

The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions

Roger Brownsword* and Jeff Wale**

I. Introduction

Early in 2016, following a successful trial led by Professor Lyn Chitty at Great Ormond Street Hospital,¹ the UK National Screening Committee announced that it would recommend the cautious piloting of non-invasive prenatal testing (NIPT) within the existing screening pathway for Down syndrome.² So long as NIPT is used only as an additional test for the trisomies within an existing screening pathway, the procedure (and return of results) is, if not entirely unproblematic, at least relatively uncontroversial.³ Indeed, if NIPT lives up to its promise, reducing the number of more invasive tests and, with that, the number of babies lost during pregnancy, many will see it as a positive development.

However, in principle, NIPT might be used to provide extensive genetic information about the fetus,⁴ as well as about the mother's own health status.⁵ Already, the prospect of

* King's College London and Bournemouth University. Roger Brownsword, who is a member of the UK National Screening Committee, wishes to make it clear that the views expressed in this paper in no sense represent the views of the Committee.

** Bournemouth University

¹ <http://www.rapid.nhs.uk/about-rapid/evaluation-study-nipt-for-down-syndrome/>.

² See J. Gallagher, 'Safer Down's test backed for NHS use' (<http://www.bbc.co.uk/news/health-35311578>).

³ In the UK, cell-free fetal DNA testing has been available as a service to hospital trusts since 2001 to determine fetal RhD status in high risk sensitised women, and the test is also available in some NHS hospitals for fetal sex determination where there is clinical justification: see Caroline Wright, *Cell-free fetal nucleic acids for non-invasive prenatal diagnosis: report of the UK expert group (Executive Summary)*, Cambridge, PHG Foundation, 2009, available at: http://www.phgfoundation.org/download/ffdna/ffDNA_report_executivesummary.pdf. For recent Prime Ministerial comment on the implementation of NIPT see <http://jerseyeveningpost.com/news/uk-news/2016/05/04/dna-test-for-downs-syndrome-must-be-done-in-the-right-way-says-david-cameron/> (last accessed May 9, 2016).

⁴ 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 25, 2016).

⁵ See, K. Oswald, 'Prenatal blood test detects cancer in mothers-to-be', (2015) *Bionews* 739 at http://www.bionews.org.uk/page_503998.asp.

such a test exacerbates 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, as NIPT is rolled out, it will surely provoke a new round of questions relating to what a pregnant woman has a right to know, or not to know.⁶

Since the benefits of NIPT cannot be realised without returning the primary results of the test to the mother (so that, if the result is negative, she can decide not to proceed with an amniocentesis test or with chorionic villus sampling), the woman’s right to know is likely to be contested only in relation to secondary or incidental findings.⁷ On the other hand, the right not to know might be an issue for all results—and this is likely to become more contentious as genetic information is widely relied on in health care and freely circulated in clinics and hospitals. In that context, it should not be assumed that those women who really do not wish to know will be recognised as having a protective right.

Our paper is in four principal parts. In the first part, the general plausibility of a claimed right to know and right not to know is considered; in the second, with a view to developing an improved understanding of these rights, a number of responses and counter-responses to those who advance such claims are explored; in the third, the possible relevance to these issues of recent medical law jurisprudence in the United Kingdom—particularly, the landmark decision of the UK Supreme Court in *Montgomery v Lanarkshire Health Board*⁸—is assessed; and, in the fourth, we consider how far a ‘right to know’ might be constrained by a ‘lawful and proper purpose’ proviso.

II. The Plausibility of a Claimed Right to Know and Right Not to Know

With rapid developments in human genetics, while some humans might wish to know more about their own genetic profile, other humans might prefer not to inquire and not to be

⁶ Generally, see R. Chadwick, M. Levitt, and D. Shickle (eds), *The Right to Know and the Right Not to Know*, Cambridge, Cambridge University Press, 2014.

⁷ There might also be questions about the use of public funds for such purposes; but, for the purposes of our discussion, we can assume that the introduction of NIPT within the existing screening pathway will be cost-neutral.

⁸ [2015] UKSC 11.

told.⁹ Before long, advocates for those who so wish and for those who so prefer press for recognition of respectively ‘a right to know’ and ‘a right not to know’. No doubt, asserting these interests in knowing and not knowing as ‘rights’ can make good political sense.¹⁰ However, some might question the plausibility of these claims.

1. *The plausibility of the claimed rights: in general and in particular circumstances*

On the face of it, the proposition that there is a *general* ‘right to know’ as well as a ‘right not to know’ seems both vague and implausible. Simply because A would like to know something about B (e.g., about B’s genetic profile) it surely does not follow (absent special circumstances) that A has a claim-right against B, or against others who have the information in question, that the information should be disclosed. After all, the whole point of recognising a right to informational privacy and confidentiality is to *deny* that there is a general right to know. Similarly, simply because A would prefer *not* to know something about B, it surely does not follow (absent special circumstances) that A has a claim-right against B, or against others, that they should not disclose the information to A.

