moral reasoning that are currently in play in the discourse around genome editing’, see para 3.1.

¹²³ Schmidt and Schwartz (n 115), at 448.

¹²⁴ Nuffield Council on Bioethics (n 26).

¹²⁵ Nuffield Council on Bioethics (n 26), para 10.8. According to the Council, at para 10.6, the task of public discourse ethics is to find ‘the terms of an unbiased and open engagement between relevant positions and interests so that it is not captured by particular interests or interpretive frames’. Compare, too, the Nuffield Council on Bioethics (n 122), esp. paras 3.19-3.20.

and deliberative democratic decision-making. Alternatively, the Council might see itself as more of a player in policy circles than as a facilitator of public debate. Taking this approach, the Council would target key policymakers as its audience; its reports and recommendations would be sharpened to serve as scripts ready for immediate adoption by policymakers;¹²⁶ and, the measure of its impact would be whether its views were reflected in government policy and practice.

For our own part, we favour the former model. Unlike many other countries, the United Kingdom does not have a national bioethics council and, at a time of unprecedented technological disruption, the Council's non-partisan facilitation of reflection on the public good would be more valuable than ever. However, the viability of this model is subject to a number of conditions: one is that this is actually the vision that the funders have for the Council; a second is that the new governance arrangements do not compromise the possibility of the Council acting as independent facilitators; and a third is that the Council resists the temptation to demonstrate 'impact' by closing down options that need to be kept open or by advocating too hard for recommendations that are clearly contestable (whether because they are not evidence-based¹²⁷ or because, normatively, they are not sufficiently robust).¹²⁸

In a world where emerging technologies are disruptive in both positive and negative ways¹²⁹, the Council has made a significant contribution to public deliberation and to helping communities to focus on doing the right thing (emphasising that the fact that 'we *can* do x' does not entail that 'we *should* do x'). If the process of renewal helps the Council to do this better, then that is all to the good; but, if the renewal signals a change of direction for the Council, then we should reserve judgment until we know precisely what role it is playing.

Concluding remarks

In this article, we have reviewed the Nuffield Council on Bioethics' Report on NIPT, particularly the ethical framework that is developed to guide the Council's recommendations on the legitimate use of NIPT; we have begun to sketch the bigger picture implicated by the Report, introducing two general questions arising therefrom, each of which speaks to the kind of community that we distinctively want to be; and we have offered some short reflections on the renewal of the Council itself and the role that it might play in society.

¹²⁶ Whether or not such scripts and their recommendations are adopted, and how they are adopted, is quite another matter: see, e.g., W.G. Runciman, 'An Outsider's View of the Criminal Justice System' (1994) 57 MLR 1, 8.

¹²⁷ Compare Report (n 3) para 6.12, where the Council concedes that 'in many areas there is a lack of evidence relating to the risk of harms, what those harms might be and the extent of those harms.'

¹²⁸ Compare Bruce Bimber, *The Politics of Expertise in Congress* (Albany: State University of New York Press, 1996) charting the rise and fall of the US Office of Technology Assessment and drawing out some important tensions between 'neutrality' and 'politicisation' in the work of such agencies.

¹²⁹ See, Brownsword et al (n 30).

Our view of the Report is that the ethical framework does not, and cannot without more, justify taking a particular position where the relevant considerations are in tension. The Council takes a relatively conservative view but it would face precisely the same problem if it had taken a more liberal view. So long as the question of the legitimate use of NIPT is framed in terms of finding a balance between various competing interests, there is no compelling reason for striking one balance rather than another. Without some sense of the relative importance of the various interests, there are just too many apparently ‘reasonable’ or ‘not unreasonable’ positions to be struck. In our remarks on the bigger picture, we have given some indication of how we might approach the importance of different human interests so that we can identify some positions as categorically unreasonable, others as inconsistent with a community’s fundamental values, and others as within the range of reasonableness. If, following its renewal, the Council could help the community to engage with new technologies against this kind of backcloth of human needs and interests, it would play an even more important role in stimulating and guiding public deliberation. Failing this, the Council should be slow to make hard recommendations but, instead, should focus on facilitating public engagement by making clear that there are a number of options to be considered and then choices to be made.

As things stand, we find ourselves in a period of transition, of ‘inbetween-ness’, and of uncertainty—indeed, in a period of ‘liminality’ of just the kind that is being researched by Graeme Laurie and his team at Edinburgh.¹³⁰ First, it remains to be seen whether the conservative recommendations in the Report will be acted on and will actually hold the line. Secondly, there are already new research findings about the accuracy of NIPT¹³¹ and questions being raised about how best to offer the test.¹³² Thirdly, the ‘piloting’ of NIPT within the NHS Fetal Anomaly Screening Programme, leaves its status somewhere between ‘research’ and ‘implementation.’ Fourthly, while public health providers make up their minds about NIPT, private provision of the test is subject only to the usual market rules. Fifthly, NIPT finds itself caught between a public health paradigm (with a mission for collective health and well-being) and a paradigm of reproductive autonomy and patient-centred health care (with a prospectus for individual rights).¹³³ Sixthly, with some now making an ambitious call for ‘a broad renegotiation of the social contract for medical research and medical practice

¹³⁰ See, e.g., Samuel Taylor-Alexander, Edward S. Dove, Isabel Fletcher, Agomoni Ganguli Mitra, Catriona McMillan, and Graeme Laurie, ‘Beyond regulatory compression: confronting the liminal spaces of health research regulation’ (2016) 8 *Law, Innovation and Technology* 149.

¹³¹ See Timothy J. Lee, Daniel L. Rolnik, Melody A. Menezes, Andrew C. McLennan, and Fabricio da Silva Costa, ‘Cell-free fetal DNA testing in singleton IVF conceptions’ *Human Reproduction* 15 February 2018, available at <https://doi.org/10.1093/humrep/dey033> (last accessed February 19, 2018), suggesting that NIPT might be less reliable and accurate in relation to singleton IVF foetuses than those conceived spontaneously.

¹³² Particularly involving the so-called ‘reflex’ method: see <http://nuffieldbioethics.org/news/2017/nuffield-council-bioethics-raises-concerns-reflex-prenatal-screening> (last accessed February 26, 2018).

¹³³ Compare Ravitsky (n 17).

in the NHS',¹³⁴ there is an opening for engagement with the more general questions that we have identified. Last but not least, the NCOB itself is in transition and there is a questionmark about its future role. On all fronts, we conclude that there are testing times ahead.

¹³⁴ Lucassen et al (n 93) at 12.