

# Regulating disruptive technology and informational interests in the arena of reproductive tests

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## Introduction

You are informed that a test has been devised that could identify your genetic profile and be used to predict future potential, flaws, characteristics, traits and health. You might see this development as a positive advance but what if the resultant information could be accessed not just by your family but also healthcare providers and future educators, employers and insurers? Would you welcome the creation and implementation of this technology or might there be concern about the informational implications for current and future generations? Would it make any difference if you discovered that this technology already exists, that it can be used by prospective parents to establish information about their unborn child and is widely available in the commercial sector in over sixty countries globally?<sup>1</sup>

This paper seeks to address the impact of this new technology – called non-invasive prenatal testing (NIPT) - that enables access to whole range of genetic and other information about the unborn child via a maternal blood sample during the early stages of pregnancy. Although this technology throws up a whole host of issues,<sup>2</sup> the specific focus of this paper concerns the potential impact on and possible regulation of related informational interests. The paper is divided into five distinct parts. In part one, we introduce the new technology, the underlying rationales for implementation and identify the specific informational issues posed by NIPT. In part two, we examine possible informational interests and focus on a range of arguments addressing access to these tests and to information about the unborn child. In part three, we consider how we might address any competing informational interests in this context. In part four, we move on to examine a range of possible regulatory responses both on the domestic and international front, before making some closing remarks about the challenges presented by NIPT in part five.

Our core conclusions in this paper are threefold. First, the informational interests that we recognise (whose and which interests we recognise) and which we prioritise speak to the kind of society that we want to be. Secondly, we should not assume that it will be easy to regulate for the kind of society that we want to be and there are no guarantees of regulatory effectiveness in any event. And, thirdly, unless we do clarify our thinking about our

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\*References to unborn child or baby should not and do not infer or denote any specific position on moral status for that entity.

<sup>1</sup> Nuffield Council on Bioethics (NCOB), *Non-invasive prenatal testing: ethical issues* (London, March 2017), para 4.1.

<sup>2</sup> For further discussion, see Jeff Wale, 'Don't forget the legal framework: The public provision of non-invasive prenatal testing in England and Wales,' (2015) 15(4) *Medical Law International* 203; Roger Brownsword and Jeff Wale, 'The development of non-invasive prenatal testing: some legal and ethical questions,' (2017) 24 *Jahrbuch für Recht und Ethik* 31; Roger Brownsword and Jeff Wale, 'The Right to Know and the Right Not to Know Revisited,' (Two Parts), (2017) 9 *Asian Bioethics Review* 3; Roger Brownsword and Jeff Wale, 'Testing Times Ahead: Non-Invasive Prenatal Tests and the Kind of Community that We Want to Be.' (2018) 81(4) *Modern Law Review* 646.

informational interests, there is absolutely no chance of regulating in support of our societal vision. Each community needs to urgently address their specific priorities around the protection and promotion of informational interests before it is too late to roll back this technology and the societal demand for these tests.

For the avoidance of any doubt, this paper focuses on testing during the course of an established pregnancy. This paper does not seek to address either pre-implantation genetic diagnosis/testing in the context of assisted reproduction or the need for regulatory coherence and consistency with NIPT.

## 1. The Technology and Informational Issues

Conventional combined screening - involving the use of maternal serum tests and ultrasound imaging - is a routine part of prenatal care during the early/mid-stages of a pregnancy in many countries and is used to identify the risk of certain conditions in the unborn child. These tests have relatively high false positive rates, and further invasive tests involving an elevated risk of miscarriage are usually required for a diagnostic result<sup>3</sup>. NIPT technology was first introduced for aneuploidy<sup>4</sup> detection in about 2011 – utilising the discovery of circulating cell free fetal DNA in the maternal blood stream - and has been developed and exploited by the commercial sector as a clinical offering across the globe. The testing process involves the taking of a maternal blood sample during the early stages of pregnancy (and before conventional screening is possible) and subsequent laboratory analysis enables the detection of cell-free fetal DNA in the blood. This analysis can reveal a range of information about the developing fetus including the likelihood of aneuploidy or other anomalous genetic conditions. It can also provide secondary findings about the pregnant woman. On the face of it, there seems good reason to welcome a safe and easy test procedure that will provide useful information to the parents. However, the accuracy and quality of the information produced by testing can vary from the diagnostic, to borderline diagnostic,<sup>5</sup> to variable and uncertain.<sup>6</sup> NIPT also has the potential to provide a range of non-health related information, and whole human genome testing and exome sequencing has been demonstrated in a research setting.<sup>7</sup> This mixed pattern of accuracy and the potential to generate a wide range of risk-based information can generate adverse issues for a range of stakeholders including the prospective parents. Against this background, it is generally agreed that non-directive counselling is required to inform the non-invasive testing process.<sup>8</sup>

The core rationales for this technology focus on enhancing reproductive autonomy and the generation of various public health benefits. The former builds on individual parental (and specifically maternal) interests, and the latter focuses on wider societal interests. Some regard these as competing and irreconcilable rationales and narratives.<sup>9</sup> The push for implementation in relation to anomaly testing has concentrated (for understandable reasons) on the autonomy rationale - that testing will facilitate and enhance decisions and choices in relation to pregnancy. It rests on the foundation that any resulting choices from the testing

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<sup>3</sup> About 1% increase in risk.