If we concede that there is no *general* right to know, we might nevertheless argue that, in some particular contexts (such as insurance and employment) or special circumstances (such as B making the equivalent of an easy rescue by passing on potentially life-saving information to A¹¹), there is a reasonable expectation that certain information will be disclosed (and, thus, a *prima facie* right to know). Similarly, we might argue that there are some special circumstances (for example, where A does not want to know about a close relative’s genetic profile because this information might have implications for A’s health and well-being) where there is a reasonable expectation that certain information will not be disclosed to us (and, thus, a *prima facie* right not to know).

With regard to the use of NIPT, the fact that the context is medical and that the test is genetic might seem to be less important than the fact that the woman’s claimed rights relate

⁹ For an early appreciation of the issues arising from these developments and differences, see Nuffield Council on Bioethics, *Genetic Screening: Ethical Issues*, London, 1993.

¹⁰ For an important discussion, see Stuart A. Scheingold, *The Politics of Rights: Lawyers, Public Policy, and Political Change*, Ann Arbor, University of Michigan Press, 1974.

¹¹ In the context of biobanking, see Deryck Beylveveld 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.

to her ‘personal’ information. This is not a case of A seeking information about B or, conversely, resisting the disclosure of information about B; the information in respect of which A claims a right to know, or not to know, is about herself or her baby. If anyone has a right to know, or not to know, about herself or her baby, it is surely A.¹²

While it might be accepted that A has a plausible right to know, or not to know, in relation to information that is ‘personal’ (in the sense of being information about A)—possibly, with the rider that the information should be non-trivial, or that having or not having the information might impact negatively on A’s physical or psychological well-being—there is a tricky question about whether A’s rights extend to information about her baby. For the purposes of settling the scope of A’s rights, should we treat information about A’s baby as equivalent to information about A?

2. *Is the mother to be identified with her baby?*

If A is to be identified with her baby, then information about A’s baby seems to fall within the scope of A’s personal information; information about A’s baby is information about A. However, is a mother to be so identified with her baby?

Characteristically, from the perspective of a rights-ethic, a human fetus is not yet a direct holder of rights (any protection that it enjoys is indirect or ‘precautionary’); and this view is strongly supported by the jurisprudence of the European Court of Human Rights.¹³ It might also be thought to be relevant that, because the use of NIPT becomes feasible towards the end of the first trimester of the pregnancy, the information that it yields comes at a time when the baby is not independently viable and when, where legal systems permit abortions, a woman’s right to terminate her pregnancy is likely to be least constrained. On the other hand, rival ethics, such as those espoused by utilitarians and duty-based dignitarians will regard a 12-13 week fetus as having directly protected interests¹⁴; and, in *Attorney General’s*

¹² Arguably, in relation to the health status of the baby, the father, too, has strong claims to know, or not to know; but, in the event of a conflict between the mother and the father (one wanting to know, the other not wanting to know), we might expect the mother’s interests to prevail.

¹³ *Vo v France* (Application no. 53924/00) (Grand Chamber, July 8, 2004); *Evans v United Kingdom* (Application no. 6339/05) (Grand Chamber, April 10, 2007).

¹⁴ 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; and *Rights, Regulation and the Technological Revolution*, Oxford, Oxford University Press, 2008, Ch. 2.

*Reference No 3 of 1994*¹⁵, while the Court of Appeal ruled that, prior to birth, the fetus should be ‘viewed as an integral part of the mother’¹⁶, the House of Lords disagreed, saying that, as between a mother and her 22-24 week old fetus, ‘the relationship was one of bond, not identity. The mother and the foetus were two distinct organisms living symbiotically, not a single organism with two aspects.’¹⁷ What should we make of these different views?

Arguably, the key to this is that, so long as the mother is recognised as having a right to terminate her pregnancy, and so long as the NIPT results are relevant to her decision, she has the right to know about the status of her baby. Even if the baby is not integral to the mother, even if information about the baby is not the same as information about the mother, it would be incongruous to recognise the mother’s right to terminate but to deny her access to information that is relevant to that decision.

Turning to the mother’s right *not* to know, how should we view such a claim where the information concerns, not herself as such, but her baby? The context here is likely to be somewhat different to that assumed above. One possibility is that this is a special case where the mother claims the right not to know about her baby’s status (e.g., whether the baby has the markers for Huntington’s Disease) because she does not wish to know about her own status.¹⁸ Here, the fact that the baby might be characterised as a distinct organism does not weaken the mother’s interest in not knowing. The circumstances, however, might be otherwise; possibly, this is a mother who does not wish to know because, quite simply, she has decided to continue with the pregnancy regardless of the test results. If this is so, the resistance to the mother’s claim might not be so much that, at the time of the NIPT, the baby is already a distinct organism but that, once born, he or she might have expensive health care needs. If the family will cover the costs, that might be fine; but, if not, some might object that the mother’s right not to know comes at too high a public price.

¹⁵ [1996] QB 581 (CA); [1997] 3 All ER 936 (HL).

¹⁶ [1996] QB 581, 598.

¹⁷ [1997] 3 All ER 936, at 943d (per Lord Mustill).

¹⁸ However, we note that it might be possible, if not necessarily straightforward, to inform the mother about the baby’s status without also informing her about her own status: see Deryck Beyleveld, Oliver Quarrell, and Stuart Toddingon, ‘Generic Consistency in the Reproductive Enterprise: Ethical and Legal Implications of Exclusion Testing for Huntington’s Disease’ (1998) 2 *Medical Law International* 135.

