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For your interest? The ethical acceptability of using non-invasive prenatal testing to test ‘purely for information.’

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ABSTRACT

Non-invasive prenatal testing (NIPT) is an emerging form of prenatal genetic testing that provides information about the genetic constitution of a foetus without the risk of pregnancy loss as a direct result of the test procedure. As with other prenatal tests, NIPT can help to make a decision about termination of pregnancy, plan contingencies for birth or prepare to raise a child with a genetic condition. NIPT can also be used by women and couples to test purely ‘for information’. Here, no particular action is envisaged following the test; it is instead entirely motivated by an interest in the result. The fact that NIPT can be performed without posing a risk to the pregnancy could give rise to an increase in such requests. In this paper, we examine the ethical aspects of using NIPT ‘purely for information,’ including the competing interests of the prospective parents and the future child, and the acceptability of testing for ‘frivolous’ reasons. Drawing on several clinical scenarios, we claim that arguments about testing children for genetic conditions are relevant to this debate. In addition, we raise ethical concerns over the potential for objectification of the child. We conclude that, in most cases, using NIPT to test for adult-onset conditions, carrier status or non-serious traits presenting in childhood would be unacceptable.
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INTRODUCTION

For better or worse, the availability of prenatal screening and testing has undoubtedly increased the choices available to women and couples. Women may choose to access a prenatal test to determine the course of the pregnancy, to prepare for a safe birth or to adjust to the prospect of parenting a child who has or who will develop a genetic condition. The prenatal testing landscape has recently been changed by the development of non-invasive prenatal testing (NIPT), a new method of obtaining foetal DNA for analysis. A notable advantage of NIPT is that, unlike current prenatal diagnosis (PND), the test itself does not carry a risk of miscarriage.

NIPT is not yet as robust and reliable as ‘traditional’ methods of prenatal diagnosis (PND), such as amniocentesis and chorionic villus sampling. This means that it is still often regarded as only an “advanced screening” method, whether offered in a screening programme or as a stand-alone test.\(^1\)

However it is already possible to use NIPT to test for many of the same single-gene and chromosomal genetic conditions as PND; be it for a serious medical condition that presents in childhood, a serious medical condition

that presents in adulthood, a non-serious medical condition or carrier status. There has been considerable success in developing NIPT for a range of conditions and traits such as haemophilia, sex determination and trisomy 21. Complete sequencing of the foetal genome has also been achieved in a research setting. Although it remains a challenge, this paper rests on the assumption that NIPT can be used to interrogate the foetal genome in just the same way as with an invasive test.

The wider ethical, legal and social implications of NIPT have been discussed elsewhere. However, one of the most striking possible implications of NIPT has not yet been addressed. Women and couples choose prenatal screening or testing for a variety of reasons, including determining whether to continue or terminate a pregnancy, or to increase

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their knowledge of their foetus with no intention to terminate. Because of the risk of miscarriage associated with invasive tests (around 1% depending on the test and its timing⁵), until now couples have been encouraged to consider the risk to the foetus of any invasive procedure when deciding about prenatal screening or testing. If this ‘barrier’ of risk to the foetus is removed, the uptake of testing in pregnancy (including requests for testing ‘purely for information’, with no intention to terminate) might well be higher.

We are interested in the ethical implications of the use of NIPT ‘purely for information.’ An interested couple may have a desire to undergo NIPT much in the same way that some people find out the sex of their foetus in utero through ultrasound scanning; not with the intention to detect a range of abnormalities, but to obtain information about the characteristics of the foetus, perhaps to help them bond with their baby, or simply to satisfy their curiosity. This use of NIPT ‘for information only’ might arise in both individual requests for testing or an organised screening programme.

The paper is divided into four sections. Section I introduces five clinical scenarios to describe possible uses of NIPT for information only. In Section II we give an account of the main arguments about genetic testing in children, which we then apply to prenatal testing in Section III. In Section

IV we ask how, if at all, the introduction of the non-invasive aspect of testing affects the debate. We suggest that the most notable difference between using childhood or invasive prenatal testing for information only and using NIPT for information only is that NIPT may give rise to testing for ‘frivolous’ reasons, something that may be objectionable not because of its potential for harm, but because it may encourage the objectification of children.