<sup>4</sup> Conditions with an unusual number of chromosomes.

<sup>5</sup> eg Down Syndrome where the sensitivity and specificity rates have been demonstrated to be greater than 95% (NCOB (n1), para 1.29).

<sup>6</sup> eg chromosomal micro deletions and micro duplications (NCOB (n1), paras 1.30-1.34.).

<sup>7</sup> NCOB (n1), paras 1.30-1.34.

<sup>8</sup> NCOB (n1), paras 2.16-2.37.

<sup>9</sup> Vardit Ravitsky, 'The Shifting Landscape of Prenatal Testing: Between Reproductive Autonomy and Public Health,' in *Just Reproduction: Reimagining Autonomy* (2017) 47(6) *Reproductive Medicine, Special Report, Hastings Center Report* S34.

are both free and informed. The former requirement necessitates an absence of undue influence and pressure on the decision-maker and the choices made using the results. The ‘informed’ requirement means that the parents need to have adequate information about the tests, the test conditions and what the results mean in practice. These requirements are challenging because of the complexity of genetic risk and the range of information that could be available to us in the future. The public health rationale focuses on the promotion of consequential public health benefit and/or the avoidance of some consequential public harm. It is clearly relevant when testing for treatment purposes (whether in utero or post birth options) but tends to generate negative eugenic concerns in the context of anomaly and non-health related testing.

NIPT has been rolled out by the private sector in various forms globally and there are already a range of private test providers from the US, China and Europe. There have been intellectual property challenges that remain ongoing.<sup>10</sup> Implementation in the public health sector has been mixed and more tentative. Following a period of research and evaluation, the UK is now in the process of implementing NIPT for certain aneuploidies (including Down’s Syndrome) within the NHS Foetal Screening Programme. We have opted for contingent use – NIPT will not replace conventional screening mechanisms but will be used as a secondary option for parents in circumstances where conventional testing identifies an elevated risk of these specified genetic conditions. The advantage of contingent testing is that NIPT will offer parents a more accurate picture of the likely genetic status of their unborn child without the consequent risk of an invasive procedure but will not be offered as a norm during the pregnancy unless conventional screening reveals an elevated risk.

From an informational perspective, there are a range of pre-test, post-test and post-birth considerations. Before testing, there are issues around the information circulation in relation to the tests and the conditions that are being tested. These concerns are exacerbated by the fact that information and testing services are freely and commercially available in an online and global environment.<sup>11</sup> There are issues around the ‘reasonable informational’ entitlement of parents – what range of information can parents seek legitimately about their unborn child. Already parents can test through commercial operators for a range of genetic conditions and fetal sex.<sup>12</sup> Post-test the informational concerns relate to how results and options including termination of the pregnancy are presented and communicated. There are data and related disclosure issues including concern about the availability and disclosure of secondary findings. Post-birth issues extend to the security, use and management of test data. These are matters that we will return to.

## **2. Informational Interests**

Increasing amounts of personal information and related data is created, processed, disseminated, and stored in a variety of formats in the public and private domains. For current purposes, ‘personal information’ includes information that can be used on its own or with other sources to identify an individual and which can be attributed to, be related to, or about that person. In the context of NIPT, that might include present or likely future characteristics and traits about an individual. Contemporary worry about the accuracy and integrity of personal data, and the availability, access and use of personal information is

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<sup>10</sup> NCOB (n1), para 4.19.

<sup>11</sup> Roger Brownsword and Jeff Wale, ‘Regulating in the Global Village: The Case of Non-Invasive Pre-Natal Tests’, In: Symeonidou-Kastanidou, E., Kipouridou, K., Milapidou, M. and Vasileiou, M., eds. *Medicine, Law and the Internet*. (Greece: Nomiki Bibliothiki S. A., 2018).

<sup>12</sup> See for eg, <https://www.sequenom.com/tests/reproductive-health/maternit21-plus> (accessed 19 April 2018).

highly topical - there are plenty of examples to choose from including the Wannacry Ransomware attacks on the NHS and the recent Facebook Cambridge Analytica scandal. The increasing use of technology and the pressure to share information through online mechanisms is as relevant within the sphere of reproductive healthcare as it is elsewhere.<sup>13</sup>

We intuitively claim an interest to information that concerns or is about us. Roger Brownsword suggests that: “*we might define our informational interests as relating primarily 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.*”<sup>14</sup> The availability of personal information, whether directly or inferentially related, has the potential to impede and promote personal rights and freedoms. Negative or adverse personal information may remove or restrict opportunities and impact on physiological states of wellbeing. Conversely, positive and favourable information can enhance and facilitate our life choices, experience and wellbeing. Having some degree of control over our own and third-party access to personal information is central to the exercise of personal autonomy (in the senses of self-determination and self-governance). Herring and Foster contend that: “*(b)oth these forms of control are important for maintaining psychological integrity and general well-being and for fostering relationships. Knowing something about oneself can affect relationships with others and have wider societal consequences.*”<sup>15</sup>

In the specific context of NIPT, there are a range of parties with potential informational interest(s) in the information produced by testing, including the pregnant woman, her partner<sup>16</sup>, the unborn fetus and the future person that entity might become. We might add to the list the wider informational interests of society, or sections thereto, in knowing or not knowing certain information yielded by these tests. There is scope for tension and conflict between these respective interests - where there might be competing interests in keeping information private or restricted, and in developing or maintaining free-flowing information in society. This potential tension arises not just in the now – for example, how the tests might be used to make decisions about the pregnancy - but also in the future where access to information could impact on the parents or the future person and on the choices that are available to them.