3. *Another way of formulating the mother's right to know*

There is one other thought: perhaps the mother's claimed rights should not be formulated in terms of her 'personal' information but, rather, in terms of information that she reasonably needs to have, or not to have, for the sake of her physical or psychological well-being. In other words, the rights protect the mother's interest in her physical or psychological well-being rather than relating to some kind of informational proprietary interest. The logic of this is that, even if it is conceded that information about the baby is information about another, or about someone other than the mother, this is irrelevant because the mother's rights rest on her own physical and psychological well-being. Given the connection, biologically and emotionally, between a mother and her 12-13 week baby, it is plausible to think that the mother has a reasonable expectation that she should be permitted to know, or not to know, about the NIPT results as they relate to her baby and, in consequence, as they directly and intimately concern her own well-being.

Already, in trying to assess the relevance of the baby's distinct identity relative to the mother, we are getting ahead of ourselves. At this stage, it is enough to say that, while a general right to know or a general right not to know is implausible, there are reasons for thinking that, in the context of pregnancy screening, the claimed rights have a sufficient plausibility to put the burden on to those who would deny them.

III. Responding to A's Claimed Right to Know and Right Not to Know

Let us suppose that, in the context of the use of NIPT, A (a pregnant woman) claims a right to know, or not to know, against B (the screener). While, as we have seen already, the precise scope of each claimed right is somewhat unclear, this is just one of a number of potentially contentious points. In principle, there are a number of responses open to B and counter-responses open to A. We can sketch five such exchanges between B and A.

1. *NIPT and pregnancy screening is a rights-free zone*

B might assert that public screening programmes are rights-free zones. This is not to suggest that screeners have no ethical commitments; B simply denies that 'respecting the rights of others' is the relevant test of doing the right thing. Rather, the justification for proposed public health interventions or practices is that they promise to promote the general utility; and, in clinical settings, medical professionals strive to avoid doing any harm as well as trying to do some good for patients. In response, there are many things that A might say.

However, perhaps it suffices to point out that, so long as the practice is to ‘invite’ individuals to be screened, the clear implication is that individuals have a prior *right* not to be screened. It follows that, if the default position in relation to current practice is that individuals have a right not to be conscripted, then this undermines any claim that screening is a rights-free zone.

2. *The particular rights are not recognised*

Even if it is conceded that pregnant women who are screened have some rights, B might object that the claimed rights are simply not recognised.

In response A might look for international legal support. For example, A might point to Article 10.2 of the Convention on Human Rights and Biomedicine (according to which ‘Everyone is entitled to know any information collected about his or her health’; and, moreover, ‘the wishes of individuals not to be so informed shall be observed’) as well as Article 5(c) of the UNESCO Declaration on the Human Genome (which endorses the ‘right of every individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences’). However, the United Kingdom has not signed up to the former Convention which, in any event, leaves it unclear whether fetal data (obtained from the maternal blood) falls within the ambit of ‘his or her health’; and the latter Declaration, while not to be ignored, is largely symbolic and aspirational and, arguably, something of an ethical cocktail, mixing liberal rights with rather conservative dignitarian ideas.¹⁹

A might also appeal to the jurisprudence of the domestic common law. What the case-law indicates is that, if the screeners have voluntarily assumed a responsibility for the return (or the non-return) of NIPT results, or if this is settled custom and practice, A’s claim should be reasonably straightforward. However, absent such evidence, the critical legal question seems to be whether it would be ‘fair, just, and reasonable’ to place screeners under the claimed duties—apparently, restating the original question of whether the claimant’s

¹⁹ For the latter, see e.g., Article 4 (no financial gain to be made from the human genome in its natural state) and Article 11 (prohibiting practices, such as human reproductive cloning, that are contrary to human dignity). Generally, see Deryck Beyleveld and Roger Brownsword, *Human Dignity in Bioethics and Biolaw*, Oxford, Oxford University Press, 2001, and Roger Brownsword, ‘Human Dignity from a Legal Perspective’ in M. Duwell, J. Braavig, R. Brownsword, and D. Mieth (eds), *Cambridge Handbook of Human Dignity*, Cambridge, Cambridge University Press, 2014, 1.

expectation is a reasonable one. Whether or not the decision of the UK Supreme Court in *Montgomery v Lanarkshire Health Board* might impact on this is a matter to which we will return later in the paper.

More ambitiously, A might argue that the claimed rights are immanent within our existing understanding of such concepts as agency, property, and privacy (and our understanding of their associated rights). For example, A might argue that we already presuppose that each agent has a critical interest in the free construction of his or her personality.²⁰ In an age of burgeoning genetic information, some agents, preferring to be aware of risks and to manage them, will want to know as much as they can about the details of their genetic profile; but others will prefer not to anticipate their futures and to cross whatever bridges have to be crossed as and when they meet them. While the former will claim a right to know, the latter will insist on a right not to know.