SECTION I. CLINICAL SCENARIOS

To illustrate how the issue of using NIPT ‘purely for information’ may arise in practice, we have outlined five clinical scenarios. Each involves a planned pregnancy.

(i) Requesting a test for carrier status
Ms A is pregnant and is a known but unaffected carrier of the cystic fibrosis gene change. No gene change has been able to be identified in her partner, so their foetus is at low risk of being born with this condition. However Ms A is very interested to know whether the foetus also carries her gene change, even though she will not take any action based on this information.

(ii) Requesting a test for a minor genetic condition
Ms B is pregnant and has a genetic condition which carries no health implications but for shorter than normal height. A gene change causing this condition is known. Ms B wishes to know whether her
foetus also has this gene change but she wishes to continue the pregnancy whatever the result.

(ii) Requesting a test for foetal sex
Ms C and her partner are in the early stages of pregnancy. They are very excited to be pregnant after experiencing three miscarriages. They are intrigued to know the sex of their foetus and don’t wish to wait for a mid-pregnancy ultrasound to find out. They don’t have a preference for a particular sex.

(iv) Requesting a test for a serious adult-onset condition
Ms D is pregnant, and her partner has the gene change that will lead to Huntington’s disease (HD; an adult-onset neurodegenerative disorder), although he is currently symptom-free. Given their experiences, such as caring for a recently deceased relative who had HD, they would like to know whether their foetus has the HD gene change so that they could prepare themselves, and their child, for the future. They have no plans to terminate the pregnancy.

(v) Offering foetal whole genome sequencing
Ms E is pregnant with her first child. Her maternity care provider is linked to a research institute that has recently commenced a trial of foetal whole genome screening for any pregnant woman regardless of medical history. The trial involves analysing the whole genome of the foetus, using material obtained via NIPT. Results will provide information about all known conditions and traits. Ms E would like
to participate in this trial to obtain this information. She would like to know more about her foetus, but plans to continue the pregnancy whatever the tests reveal.

In many instances of prenatal diagnosis or screening, a request for testing ‘for information only’ (with no intention to terminate) would be relatively uncontroversial because there may be medical benefits such as managing pregnancy or birth, or providing the newborn with treatment that could be balanced against the risk of miscarriage. Making a test available by NIPT is therefore an unalloyed benefit in these kinds of circumstances. However in scenarios such as those described above, those requesting testing may be counselled against invasive testing as it would offer no prospect of medical intervention for a cure or alleviation of symptoms but risked the pregnancy. NIPT will alleviate this risk – does this make these kinds of prenatal tests defensible? Or is the converse instead true, that the ability to perform a test without risk is in fact something of a disadvantage as it is more likely to generate ethical difficulties and conflicts?

In the analysis that follows, we recognise that there is no way of really knowing why a woman or couple will opt for a test; whether it be ‘for information only’, to inform a decision to terminate or continue with pregnancy.\(^6\) It is also possible that a person embarking on a test purely to gain information might change her mind about continuing the pregnancy on the basis of the results, especially if a serious genetic condition is revealed.

\(^6\) Duncan RE, Foddy R, Delatycki MB. Refusing to provide a prenatal test: can it ever be ethical? BMJ 2006; 333: 1066-8.
For the purposes of this paper we are basing the option of testing ‘purely for information’ on expressed preferences at the time of testing. We acknowledge that generating information about a foetus can only ever be said definitely to have been 'for information only' with the benefit of hindsight. However there is always a chance that a woman may choose to end a pregnancy, for a variety of reasons.

This possible difference between expressed and actual preferences might also have further moral implications, such as an increase in rates of termination. Thus the real-world scenarios are likely to be more complex than we have described them above. Nevertheless these scenarios are helpful to isolate and address the moral questions about testing purely for information.