## 2.1 Pregnant Women

A pregnant woman may use these tests to obtain information about the pregnancy and the genetic status of her unborn child, and generally to make informed reproductive choices.<sup>17</sup> The tests may be undertaken just for this information, without any desire to act or to make any consequential reproductive decisions. The tests may also yield incidental genetic and health information about the pregnant woman. Whether the woman has a right to know all of this information can be debated - we would certainly need to establish that such a right is recognised, that it belongs (in this case) to the woman claiming the right and that it covers the

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<sup>13</sup> See for eg Sergio Carmona et al. ‘Realizing the potential of real-time clinical collaboration in maternal-fetal and obstetric medicine through WhatsApp’, *Obstetric Medicine* (2018), available from [https://www.researchgate.net/profile/Sergio\\_Carmona4/contributions](https://www.researchgate.net/profile/Sergio_Carmona4/contributions) (accessed 20 April 2018).

<sup>14</sup> Roger Brownsword Infosoc 2018: *Informational Rights, Informational Wrongs, and Regulatory Responsibilities*, at 2-3, available from <https://microsites.bournemouth.ac.uk/law-review/files/2018/03/Infosoc-2018-wps.pdf> (accessed 3 April 2018).

<sup>15</sup> Jonathan Herring and Charles Foster, “Please Don’t Tell Me”, (2012) 21 *Cambridge Quarterly of Healthcare Ethics* 20, at 28.

<sup>16</sup> This might also extend to any gamete donor.

<sup>17</sup> For the importance of free and informed reproductive choice, see Elizabeth Wicks, *The State and the Body: Legal Regulation of Bodily Autonomy* (Hart 2016), 39.

type of information being sought.<sup>18</sup> We tend to specify our informational rights by asking whether it is a ‘reasonable expectation’ that the particular benefit or protection claimed should be enjoyed, employing various reference points in the law and practice etc to determine whether or not an expectation in relation to specific information is reasonable or not. This issue is not straightforward, but we have argued elsewhere that the claim that a pregnant woman has a right to know information about her developing child is plausible albeit in a qualified form.<sup>19</sup> In the context of maternal claims to information about trivial and non-health matters, the Nuffield Council on Bioethics have suggested: “*if the information on offer is not relevant to the woman’s reproductive autonomy, ie to decisions she may wish to make about her pregnancy, it is questionable that she has a right to all information of this nature.*”<sup>20</sup>

If we pause here for a moment. This statement assumes that any claimed right is based on and limited to information required for the exercise of active choice. It also predicates a disconnection between certain types of information, the woman’s choice around the continuation of the pregnancy, and her own physical and psychological well-being. To the extent that the pregnant woman’s right to know information about her unborn child rests on her own physical and psychological well-being - and given the nature and closeness of the connection between mother and fetus, this seems highly plausible even in relation to some non-health information.<sup>21</sup> On that basis, the pregnant woman appears to have - subject to a permissibility qualification - a reasonable expectation to such information if it directly and intimately concerns her own well-being. Even trivial features about the unborn child that are important to the woman and her family may be sufficient to clear the modest qualifying hurdles for the termination of pregnancy under the UK Abortion Act 1967.<sup>22</sup> The legal framework for abortion casts an inevitable shadow on the choices that pregnant woman can make post-test.<sup>23</sup> Where a connection can be made between the information sought and the lawful choices available to the parents post testing, it might be problematic to simply dismiss any claim by the parent to a right to know information about their unborn baby.<sup>24</sup>

## 2.2 The Fetus and the Future Person

What about the developing fetus<sup>25</sup> or the future person they might become - do they have an interest in deciding what information should exist and be made available either to themselves or others in the present or future? The question implicates both the potential right to know and the right not know - or perhaps more specifically the right to decide whether to know or not know information about ourselves, as well as the right to control what others know or do not know about us. The foundation and nature of these rights do not necessarily synchronise. The right to know has its clear roots in the exercise of personal autonomy – the right to self-determine or govern what we know and what personal information might be available to others. The right not to know also has some connection with autonomy – for example, in

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<sup>18</sup> CF NCOB (n1), para 4.54.

<sup>19</sup> For discussion, see Brownsword and Wale, ‘The Development’ (n2).

<sup>20</sup> NCOB (n1), para 4.54.

<sup>21</sup> Brownsword and Wale (n19).

<sup>22</sup> Section 1(1).

<sup>23</sup> For discussion of the regulatory connections between NIPT and abortion, see Wale (n2).

<sup>24</sup> However, the recent Nuffield Council on Bioethics report on NIPT simply recommends a blanket restriction on testing for trivial and non-health related forms of information ((n1), para 6.13).