A might also plead both property and the protean concept of privacy in support of the claimed rights.²¹ For example, A might argue that she has proprietary rights in relation to the blood used for the NIPT—a controversial claim to be sure²²—which then reaches through to the information derived from the test. Or, if we treat privacy as a right to maintain a state of psychological separateness, or a right not to be subject to unwilled ‘intrusions’, or as a right to be let alone, any one of these versions seems to support the idea that, via the right not to know, A should be entitled to resist the intrusion of unwanted information about herself.²³ Whether or not A also has a right to resist the intrusion of unwanted information about her baby is, as we have seen, another matter.

²⁰ Cf., too, the approach to ‘best interests’ in *Aintree University Hospitals NHS Foundation Trust v James* [2013] UKSC 67 (where the significance of a particular patient’s attitude is emphasised).

²¹ Compare *R (Tracey) v Cambridge University Hospitals NHS Foundation Trust and others* [2014] EWCA Civ 822 (for the application of privacy to a patient’s right to be consulted about a DNACPR order).

²² See, e.g., Rohan Hardcastle, *Law and the Human Body: Property Rights, Ownership and Control*, Oxford, Hart, 2007; Roger Brownsword, ‘Property in Human Tissue: Triangulating the Issue’, in Michael Steinman, Peter Sykora, and Urban Wiesing (eds), *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue*, Aldershot, Ashgate, 2009, 93; and Sarah Devaney, ‘Tissue Providers for Stem Cell Research: the Dispossessed’ (2010) 2 *Law, Innovation and Technology* 165.

²³ Compare, G. Laurie, ‘Privacy and the Right Not to Know: A Plea for Conceptual Clarity’, in Chadwick et al (fn 6) 38.

We have seen already, in the previous part of the paper, that there is more than one way of plausibly articulating the claimed rights; and, whatever we now make of the conceptual arguments just sketched, there is more than enough in them to put the burden of rebuttal back upon B.

3. *A has given a covering consent in relation to the claimed rights*

B might argue that, although A has the claimed rights, she has authorised (by giving her consent to) acts that would otherwise violate the rights. Provided that A has given a valid consent—that is to say, provided that A has the requisite capacity to consent, provided that the consent is given freely and on an informed basis, provided that the consent is clearly signalled, and provided that B’s act is within the scope of the authorisation²⁴—then B should prevail. Needless to say, there is plenty of room for A to contest B’s interpretation of these provisos. Moreover, in practice, pregnant women might find it difficult to opt-out from a screening pathway. To the extent that the norm is to return the primary results of the NIPT, this might be relatively unproblematic. However, if the NIPT consent forms state either that no incidental findings will be returned or that all findings will be returned, and if asking a patient to sign off on these terms is all very routine, A might claim that she was ‘nudged’²⁵ towards these terms in a way that undermines the idea that her ‘consent’ was freely given.

4. *The information in question falls outside the scope of the recognised rights*

In our earlier discussion of the possibly distinct identity of, on the one hand, the mother and, on the other, her baby, we have already seen that the scope of the claimed rights is moot. Additionally, though, B might argue—particularly with regard to the right to know—that the information at issue is of such uncertain significance that A could not act upon it; and, hence, it lies outside the scope of the right. Or, it might be argued that A intends to apply the information for some improper (or even unlawful) purpose which again takes the case beyond the scope of the right.

Recognising the potential uncertainty of genetic information, the different degrees of seriousness of findings, and different grades of actionability, A might concede that the scope

²⁴ See Deryck Beyleveld and Roger Brownsword, *Consent in the Law*, Oxford, Hart, 2007.

²⁵ Seminally, see Richard H. Thaler and Cass R. Sunstein, *Nudge: Improving Decisions About Health, Wealth and Happiness*, New Haven, Yale University Press, 2008 where, of course, the opportunity to opt-out is seen as preserving free choice; more recently, though, compare the more nuanced discussion in Cass R. Sunstein, *Choosing Not To Choose*, Oxford, Oxford University Press, 2015.

of the right needs to be fine-tuned. For example, A might accept that, guided by such considerations as the relative certainty, reliability, and actionability of the results together with the seriousness and treatability of the condition, we might place findings on one of three lists: (1) a ‘white list’ (results should be returned), (2) a ‘grey list’ (results may be returned), and (3) a ‘black list’ (results should not be returned).²⁶

That said, even if the information is clearly actionable, a proviso for lawful and proper use seems appropriate. This is a matter to which we will return in the final part of the paper.

5. *A’s right is overridden by a higher order right (or by a compelling consideration of the ‘public interest’)*

Finally, B might argue that A’s right to know or not to know is overridden by a higher ranking conflicting right or by some compelling consideration of the public interest. If we assume that A’s claimed rights relate to her physical and psychological well-being, these are rights that protect vital agency interests and they will not be easily outranked by either conflicting rights²⁷ or by the public interest. A’s rights ‘trump’ routine justifications and, if B’s public interest arguments are to operate as ‘super-trumps’, this presupposes an emergency of some kind and not simply the balance of convenience.

That said, while it is quite difficult to think of public interest reasons that might override a mother’s prima facie right to know, it is not so difficult to imagine scenarios in which, for public health reasons, the State pleads a compelling public interest against the mother’s right *not* to know. When communities are struggling to contain and control the spread of Ebola or the Zika virus, mothers might have additional responsibilities which mean

²⁶ Compare S.M. Wolf et al, ‘Managing incidental findings and research results in genomic research involving biobanks and archived data sets’ (2012) 14 *Genetics in Medicine* 361.