Some brief comments can also be made on the above scenarios. For example, unexpected results could arise from these tests (e.g. a lethal impairment or intersex status), potentially causing distress, and maybe also leading to a decision to terminate.⁷ Also, taking the whole genome sequencing scenario (v), would testing purely ‘for information’ be acceptable given that the information gained will be of less importance than with the ‘adult onset condition’ case (iv)? At least at the present, the ability to interpret genome wide datasets in relation to future health and the modification of lifestyle is limited, so that the harm they might cause may also be limited. However, the ability to interpret such data will doubtless improve. It would also be possible for parents to attach too much

⁷ With thanks to an anonymous reviewer for this point.
significance to the results. In the section that follows we turn to the debate surrounding genetic testing in children, which provides a partial answer to these questions.

SECTION II. SYNTHESISING THE ETHICAL DEBATE OVER GENETIC TESTING IN CHILDREN

In many ways, testing a foetus ‘purely for information’ (whether in a screening or testing context) is based on similar principles to carrying out genetic tests on children and most of the arguments about the acceptability of testing children (at least those who lack capacity) will apply. In this section we briefly outline the relevant points, which relate to the child’s interests and privacy. This will then allow us to discuss the questions that remain about prenatal testing, and then non-invasive prenatal testing.

The most salient factor in the debate about childhood genetic testing is whether the condition is a) childhood-affecting or b) adult-onset.

a) Childhood-affecting conditions

Perhaps the most compelling reason to test a child for a certain genetic condition is the interests of the child, which are usually considered paramount. There is a large literature about whether testing is in a child’s best interests.\(^8\) It is thought that, if they know their child’s genetic status,

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parents may be better able to adapt psychologically to bringing up a child with a certain genetic condition and will be more supportive and nurturing parents as a result. Following testing, parents may also be better able to put in place social, practical and financial arrangements for care of their child, and the child can prepare him/herself psychologically for the onset and development of that condition. When a negative (no gene change identified) result is given, parents and their child may be less anxious about the child’s future, and need not make unnecessary financial and social contingency plans. However, if a gene change is identified there may also be increased anxiety for all concerned of watching a child for early signs of the condition in the family, or over-interpreting possible early signs that may not manifest.

b) Adult-onset conditions

Where a genetic test in a child is not diagnostic but predictive of adult health, a similar interests-focussed discussion may be had. Here the interests under consideration are those of the future adult whom the child will become. For example, parents may be able to prepare their child psychologically or financially for a future with a certain condition.


9 Clarke cautions against relying on genetic testing as a source of reassurance, since some will receive a mutation-positive result. Further, results will not necessarily remove the feeling of uncertainty either, since new questions arise: Clarke, Ibid.
Conversely, they may also limit their child’s future – to the detriment of the child – by failing to set up provision for their child’s adulthood.

Notwithstanding this debate, finding out facts about an individual’s adult future is also often considered inappropriate as it delves into their (future) private sphere. Invading a competent adult’s privacy in order to improve their welfare is to exercise hard paternalism and is rarely justifiable. It may be thought that, since the individual being tested is a child at the time, decisions about that child’s interests rest with her parents or guardians, and that it is merely soft paternalism, which is deemed more justifiable (and perhaps even a duty). Indeed, parents often act against their children’s wishes in order to secure their future welfare as adults (for example by insisting on school attendance and instilling healthy eating habits). But we suggest there is good reason to think that testing children for adult-onset conditions would be to exercise hard paternalism. There are important differences between the arguments for testing for adult-onset conditions and other accepted interventions during childhood.

First, paternalistic actions such as insisting on education and healthy eating habits usually have short-term benefits for the child as well as long-term benefits for the future adult. There are no short-term benefits either to a child knowing she will (or is very likely to) develop an adult-onset genetic condition or to the parents knowing this.

Second, childhood is the most appropriate stage of development for some skills, knowledge, character traits and so on (e.g. healthy eating habits), but
is not the most appropriate stage for others (e.g. forming sexual relationships). This can be termed a principle of identifying the most appropriate life-stage for an action or intervention. For childhood genetic testing for adult-onset conditions, testing for most could not be justified at the life stage of a child. There are some genetic conditions for which effects can be lessened by early measures, such as having regular colonoscopies to identify early stages of bowel cancer in familial adenomatous polyposis coli (FAP). However there only a few such conditions.