<sup>25</sup> We have restricted reference to ‘fetus’ because in most cases these tests are undertaken during that stage of human development.

cases where the individual has expressed a prior wish not to know certain information about themselves – but also has its foundation in the concepts of privacy<sup>26</sup> and open futures.<sup>27</sup>

The Nuffield Council on Bioethics has framed the informational concern in the following terms:

*If NIPT for a wider range of genetic conditions and traits becomes available in future, NIPT might pose risks to the autonomy of those people whose genetic material was tested while they had been in their mother's womb. Usually, it is regarded as a personal choice whether or not to undergo genetic testing that could provide information about a person, including about adult onset conditions, carrier status, less significant medical conditions or non-medical conditions. It is arguably wrong to arrange a genetic test before birth because it deprives a person of her or his opportunity to make their own autonomous decision about whether to undergo testing or might undermine their **right to an open future**.*<sup>28</sup>

The Nuffield Council on Bioethics' report on NIPT goes onto identify a series of potential harms arising from the possible implementation of these tests - from an increase in terminations for current fetuses to closing down life options, adverse psychological impact and privacy violations for future persons.<sup>29</sup>

The foundations of the child's right to an open future can be found in the seminal work of Joel Feinberg:<sup>30</sup>

*[These are] rights that are to be saved for the child until he is an adult, but which can be violated "in advance," so to speak, before the child is even in a position to exercise them...His right while he is still a child is to have these future options kept open until he is a fully formed, self-determining adult capable of deciding among them.*<sup>31</sup>

The argument is that there is a 'right in trust' or more accurately a collection of 'rights in trust'<sup>32</sup> for the child that can be violated before that entity has the capacity to exercise them on a direct individual basis. Feinberg grounds the right to an open future on the values of self-determination and self-fulfilment.<sup>33</sup> The latter value incorporates the development of personal talents that enable humans to achieve self-actualisation.<sup>34</sup>

On some accounts, these rights generate correlative duties on others, most notably on parents, in relation to the preservation of an open future.<sup>35</sup> These duties can be framed in positive (to

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<sup>26</sup> Graeme Laurie says that the right not to know is better construed as a privacy interest (a genuine state of separateness including psychological separateness from others), ('Privacy and the right not to know: a plea for conceptual clarity', 38-51. In Ruth Chadwick, Mairi Levitt and Darren Shickle (eds), *The Right to Know and the Right Not to Know: Genetic Privacy and Responsibility* (Cambridge University Press, 2014)).

<sup>27</sup> It is recognised that the Right to an Open Future also has connections to autonomy.

<sup>28</sup> NCOB (n1), para 5.6 [emphasis added].

<sup>29</sup> NCOB (n1), para 5.13.

<sup>30</sup> Joel Feinberg, 'The Child's Right to an Open Future.' In *Freedom and Fulfillment* (Princeton, NJ: Princeton University Press, 1992)

<sup>31</sup> Feinberg (n30), 125-126.

<sup>32</sup> Joseph Millum, 'The Foundation of the Child's Right to an Open Future', (2014) 45(4) *J Soc Phil* 522 at 522

<sup>33</sup> Feinberg (n30), 145.

<sup>34</sup> Feinberg (n30), 91.

<sup>35</sup> Millum (n32), 522.

preserve future options) or negative terms (not closing-down certain options for the child). Joseph Millum makes the important point that a right does not automatically equate with a correlative and open-ended obligation in respect of that right. He gives the following example: if we have a right to own property, this might mean that there is a correlative (negative) duty not to restrict that right but it does not automatically follow that someone should have a positive obligation to ensure that everyone should own property.<sup>36</sup> By analogy, this can be applied to the right to an open future – parents are not automatically obligated to secure all or any particular options for a child without clear foundation for that positive obligation. Further, Wilkinson makes a clear distinction between the correlative duties that might be owed by actual parents on the one hand and prospective parents on the other. Of course, this simply begs another important question – when does parenthood commence – and that may not be capable of quick or any resolution.<sup>37</sup>

It is not entirely clear whether these rights in trust only apply to the born child or whether they extend to the unborn child, or even to a possible embryo/ future child?<sup>38</sup> Some writers clearly believe that these rights and any correlative duties extend to the unborn child. For example, Gabriel Bosslet claims that a parental obligation in respect of open futures does exist prior to conception.<sup>39</sup> However, for present purposes let us address the position of the implanted but unborn human embryo or fetus. There are three broad arguments against this kind of right in our specific context: namely, that the entity does not have rights of any kind, that the entity might not become a future person, and that on further analysis this is a funny kind of right.

The first argument speaks to those who do not accept that the fetus is (or is capable of being) a rights bearer, whether before viability, before birth or even sometime after birth. How can there be any kind of entitlement to a right or collection of rights if the entity is not a rights bearer *of any kind* at the material time?<sup>40</sup> For our purposes, the ‘material time’ would be the point at which any violation(s) occurs.

The second argument focuses on transformative and identity issues. The embryo/fetus is not a static physical entity and is in a state of developmental transition; and its ontological features and moral status are heavily contested. The liminal status of the entity – the fact it might or might not become a future human person – is important. Feinberg grounds his right to an open future on the basis that breaches violate in advance autonomy rights that a child *will* have as an adult. This makes assumptions that the entity will necessarily progress to adulthood and indeed, will be born. In the context of prenatal testing, where the outcome of testing may result in termination of the pregnancy and the entity not being born, this might be an important point. The argument in favour of open futures in this context might also fall foul of Derek Parfit’s ‘non-identity problem’.<sup>41</sup> It is sufficient to highlight the difference between genetic testing for the purpose of undertaking possible remedial steps (eg to treat or alleviate a health condition), and testing that might inform possible future decisions about the continuation of the pregnancy and the creation of different future people.