²⁷ We might note the decision in *ABC v St George’s Healthcare NHS Trust* [2015] EWHC 1394 (QB) where 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 children would also be at risk, she would have terminated the pregnancy. Somewhat surprisingly, the claim was struck out on the ground that, because the defendants obtained the information about the father’s health status in confidence, it would not be fair, just, and reasonable to impose on them a duty to inform the daughter. However, it is not clear whether the court (i) declined to recognise a prima facie duty to inform or (ii) recognised a (weak) prima facie duty to inform but treated it as outweighed by a (stronger) conflicting duty of confidence. Either way, the claimed right to know is not assisted; but, in the context of NIPT, such a right is unlikely to run up against a conflicting right to confidentiality.

that they are not entitled to insist on their prima facie right not to know. It bears repetition, though, that while the mother's rights are only prima facie, they nevertheless are *rights* and, as Ronald Dworkin famously declared, what is special about rights is that they need to be taken seriously.²⁸

No doubt, the arguments between those who claim the right to know or not to know and those who oppose such claims will continue—there will be many 'battles', legal and ethical, to be won and lost. However, at this point, we can move on to consider a major development in the jurisprudence of medical law in the United Kingdom, a development which at first blush seems to assist the proponents of these rights.

IV. After *Montgomery*

For many years, according to the so-called *Bolam* test,²⁹ English law has recognised that doctors may respond to a negligence claim by showing that a responsible body of medical opinion (not necessarily the mainstream view) supports their actions (or omissions). However, when doctors discuss with their patients the investigatory and treatment options and risks therein, such a defence seems to have been eliminated by the decision of the UK Supreme Court in *Montgomery v Lanarkshire Health Board*. After *Montgomery*, the law is predicated on a new approach to the doctor/patient relationship.

1. The New Approach

The principal question in *Montgomery* was whether a pregnant woman who was a diabetic, and whose pregnancy was regarded as high-risk requiring intensive monitoring, should have been informed that there was a risk of shoulder dystocia and given the option of delivery by Caesarean Section. Instead, as the court narrated the story,³⁰ she was not made aware of this particular risk; the risk eventuated during an attempted vaginal delivery that went horribly wrong; and, as a result, the baby was born with severe disabilities. The lower courts, following the *Bolam* principle, held that the acts of the consultant obstetrician and gynaecologist, who was by her own admission reluctant to steer women towards a Caesarean

²⁸ Ronald Dworkin, *Taking Rights Seriously*, London, Duckworth, 1978.

²⁹ *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.

³⁰ For some critical comments on this version of the story, see Jonathan Montgomery and Elsa Montgomery 'Montgomery on informed consent: an inexpert decision?' (2016) 42 *J Med Ethics* 89.

Section, was sufficiently supported by medical practice. However, the UK Supreme Court, resoundingly rejecting the *Bolam* test, held that the relationship between clinicians and patients must be rights-respecting rather than paternalistic and that patients have a right to be informed about their options (together with their relative benefits and risks).

Rewriting the legal framework, the Supreme Court recognised, first, that ‘patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession’.³¹ Secondly, the Court noted that patients, while not medical experts, are not wholly uninformed. Accordingly, it would be ‘a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent upon a flow of information from doctors’, from which it followed that it would now be ‘manifestly untenable’ to make this ‘the default assumption on which the law is to be based’.³² Thirdly, professional guidance to doctors already reflects these changes by encouraging ‘an approach based upon the informed involvement of patients in their treatment’.³³ Signalling a distinct movement away from medical paternalism and patient-dependence, the new approach is built on mutual rights and responsibilities, treating patients ‘so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices’.³⁴ In short, patients have a right to make their own judgments of what is in their best interests; and it is the responsibility of doctors not to override these judgments but to assist patients by ensuring that their choices are suitably informed.

Without doubt, the headline story in *Montgomery* is that the doctor/patient relationship is now predicated on the rights paradigm rather than ethical paradigms that prioritise professional duties or paternalistic responsibilities or that centre on maximising utility or minimising distress. As Lady Hale, giving a separate but fully concurring judgment, expressed it:

³¹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, para 75.

³² *Ibid.*, para 76.

³³ *Ibid.*, para 78.

³⁴ *Ibid.*, para 81.

A patient is entitled to take into account her own values, her own assessment of the comparative merits of giving birth in the “natural” and traditional way and of giving birth by caesarean section, whatever medical opinion may say, alongside the medical evaluation of the risks to herself and her baby...Gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also her right to act as a genuinely autonomous human being.³⁵

Moreover, in addition to noting the growing culture of consumer rights, the court remarked on the increasing influence in judicial thinking of the importance of respecting human rights: ‘Under the stimulus of the Human Rights Act 1998, the courts have become increasingly conscious of the extent to which the common law reflects fundamental values’.³⁶

2. *Montgomery and the right to know*

As with any potentially landmark decision in the law of negligence, lawyers can read the ratio of *Montgomery* in more than one way. Those who wish to minimise the impact of the decision will read it narrowly; those who wish to build on it will read it more broadly. Nevertheless, after *Montgomery*, we suggest that it is reasonable to assume that, at all stages of a pregnancy, whether in the ante-natal screening clinic or in the delivery room, a woman has a right to be informed about the options that are available to her. It follows that, once NIPT is embedded in the screening pathway, pregnant women will have a right to know about the availability of the test, and to be informed about the risks and consequences of having the test. The fact that *Montgomery* supports the right to know in relation to the primary results is probably not especially significant—because they will be returned anyway. The real question is whether *Montgomery* supports a more extended application of the right to know.