Third, there is a distinction between an action that widens an individual’s future choices and an action that narrows them down. For example, in insisting on a child’s education, a parent is increasing the future adult’s choices for further education, employment and participation in community life. In testing a child for an adult-onset condition, the parents are narrowing her options, at least because the (future) adult cannot change the past and choose for her parents not to know her results.

In addition, if her parents tell her the results, she also cannot choose not to know herself. In this way, testing could also be said to violate the child’s ‘open future’\(^\text{10}\) to decide for herself what tests to have. Having information about an adult-onset condition may be harmful to the child. Rather than feeling psychologically prepared, the child may feel greater anxiety knowing she faces a future with a particular condition. It has also been

suggested that, if results were negative, the child may still experience anxiety.\textsuperscript{11} Parents may project unrealistic or unfair expectations onto their child, with harmful effect, and the child may find herself stigmatised, or her behaviour given a medical label inappropriately.

Thus, unlike testing for conditions that usually affect children, it is arguable that knowledge about a person’s adult onset conditions is exclusively the business of the at-risk individual, not her parents. Parents who access personal information relevant to the adult their child will become are arguably invading her future privacy. Similarly, healthcare professionals who divulge information to parents about their future adult child are breaching confidentiality. Therefore there needs to be good justification for accessing and revealing personal facts about another (future) adult.

This position is reflected in clinical practice\textsuperscript{12} and professional guidance about predictive genetic testing in children.\textsuperscript{13}


SECTION III. PRENATAL TESTING

When the individual being tested is a foetus, rather than a child, the reasoning would appear to be identical unless the question arises of possibly terminating the pregnancy. Termination does not arise in the instance under discussion here, as we are considering testing ‘purely for information’ (albeit subject to the limitations identified in Section I above). Therefore, if a woman or couple intend to continue the pregnancy regardless of the result, most of the points we have made in relation to genetic testing in children can be applied to testing a foetus. The same considerations about interests and privacy apply.

What is strikingly different between a child and foetus, however, is the status of the being whose future interests are being evaluated. In many jurisdictions, the foetus does not have the legal status of a child. The moral status of the foetus is less obvious and, indeed, hotly disputed. Any argument against testing a foetus for information for the sake of that being (as we have done above with testing children) would have to rely either on the foetus having rights and interests at the time of being a foetus, or on the claim that the future child or adult has interests that ought to be safeguarded in advance.

We will not explore the question of whether a foetus has rights and interests at the time of being a foetus because this issue has been discussed
extensively in the context of termination of pregnancy.\textsuperscript{14} We also do not rest our position on the moral status of the foetus, as will be explained below. We do assume that a foetus does not have sufficient rights to override those of the prospective parents in circumstances of prenatal testing, but despite this the interests and rights of the future being remain relevant and could potentially override the rights of the prospective parents to access information.

As we have discussed above, when considering testing children for adult-onset conditions, it is fairly well accepted that the future adults’ interests should be safeguarded. In the case of a continuing pregnancy, the foetus is a future person, just as a child is a future adult. Duncan et al claim that, because the foetus is within the womb and therefore part of the woman, the woman has the right to information about the foetus.\textsuperscript{15} They claim that a woman does not lose her right to information simply because she wishes to continue her pregnancy. While this line of argument is convincing in termination cases, it cannot be applied with the same force in the case of testing for information only, simply because it is expected that there will be an individual resulting from the pregnancy. Thus, the moral rights of the potential future adult are in competition with the pregnant woman’s. It is also something of an illusion to think that the woman wants to know that her foetus does not have an adult-onset disorder. In fact, the woman wants to know that the future adult will not have the disorder.


\textsuperscript{15} Duncan et al, \textit{op. cit.} note 6.
Although in many jurisdictions the foetus does not have the legal status of a child, in cases in which a decision has been made to continue pregnancy, it is likely (all being well) to be on the same path to adulthood as an existing child. Thus, any argument for not testing a child in order to protect the privacy of the future adult also applies to not testing a foetus in a continuing pregnancy. This is to protect the interests and privacy of the future adult. As it is the future adult whose interests one is trying to preserve, it could be argued that it makes little difference when the act of gathering the information takes place. As Delatycki states:

“If the ethical consequences dictate that it is preferable not to offer … [a test for Huntington’s] the fact that the test is prenatal rather than being a test on an individual outside the womb does not make it any more justifiable.”