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<sup>36</sup> Millum (n32), 528.

<sup>37</sup> Stephen Wilkinson, *Choosing Tomorrow’s Children: the ethics of selective reproduction* (Clarendon Press, 2010), 27-31. See also Wicks (n17), 52.

<sup>38</sup> See Jason Chen, ‘The Right to Self-Development: An Addition to the Child’s Right to an Open Future’, (2016) 47(4) *J Soc Phil* 439, at 442-443 and the difficulty regarding possible futures.

<sup>39</sup> Gabriel T. Bosslet, ‘Parental procreative obligation and the categorisation of disease: the case of cystic fibrosis’ (2011) 37 *J Med Ethics* 280, at 281. See also Dena S. Davis, “Genetic Dilemmas and the Child’s Right to an Open Future,” (1997) 27(2) *Hastings Center Report* 7.

<sup>40</sup> See Wilkinson (n37), 47.

<sup>41</sup> Derek Parfit, *Reasons and persons* (Clarendon Press 1984).

This takes us onto the third kind of argument that we have framed as a ‘funny kind of a right’. These arguments examine the grounding of the right, potential conceptual flaws and what such a right might mean in practice. First, it appears problematic to base any right to an open future on the protection of autonomy unless it is protecting *current* choice and decision making. In relation to an unborn human baby, we are not susceptible to arguments that parental decision making – for example, whether to test for and act upon any results - violates entity decision making and choices *now*. According to Millum this is fatal to any claimed right to an open future where that right is formulated as a future autonomy right.<sup>42</sup> Chen argues that the solution may rest in Feinberg’s alternate foundation for the right – namely self-fulfilment, which he reframes as ‘the right to self-development’ and regards as “*a necessary (or at least a very important) component of a full human life.*”<sup>43</sup> We might frame this right as an entitlement to a context in which we can “*do our own thing*” and “*be our own person*”.<sup>44</sup> This is an important point but Chen’s specific framing as a right could still be susceptible to challenge by those that do not believe the unborn child is a rights bearing entity.

Stephen Wilkinson highlights another flaw with Feinberg’s argument – how open a future does and should such a right encompass?<sup>45</sup> It is practically impossible to preserve all choices – many parental acts and omissions will influence and impact on their child’s future. Even, if we adopt a moderate position, we would still have to decide between those choices that are preserved or restricted. It might be possible to identify a hierarchy of privileged options<sup>46</sup> but it is not immediately apparent that that this type of position stems from Feinberg’s foundations for the claimed right.<sup>47</sup> There is also the problem of unreasonable and/or disproportionate burdens should we accept open ended correlative duties. An open-ended duty to preserve all and any future options for the unborn child would place an unacceptably heavy burden on parents and possibly State actors.<sup>48</sup> It should be emphasised that a child’s right to an open future (or at least an open-ended variant) would inevitably clash with current parental autonomy rights to influence and control their own children. This discussion has clear implications in relation to prenatal screening and diagnosis, and it is notable just how much reliance was placed by the Nuffield Council on Bioethics on the concept of ‘open futures’ in their recent report on NIPT.<sup>49</sup>

There are of course other arguments in favour of open futures. There are views that the parental role in the creation of the entity, creates special responsibilities that might include not shutting down life or life choices.<sup>50</sup> This type of argument can be subjected to attack on a variety of fronts – from the issue of non-consensual conception to the difficulty of open ended responsibility.<sup>51</sup> There might also be arguments that say we should not allocate scarce resources to preserve open ended futures. Counter arguments (not focussing on open futures) might argue that scarce societal and personal resources should not be used for the pursuit of

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<sup>42</sup> Millum (n32); See also Chen (n38), 449.

<sup>43</sup> Chen (n38), 451.

<sup>44</sup> See Brownsword and Wale, ‘Testing Times Ahead’ (n2).

<sup>45</sup> Wilkinson (n37).

<sup>46</sup> Wilkinson (n37), 47.

<sup>47</sup> For discussion of the competing arguments, see Millum (n32).

<sup>48</sup> Millum (n32), 530.

<sup>49</sup> NCOB (n1), chp 5.

<sup>50</sup> William Ruddick, ‘Parents and life prospects’, 123-137. In *Having children, Philosophical and legal reflections on parenthood*, ed O’Neill and W Ruddick (1979 OUP); William, Ruddick, ‘Parenthood: Three concepts and a principle’. In *Family Values: Issues in ethics, society and the family*, ed L. D Holgate (1988)

<sup>51</sup> For discussions, see Judith J Thomson, ‘A Defense of Abortion’, (1971) 47(1) *Philosophy & Public Affairs* 47.

trivial information about the unborn child especially if it might lead to a less inclusive community. There might be circumstances when the autonomy rationale for testing cannot be guaranteed and again this might count against the open implementation of NIPT without other justification.