Suppose, for example, an NIPT screen reveals a potentially life-threatening condition that affects the mother. While *Montgomery* does not directly support the woman’s right to be informed, it certainly does not weigh against it and, arguably, by analogy with the easy rescue, she is entitled to be informed.³⁷ Similarly, *Montgomery* does not directly support the

³⁵ Ibid., paras 115-116.

³⁶ Ibid., para 80. Compare, e.g., *R (Tracey) v Cambridge University Hospitals NHS Foundation Trust and others* [2014] EWCA Civ 822.

³⁷ Compare, Roger Brownsword, ‘The Ancillary Care Responsibilities of Researchers: Reasonable but Not Great Expectations’ (2007) 35 *Journal of Law, Medicine and Ethics* 679.

woman's right to be informed if NIPT reveals information about the fetus other than that relating to the trisomies. Nevertheless, with the courts realising the importance of the common law being in line with fundamental values, a court might in future start with the proposition that, if a woman wishes to access information about the genetic profile of her baby, she has a right to do so. This would suggest that the health service has a responsibility to return to the woman whatever test results are (i) relatively easy to interpret, (ii) clear as to their clinical significance, and (iii) material to the woman's decision—the *Montgomery* test of materiality being 'whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it'.³⁸ Presumably, no reasonable person would want information on the black list; but, what would be the legal position if a particular woman (unreasonably) did want all results, on all lists, to be returned? If the scope of a right to be informed follows closely the contours of the *Montgomery* case, it might well be that it extends only to results on the 'white list'. However, if the reference point for a right to be informed is not restricted by *Montgomery*, it might be that it extends to the grey list or even to the full spectrum of results including data on the black list.

3. *Montgomery and the right not to know*

In *Montgomery*, we read that '[a] person can of course decide that she does not wish to be informed of risks of injury (just as a person may choose to ignore the information leaflet enclosed with her medicine).'³⁹ This might be read as saying no more than that a person who has the right to know may elect not to inform themselves; and, given that *Montgomery* is concerned with providing rather than not providing information—at any rate, subject to a short reservation for the so-called 'therapeutic privilege'⁴⁰—this might be all that the Court means. Accordingly, we need to be careful not to make too much of *Montgomery* in relation to the claimed right not to know.

³⁸ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, para 87.

³⁹ *Ibid.*, para 85.

⁴⁰ *Ibid.*, paras 88-91.

Although *Montgomery* is hard to interpret on the right not to know, we do know that this right is only likely to become a real issue where the practice is to return findings. Provided that the options that are available are set out and a woman then rejects an option for the return of findings, the thinking in *Montgomery* suggests that, on the one side, health care professionals must restrain any paternalistic impulses that they might have, and, on the other, the woman must live with the consequences of her decision. Yet, as Hank Greely has provocatively suggested,⁴¹ it might not be quite so easy to turn back the tide of genetic information. For example, the costs and inconvenience of administering a right not to know might not be trivial, professionals might find it difficult to accept that they should act as though patients know best when in their expert judgment they manifestly do not, and the community might think that prospective parents should not be permitted to shirk their responsibilities by claiming a right not to know. In this respect, the reproductive culture of communities in the future might be far more risk-averse.

V. A Proviso for ‘lawful and proper purposes’

Let us suppose that a woman claims a right to the return of NIPT results that are reasonably reliable and actionable. However, she makes no secret of her intention to use the results for a purpose that is plainly unlawful (for example, for the purpose of *unlawful* sex selection). In such circumstances, there are good reasons for the screeners to withhold the results—or, at any rate, to withhold results that reveal the sex of the baby. Where the woman does not declare her intention to use the results for an unlawful purpose, or where the woman forms her unlawful intention only at a later stage, the circumstances are more complex. Notwithstanding that there are some hard cases, the easy cases prompt the thought that the woman’s right to know needs to be qualified by a ‘lawful and proper purpose’ proviso.

Assuming such a proviso, we take it that the easy cases are those in which the woman’s known purpose is either ‘both lawful and (by common consent) proper’ or ‘both unlawful and (by common consent) improper’. The intermediate cases are those where the woman’s known purpose is either ‘lawful but (as some would have it) improper’ or ‘unlawful but (as some would have it) proper’. An example of the former might be where a woman is simply curious to know the sex of her baby, with no intention to apply the information for an

⁴¹ Henry T. Greely, *The End of Sex and the Future of Human Reproduction*, Cambridge, Mass., Harvard University Press, 2016; and nb Robert C. Green et al, ‘ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing’ (2013) 15 *Genetics in Medicine* 565.

unlawful purpose.⁴² From a rights perspective, there is no good reason to resist or restrict her right to know on the ground that her purpose, albeit lawful, is improper (any more than there would be reason to resist her right *not* to know on the ground that it would be improper for her to decline to have this information). Moreover, after *Montgomery*, such restrictive moral paternalism would be difficult to defend. An example of the latter might be where the woman intends to apply the information for unlawful sex selection purposes, but some (possibly some rights theorists) regard the purpose as proper. This might give rise to a dilemma for a screener who sympathises with the woman's purpose but we assume that, in most cases, the fact that the purpose is unlawful will be the dominant consideration.