If our claim that predictive genetic testing in children is usually inappropriate can be supported, and our claim that a foetus in utero in a continuing pregnancy will be subject to the same considerations, then it would appear that testing a foetus ‘purely for information’ will not always be appropriate. Clinical scenarios (i – carrier testing), (iv – testing for an adult onset condition), and (v – whole genome sequencing) may be deemed inappropriate on this reasoning; while scenarios (ii – testing for a minor condition) and (iii – testing for sex) will require further analysis.

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16 Duncan et al, op. cit. note Error! Bookmark not defined., p. 1067.
SECTION IV. (HOW) DOES THE NON-INVASIVE ASPECT OF NIPT MAKE IT MORE ACCEPTABLE TO TEST FOR INFORMATION ONLY?

When considering prenatal testing ‘purely for information,’ the most important clinical difference between invasive and non-invasive testing is the lack of risk. In this section we explain how this difference may affect the debate on testing foetuses for information only.

As mentioned above, NIPT poses no medical risk to the viability of a pregnancy. Opening up access to NIPT may therefore increase the overall uptake of NIPT and may attract those whose reluctance to test purely for information had been due solely to the risk of miscarriage. In clinical scenario (v), involving Ms E considering whole genome sequencing for her foetus, this might include non-health traits, such as muscle fibre types associated with athletic ability. Such tests might pejoratively be termed ‘frivolous,’ given that they are motivated by a mere interest in the information rather than for medical reasons.

In this context, we take ‘frivolous’ testing to mean testing that is motivated by values that are not worthy of being taken seriously. However we recognise that this needs further qualification in order to be meaningful in practise. At their extremes, the notions of frivolous and non-frivolous will be universally (though not comprehensively) shared. For example, using NIPT to detect foetal rhesus status to detect risk of haemolytic disease of the newborn (preventable via administering anti-D to the pregnant woman) is a
good candidate for a non-frivolous reason. As a comparator, clinical scenario (ii), involving testing for a condition that only indicated height, purely for information, would be harder to defend; why would this information be needed in pregnancy? Nevertheless, there are traits and motivations that lie between these extremes (perhaps such as clinical scenario (iii) involving sex testing), and frivolity is subjective. Drawing the boundaries between those values to be taken seriously and those that should not be is a challenging task, and we will not attempt it here. Rather, we raise this as a moral principle by which access to NIPT purely for information could be allowed or restricted.

For minor conditions or traits, removing the risk of prenatal testing may open up a host of possibilities for testing out of curiosity; as several of the clinical scenarios in Section I suggest. On the other hand, the potential impact of the results for serious conditions (such as clinical scenarios (iv) or (v)) has not changed. NIPT may be disproportionately easy to undergo given the potential impact of the results. Therefore, when making a judgement about whether testing a foetus is acceptable, we should recognise that ‘frivolous’ testing might be in higher demand once the technology is simplified. Testing for serious childhood conditions will still entail a careful weighing of the potential benefits and harms, with only one of the potential harms (miscarriage) removed.

Thus far we have largely focused on concerns about interests or the preservation of privacy for the future adult. There remains a more subtle objection to some prenatal testing, one which recognises a certain loss of
humanity or respect for persons. This is that ‘unnecessary’ testing in pregnancy may be regarded as troubling is that it may objectify the foetus and resulting child. By making an effort to reveal certain traits, the expectant parents in several of the above clinical scenarios would be showing an inappropriately motivated interest in those traits, and in doing so would be expressing their views about what they valued. That expectant parents could value a non-serious characteristic of their foetus this much is, to some, distasteful.

A helpful approach might be to consider that of the ‘virtuous’ parent or perhaps a ‘virtuous counsellor.’ While a detailed analysis of this concept is beyond the scope of this paper, relevant questions relate to the kind of parents that women and couples should aim to become (or the kind of professional someone practising in this area should be), what information couples require in order to be at least a ‘good (enough)’ parent, and what information is not required and might even be regarded as excessively intrusive? From a virtue-oriented perspective, there is no reason to distinguish actions of a parent or professional towards a future child from those towards a young child. There is no need to generate unhelpful information in the short term if that information might lead to harm or an invasion of privacy of the future child or adult. It is difficult to see any justification for generating such ‘trivial’ information from this perspective.