### 2.3 Disabled People and Wider Society

It has been argued that NIPT has the potential to cause specific harm and to undermine equality, fairness and inclusion for disabled people.<sup>52</sup> Concerns range from the potential to create discrimination/ stigma for this group to the spectre of eugenics and the elimination of disability from society.<sup>53</sup> Possibly the most potent argument in this debate - the 'Expressivist Objection' - has an informational component:

*It may be claimed that prenatal diagnosis discriminates against disabled children and adults, because it **sends the message** that it would have been better if they, too, had not been born. The argument is often called 'the expressivist objection', because it suggests that genetic diagnosis and selective abortion 'expresses' discriminatory or negative views towards disabled people.<sup>54</sup>*

There are some problems with this argument because it conflates the intended message with the recipient's belief as to the content of the message.<sup>55</sup> The discriminatory message must actually be false – there is nothing wrong per se in sending out a true messages providing it is done in a sensitive manner.<sup>56</sup> Wilkinson accepts that there is a version of the expressivist argument that succeeds albeit he is doubtful about the impact for law and policy. He claims that expressivist objection might have traction in anomaly cases where the parents decide to: (1) avoid having any children, (2) for impersonal reasons (and not because of self-interest) because the world considered overall would be a better place, (3) they do not see themselves as exceptionally unsuitable parents or if they do it is not causative in any decision to not have children and (4) their beliefs are false or unjustified.<sup>57</sup> There is, however, still the potential danger of influence across society if we normalise testing for a range of genetic conditions and disabilities. If testing becomes the norm and is perceived as something a reasonable person would do, there might be a danger that any claimed right to know becomes a 'responsibility to know' information about the unborn child.<sup>58</sup>

### 3. Competing Interests

So, we have the interests of pregnant women in making informed reproductive choices (including having information about the genetic status of their unborn baby) and the possible interest of future persons in deciding for themselves what information about their genetic profile should be available. Against this background, how might we resolve any conflict between competing informational interests, and how should we strike a balance between the individual and collective interests identified? We can debate whether this should be resolved

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<sup>52</sup> NCOB (n1).

<sup>53</sup> NCOB (n1), para 5.18

<sup>54</sup> Tom Shakespeare, *Disability Rights and Wrongs* (Routledge, 2006), 35 [emphasis added].

<sup>55</sup> Jonathan Glover, *Choosing Children: Genes, Disability, and Design* (Clarendon Press, 2006); Wilkinson (n37), 171-172.

<sup>56</sup> Wilkinson (n37), 178.

<sup>57</sup> Wilkinson (n37), 180-185.

<sup>58</sup> Mairi Levitt, 'Empowered by choice?' at 96. In Ruth Chadwick, Mairi Levitt and Darren Shickle (eds), *The Right to Know and the Right Not to Know: Genetic Privacy and Responsibility* (Cambridge University Press, 2014).

in rights or duty terms – a rights-based approach has the danger of getting bogged down in debates about the moral and rights bearing status of the unborn child. From a rights perspective, it is certainly not immediately apparent why we should prioritise the position of the fetus over that of the pregnant woman (an ostensible if not a clear rights bearer). Admittedly we would still need to be satisfied that the woman’s right to know incorporates the information sought and that such information is permissible, although these may not be significant hurdles for the reasons discussed. We also need to be careful to distinguish a desire to know information about the unborn child, and a clear aim to use the information to make decisions on the continuance of a pregnancy. It must also be recognised that any competing interests between the pregnant woman and her unborn child are not just occurring in an abstract sense – there is clear biological and psychological interconnection between the woman and the unborn entity during pregnancy.<sup>59</sup> Indeed, technology (including NIPT) arguably disrupts this interconnection and reinforces the framing of the mother and her unborn child as separate entities.<sup>60</sup> This has implications for how informational interests are framed viz-a vis the unborn child.

State intervention to protect the pregnant woman – for example, by withholding wanted information about herself or her unborn child - for beneficent reasons is contentious and would need careful and specific justification. A State might have a legitimate basis to intervene in relation to NIPT where there is clear evidence of likely harm to ‘others’ and the intervention is necessary to avoid that harm. There may be a specific State responsibility where that harm or potential of harm arises from technology that has been released and is managed/ controlled in a public health context.<sup>61</sup> Whether the categorisation of ‘others’ includes the fetus might again depend on whether you view that entity as a rights bearer. For Feinberg<sup>62</sup> and Wicks<sup>63</sup> state intervention will not be legitimate in Millian terms *unless* the harm to ‘others’ is both morally indefensible (neither excusable nor justifiable) and rights violating.<sup>64</sup> These positions are problematic for those who seek to oppose prenatal testing, and is especially difficult, because we are concerned with testing at the early stages of pregnancy and before the fetus has viability.

This takes us onto the next point and links back to our earlier discussion of open futures and self-development. Wicks argues that “*only interventions based on Mill’s harm principle or, in tightly confined circumstances, the dignity of the human species as a whole should suffice to justify public intervention into private choices about the body*”.<sup>65</sup> So it might be legitimate for the state to interfere in reproductive and testing choices (even if deemed within the private sphere) where the dignity of humanity as a whole is at stake. It is not hard to envisage circumstances when open ended genetic testing in a context that normalises termination for minor anomaly might count as a justification for intervention. Earlier we alluded to the possibility of producing a hierarchy of privileged options – and that might include those matters deemed essential or vitally important to our self-development and dignity as humans and that ought to be protected. We live in a world where conventional expectations around privacy are under pressure from online and technological advances and each community needs to decide how we might systematically rank those options and those informational expectations that are essential pre-conditions for human existence or an

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<sup>59</sup> Wicks (n17), 15.