Thus far, we have assumed that the legal position will be clear; we will know whether the mother's purpose is lawful or unlawful. However, legal systems are rarely clear and comprehensive in all respects and there might be grey areas where the legal position is contestable. Accordingly, using the English legal system as our reference point, what kind of information and what kind of reproductive purposes might be questionable?

To start with the kind of information, a mother might claim a right to know about genetic anomaly or the health of her developing child. She might extend that claim to knowledge about gender or more trivial genetic information⁴³ about the fetus. If the purpose of such a claim is to inform and make a straightforward choice between the continuation and termination of the pregnancy, it might matter what type of information is being sought through the screening process. In England and Wales, there is no unfettered legal right to demand an abortion on any basis, even if the practical realities are that abortions may be available on demand, at least, within the first 24 weeks of the pregnancy.⁴⁴ Certainly, if a woman can persuade the assessing doctors that continuation of the pregnancy would involve a greater risk to her 'physical or mental health'⁴⁵ than a termination, it would provide a lawful basis for any subsequent abortion providing the pregnancy has not exceeded its 24th week.⁴⁶

⁴² 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"' (2015) 29 *Bioethics* 19.

⁴³ For example, the colour of the child's hair.

⁴⁴ By virtue of s1(1)(a) Abortion Act 1967. For a discussion of the issues, see Emily Jackson, 'Abortion, Autonomy and Prenatal Diagnosis' (2000) 29 *Social and Legal Studies* 467, at 470-471.

⁴⁵ Or that of any existing children of the family.

⁴⁶ (fn 44).

It is also easy to imagine a scenario where the doctors are willing to certify that information about the health or genetic profile of the developing child is or will be likely to impact on the well-being of the pregnant woman. However, there is no explicit statutory or other legal endorsement of abortion where the sole criterion is the gender of, or other trivial information about, the fetus.⁴⁷

With regard to the kind of reproductive purposes that a mother might have, the Abortion Act 1967 also provides a lawful basis to terminate a pregnancy (at any stage) if two doctors form the opinion, in good faith, that there ‘*is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped*’.⁴⁸ There is considerable uncertainty about the precise meaning of this provision in terms of risk and purpose.⁴⁹ The section certainly links abnormality with a serious degree of disability and therefore we can reasonably state that this lawful ground does *not* include minor handicap or disability within its scope.⁵⁰ It is also arguable that there is doubt about the legal basis of abortions where the sole criterion is uncertain and/or future disability.⁵¹ So it would seem plausible to constrain the exercise of a right to know where it is understood that information is being sought for the sole purpose of terminating a pregnancy on the grounds of gender, trivial information, minor abnormality or uncertain/future disability. Of course, there is the practical problem here—such intentions or purposes are unlikely to be disclosed or even formulated prior to the availability of test results. Even if it were a requirement that women should provide advance assurances as to the future usage of test results,⁵² such promises would offer little security and, in any event, they surely would prove unworkable or unenforceable.

⁴⁷ See for eg, Department of Health, *Guidance in Relation to the Requirements of the Abortion Act 1967*, London, HMSO, 2014, para 25 at 10.

⁴⁸ S1(1)(d) Abortion Act 1967.

⁴⁹ For a more detailed discussion, see S, McGuinness, ‘Law, Reproduction, and Disability: Fatally ‘Handicapped?’ (2013) 21 *Medical Law Review* 213.

⁵⁰ However, the case of *Jepson v Chief Constable of West Mercia Police Constabulary* [2003] EWHC 3318 (Admin) provides an illustration of the difficulties in defining the boundaries of s1(1)(d).

⁵¹ For a discussion of the issues, see A Grubb, ‘The New Law of Abortion: Clarification or Ambiguity’ [1991] *Criminal Law Review* 661.

⁵² See for example, the suggestion by A Hall, A Bostanci, and S John, *Ethical, Legal & Social Issues Arising from Cell-Free Fetal DNA Technologies*, Cambridge, PHG Foundation, 2008 in Wright (fn3) at 37.

Further, even if we were to assume that a woman has a right to know about the health/genetic profile of her developing child irrespective of purpose, there might still be arguments against a State facilitating that right,⁵³ unless it is likely to be connected to a lawful and proper purpose. Such arguments might include consistency in the public narrative around the exercise of reproductive autonomy.⁵⁴ So, even if a pregnant woman has the right to know some trivial information about her developing child, a State may not want to directly or indirectly support or encourage choices⁵⁵ that ultimately are unlawful. Doing so could communicate confused and inconsistent messages to the public and challenge the legitimacy of any connected legal framework.⁵⁶ Of course, information might be claimed for many purposes and it may not be a simple case of deciding whether to continue or terminate the pregnancy. There may very well be cases where the information sought could equally enable the pregnant woman to ready herself psychologically and physically for the arrival of a child with a particular disability or health condition. A mother might also want to test for conditions that are treatable or otherwise remedial during the pregnancy.⁵⁷ So, in practical terms, it may prove difficult to separate out the ‘lawful and proper’ from the ‘unlawful and improper’ purpose.