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Considering the clinical scenarios in Section I, if a woman or couple elected to have NIPT to test for carrier status (scenario (i)), stature (scenario (ii)), or everything (scenario (v)), she may be putting undue value on this information and demonstrating a distasteful degree of interest in her future child’s genome. Testing out of curiosity does not itself seem to be particularly morally problematic (for example the incidental indication of sex during medical ultrasound)\textsuperscript{18} but it may seem distasteful to test for certain traits. Doing so is not harmful in itself, but it may be an expression or indication of an attitude that is not in keeping with a parent who values his or her child for who that child is, not the traits it will have.

The clinical scenario that is less obvious to make a determination on is Scenario (iii), involving sex identification in early pregnancy. NIPT for foetal sex is already available and is used ‘purely for information’ by people like Ms C and her partner. In genuine cases of ‘information only’ this is fairly trivial information and could be said to be analogous to determination of sex via ultrasound (which many parents opt to do).\textsuperscript{19}

\textsuperscript{18} What counts as ‘frivolous’ varies between cultures and individuals. Sex determination, for example, is not a mere curiosity in many cultures. Foetal sex determination is illegal in some jurisdictions because such information is frequently abused, and is leading to major shifts in sex ratios: Manchanda S, Saikia B, Gupta N, et al. Sex ratio at birth in India, its relation to birth order, sex of previous children and use of indigenous medicine. PLoS One 2011; 6(6): e20097.

\textsuperscript{19} This is a good example of a case in which testing ‘for information only’ may lead to action on the basis of information, and to wider socially damaging consequences. While this use of NIPT may appear innocuous, we should also be mindful that it could greatly exacerbate discrimination against women in misogynistic societies if it were to lead to
Finally, the wider context of this kind of testing should not be overlooked. For example, legitimate questions remain as to how such testing would be funded, and who would have access to it. Testing for non-medical traits using NIPT is likely to be considered outside the remit of either private health insurance or a state-funded health service, possibly rendering this kind of testing a luxury only for those who can afford it. If a state-funded health care system did fund such tests, this would presumably be costly, and could further stretch scarce resources (such as access to genetic counsellors).\textsuperscript{20} The justice of offering NIPT for information, particularly if an offer of testing is made in the context of a screening programme, also raises issues around the responsibility of health professionals (such as genetic counsellors) to help ensure that any screening programs incorporating NIPT target serious conditions and do not impinge on a child’s right to an open future.

CONCLUSION

We began this paper by posing the question of whether it is ethically acceptable to use NIPT to perform genetic tests on a foetus when the

\textsuperscript{20} With thanks to two anonymous reviewers for this point.
purpose of that test is purely to gain information about the foetus and not to seek a termination of pregnancy. We have made the case that a consideration of interests and privacy applies equally to children and foetuses, since they are on the same trajectory to adulthood, and that the same boundaries for testing children should apply for prenatal testing ‘purely for information’.

Unlike invasive testing, NIPT has the potential to allow prenatal testing for information without the critical drawback of risk of miscarriage. Healthcare professionals and prospective parents should recognise that the removal of risk would not make the results any less significant, and they should regard a prenatal test as seriously as they would a test during childhood, whether the test is requested or offered as part of a screening programme. A second effect of the removal of the risk of miscarriage is that there will be one fewer reason against testing for what we have termed ‘frivolous’ traits. The remaining objections to allowing testing for such traits are that it objectifies the foetus and future child and is not part of a virtuous parent’s conduct.

The claims we have made in this paper can perhaps be drawn together under a consideration of the kinds of parents that women and couples should aim to become. Those seeking NIPT purely for information, such as those described in Section I, should be encouraged to reflect on their motivations for such a request and the impact this information may have on their pregnancy and child once it is born. We may not yet have precise ‘informational expectations’ that could be said to be reasonable to have in
pregnancy, but we suggest that the information that is necessary to fulfil this expectation may not be as voluminous as we might initially think.