<sup>60</sup> Samantha Halliday, *Autonomy and Pregnancy* (Routledge 2016).

<sup>61</sup> NCOB (n1), para 1.67.

<sup>62</sup> Joel Feinberg, *Moral Limits of the Criminal Law* (OUP 1984).

<sup>63</sup> Wicks (n17).

<sup>64</sup> Feinberg (n62); Wicks (n17), 48.

<sup>65</sup> Wicks (n17), foreword [emphasis added].

essential context for any social human existence.<sup>66</sup> In relation to NIPT, we need to ask ourselves whether testing the whole exome of our future children might impede the self-development of those children and the community as a whole. Each community will also need to decide what information they reasonably need to know, and that which they do not within their own societal context.<sup>67</sup> It is also significant that prenatal testing is just one topical example of a general but unmistakeable shift from ex post to ex ante responses within society. NIPT presents society with an easy opportunity to prevent, deselect or even enhance certain characteristics and conditions within the gene pool. How far do we want to go down the path, and when will it be too late to turn back the clock in respect of demands and access for genetic information? Open access to genetic data does have certain research advantages but as with other informational technologies, we do need to acknowledge the possible risks connected with these developments. These are issues that we need to address now – NIPT technology is advancing rapidly and whole exome sequencing in the commercial sector is not far away.

#### **4. Possible Regulatory Responses**

In this part, we attempt to address some possible regulatory responses to NIPT in an informational context. Whilst we do touch upon the issue of legitimacy, we do not attempt to resolve whether all or any of these possible responses might be legitimate ones. For the reasons discussed, society needs a clear picture of our informational interests and those matters/ features/ requirements that are essential to future human existence, society and personal self-development before finalising the regulatory environment. These are debates that need to be undertaken quickly.

If we start with the premise that any regulatory framework should involve only legitimate intervention into individual freedom, address foreseen issues and avoid the creation of unintended consequences and unplanned gaps in regulation. Modern regulatory approaches, whether risk or principle based, usually endeavour for some longevity and this necessitates some inherent fluidity and the capacity to facilitate responses to further technological revolution and significant societal shifts in public opinion. Alternative fixed or static approaches generally require regular oversight by the legislature, or more controversially by the executive, to address gaps and issues that may emerge within and without the regulatory framework.<sup>68</sup> With NIPT there are clearly practical and cultural<sup>69</sup> challenges in regulating tests that are on offer privately in over sixty countries without any clear and co-ordinated agreement between states.<sup>70</sup> The fact that this fast changing technology is being piloted in online and commercial environment makes the ability of State regulators to control access challenging. Those implementing regulatory policy will want to consider the kind of multi layered and flexible responses that will be necessary to achieve any realistic regulatory outcome in this environment. Static responses are probably not going to be effective and

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<sup>66</sup> For a discussion about how we might go about doing this, see Brownsword and Wale, ‘Testing Times Ahead’ (n2).

<sup>67</sup> Richard Watermeyer, ‘The inescapability of knowing and inability to not know in the digital society’ at 180-195. In Ruth Chadwick, Mairi Levitt and Darren Shickle (eds), *The Right to Know and the Right Not to Know: Genetic Privacy and Responsibility* (Cambridge University Press, 2014).

<sup>68</sup> For a general discussion on regulatory compromise using medicalisation, please see Roger Brownsword & Jeff Wale, ‘Compromise Medicalisation’ in C Stanton, S Devaney and A Farrell. (eds), *Pioneering Healthcare Law: Essays in Honour of Margaret Brazier* (Routledge 2015), 292-304.

<sup>69</sup> See Jessica Mozersky, Vardit Ravitsky, Rayna Rapp, Marsha Michie, Subhashini Chandrasekharan, and Megan Allyse, ‘Toward an Ethically Sensitive Implementation of Noninvasive Prenatal Screening in the Global Context’ (2017) 47(2) *Hastings Center Report* 41.

<sup>70</sup> For further discussion, see Brownsword and Wale (n11).

current for long in this context, and policy and/or risk-based approaches to regulation might have more traction and effect in the longer term.

Implementation of this technology through the public health sector – whilst offering an alternative to the commercial providers and addressing possible equality / access issues – might also have the capacity to normalise testing and resultant choices. If States cannot ensure the original aims of the technology (eg enhanced reproductive autonomy), then we should be cautious about expansion of any associated public health testing regime.<sup>71</sup> There is also the issue of regulatory coherence and the need for clear narratives and messages around NIPT and the legal environments that these tests operate in (including those applicable to the termination of pregnancy).<sup>72</sup>

As discussed, a pure Millian account poses legitimacy issues for those who maintain that the only legitimate State intervention is to prevent wrongful harms to other right bearers. However, for the reasons already discussed, there may be other legitimate ground for intervention. There may also be: “*a plausible role for the State exercising a precautionary jurisdiction where the longer-range consequences of individual choice are unclear or where we cannot be entirely confident that an act has no negative impingement on rights-holders or on arguable rights*”.<sup>73</sup> Precautionary reasoning should not be abused by State institutions and any regulatory framework needs to be flexible enough to make modifications when evidence becomes available. This is important in the context of NIPT when the test technology and the online environments in which it partially operates are constantly evolving.