Summing up, we can say that the interpretation, application, and enforcement of the proviso will present problems where the background law on reproductive choices is unclear, where there is a lack of fit between what the law permits or prohibits and what the community judges to be a proper or an improper purpose, where the woman’s purposes are not known (do screeners have a right to know?), and where a woman, not having an unlawful intention at the time of the test, subsequently applies the results for an unlawful purpose.

⁵³ Through the funding of access to this information.

⁵⁴ For a fuller discussion of the arguments, see J. Wale, ‘Don't forget the legal framework: the public provision of non-invasive prenatal testing in England & Wales’ (2016) *Medical Law International* available from <http://mli.sagepub.com/content/early/2016/04/27/0968533216646154?paperocn> (last accessed May 3, 2016).

⁵⁵ E.g., terminations of the pregnancy.

⁵⁶ For example, the legal framework that regulates *ex vivo* embryo testing and implantation which, in the UK, does not permit selection on the sole basis of gender unless there is a genetic condition related to sex and the selection is being made to avoid the risk of that condition (see Schedule 2 para 1ZA of the Human Fertilisation and Embryology Act 1990).

⁵⁷ E.g., testing for rhesus status.

VI. Concluding remarks

As the piloting of NIPT in the UK national screening programme proceeds, and with the Nuffield Council on Bioethics having very recently announced a new Working Party to consider the ethical issues raised by potential future uses of NIPT,⁵⁸ we can be confident that public debate about the ethical and legal questions raised by this test has only just begun. Drawing on our discussion in this paper, what would be our starting points for debating a pregnant mother's claimed right to know or not to know the results of such a test with regard to her own health status or (if it is distinguishable) that of her baby?

First, the claim that there is a general, unqualified, right to know and not to know is implausible. Nevertheless, there are some contexts and some circumstances in which a party may plausibly claim that they reasonably expect certain information to be disclosed or not to be disclosed. To the extent that the claimed rights to know or not to know draw on reasonable contextual and circumstantial expectations, the rights claims themselves then pass a threshold of plausibility.

Secondly, because the mother is claiming the right to know and not to know in relation to information that concerns her own health and well-being, or that concerns the status of her baby, her claims have to be taken seriously. Insofar as the mother's claimed rights hinge on information about the baby being equivalent to information about herself (the baby being treated, in effect, as an integral part of the mother), there is a debate to be had about whether such an equivalence holds. However, if the mother claims the rights relative to information about the health status of her baby on the ground that such information, albeit not directly about herself, touches and concerns her own physical and psychological well-being, then these claims are no longer vulnerable to the objection that the baby is not an integral part of the mother.

Thirdly, if the burden shifts to those who wish to contest the mother's prima facie rights, there are many points on which such resistance might focus, including questions about the most compelling articulation of the rights (in terms of an agent's interest in their basic well-being, or in terms of a proprietary interest, or in terms of a personality interest, and so

⁵⁸ <http://nuffieldbioethics.org/news/2016/new-project-on-non-invasive-prenatal-testing/> (last accessed April 19, 2016). For a very helpful background paper, see Vardit Ravitsky, 'Non-Invasive Prenatal Testing (NIPT): Identifying Key Clinical, Ethical, Social, Legal and Policy Issues': available at <http://nuffieldbioethics.org/wp-content/uploads/NIPT-background-paper-8-Nov-2015-FINAL.pdf> (last accessed April 27, 2016).

on), and about the scope and weight of these rights as well as about their relationship with public health and public interest considerations.

Fourthly, it is not at all clear that the basis of the right to know is the same as that of the right not to know. Perhaps, the most plausible common basis for these claimed rights is that the mother has a fundamental interest in defining her identity (as one who wishes to be genetically informed or as one who does not wish to be identified with such information).

Fifthly, it is also not clear whether the two claimed rights, so to speak, articulate symmetrically. For example, we have suggested that it might be difficult to find compelling public interest reasons for denying a woman a right to know the results of an NIPT, but that there might be public health and other reasons for overriding her right not to know about both her own and her baby's health status.

Sixthly, the decision in *Montgomery* points towards a possible framework for a qualified maternal right to know. The position is less clear in relation to the mother's right not to know—and it might well be that this is the right that, in practice, encounters more resistance. Furthermore, there are likely to be practical and resource implications for any State that chooses to facilitate a right not to know.

Seventhly, any right to know (qualified or not) may be subject to some restriction or constraint represented by a proviso that requires that the mother's purpose is 'lawful and proper'. Although there might be some easy cases for the application of this proviso, we should not assume that, in practice, its enforcement will always be straightforward.

Finally, it is perhaps worth repeating that while, in the early days of human genetic screening and testing, it might be the right to know that is in the spotlight, as health care comes to routinely rely on genetic information it might be the right not to know that is more hotly contested.