There are a range of policy based domestic regulatory responses that State actors might consider in relation to informational interests. These can be grouped into 4 broad policy categories: authority, incentive, informational and organisational:

#### **4.1 Authority**

Here the focus is on the use of hard forms of regulation (laws) to restrict certain activities within a jurisdiction. Marketing prohibitions or restrictions might be possible relating to the claims made about the tests or the conditions being tested for.<sup>74</sup> As the tests require a blood sample, there is some scope for domestic control within a package of healthcare or by restricting/ prohibiting direct consumer interaction, again controlling access to information and services by users.<sup>75</sup> There would need to be an effective mechanism to avoid or restrict user circumvention via service tourism - this may not be an easy task given the simplicity of the blood sampling process. Although the manufacture/ sale of these tests kits is already regulated in the UK,<sup>76</sup> control may not extend to testing outside the EU where many commercial providers operate. States need to resolve what conditions and traits are permissible test subjects and be able to justify restrictions on any parental right to know. As discussed, the environmental context in which post-test choices are made are likely to shape user behaviour. For example, testing in a State with restrictive abortion laws may produce different outcomes to that in a more permissive regime.

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<sup>71</sup> Jeff Wale, ‘Screening Human Life - The Legal and Ethical Implications of Non-invasive Prenatal Testing’, (2018) 11 *AMPS Journal Proceeding Series* 20-28.

<sup>72</sup> Wale (n2).

<sup>73</sup> Roger Brownsword, ‘Happy Families, Consenting Couples, and Children with Dignity: Sex Selection and Saviour Siblings’ (2005) 17 *Child & Fam LQ* 472.

<sup>74</sup> NCOB (n1), paras 6.7, 6.26, 6.28.

<sup>75</sup> NCOB (n1), para 6.40.

<sup>76</sup> *UK Medical Devices Regulations* 2002 (as amended). To be replaced by the *EU IVD Regulations* (subject to Brexit).

## 4.2 Incentive

The availability of public funding and provision will undoubtedly shape the commercial market. A restrictive and limited public test offering without strict and effective authority instruments at a domestic and international level, could increase the level of service tourism and the general demand for test services unavailable lawfully within a State. Of course, the resources of test users will also shape demand, as will the prevalence of specific genetic conditions within a State. The use of nudges and boosts<sup>77</sup> by a State would need to be justified in terms of the possible impact on personal autonomy. In informational terms, State certified sources of information about the tests may play a role in shaping the demand and use of services and the choices made post-test.

## 4.3 Informational

There are a range of informational policy instruments that a State might use from renewable certification of NIPT websites, online forums and related services and ‘internet prescriptions’ (where doctors highlight approved online sources of information and support about these tests and related conditions).<sup>78</sup> National guidance could be circulated to NIPT service providers.<sup>79</sup> If post-birth concerns about information are to be addressed, we need a regulatory framework that makes provision for the storage, security, access and future destruction of specific genetic data, including one that takes an acceptable position on any right to know and not to know.

## 4.4 Organisational

There is a link here with incentives. How we organise and fund NIPT services and resultant choices may make a significant difference to the success of any State intervention. If a State chooses to fund open ended access or authorises the same through the commercial sector, there may be resourcing and allocation issues that need to be addressed and overcome.<sup>80</sup> How tests are organised within a public health regime may prove critical to the public narrative.

For the reasons already articulated, States would need a multi layered regulatory response to have any hope of being effective. They are likely to encounter a range of problems given the factors (ie fast evolution, simplicity etc) and the online global commercial environments that would need to be controlled.

## 5. Conclusions

We have seen that NIPT raises a whole host of current and future issues, including the opportunity to prevent, deselect and enhance characteristics/ conditions within the human gene pool. The technology brings into sharp focus the possible informational interests of a range of stakeholders and the need for an appropriate balance to be struck in the event of conflict. We have examined the circumstances and foundations for legitimate State interference in this arena, including responses necessary to protect conditions/ features essential or vitally important to our self-development and dignity as a human species, or

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<sup>77</sup> Cass R. Sunstein, *Choosing Not to Choose: Understanding the Value of Choice* (Oxford University Press, 2015).

<sup>78</sup> See the NCOB (n1) recommendations at paras 6.27 and 6.39.

<sup>79</sup> <http://nuffieldbioethics.org/news/2017/guidance-patient-information-nipt-fo> (accessed 24 January 2018).

<sup>80</sup> Christian 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.

otherwise regarded as essential preconditions for human existence or the context for social human existence. In this context, unqualified genetic testing for trivial features warrants careful consideration within each community.

We also examined the regulatory difficulties generated by rapid technological evolution and by the release of NIPT within the global village. Before society can mount an effective response to these challenges, there are three important considerations. First, the informational interests that we recognise (whose and which interests we recognise) and which we prioritise speak to the kind of society that we want to be. Secondly, we should not assume that it will be easy to regulate for the kind of society that we want to be and there are no guarantees of regulatory effectiveness in any event. And, thirdly, unless we do clarify our thinking about our informational interests (as per the first point), there is absolutely no chance of regulating in support of our societal vision. To that end, each community needs to address their priorities before it becomes too late to roll back the technology and the demand for these tests.

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## **Conflicts of Interest**

There are no known conflicts to declare.