

NUFFIELD COUNCIL^{ON} BIOETHICS

Roundtable meeting

Non-invasive prenatal testing

18 January 2016, London

NOTE OF THE MEETING

- 1 The Nuffield Council on Bioethics convened a roundtable meeting in London on 18 January 2016 to discuss any clinical, ethical, social, legal and policy issues raised by recent developments in non-invasive prenatal diagnosis, testing and screening. The meeting was attended by 31 people, who included healthcare professionals, academic researchers, policy makers, representatives of charities and patient groups, and members of the Nuffield Council on Bioethics. A list of the participants is at **Annex A**. This note reports the comments made by the participants at the meeting and should not be taken as the view of the Nuffield Council on Bioethics. A financial interest was declared by participant Pran Pandya, who offers NIPT to women through private practice.

Current evidence and clinical application

Non-invasive prenatal diagnosis

- 2 Cell free fetal (cff) DNA can be detected in the mother's blood from four weeks of pregnancy and can be used to identify alleles that are not present in the mother but are present in the baby. Non-invasive prenatal *diagnosis* (NIPD) using cffDNA is available for fetal sex determination, paternally dominant inherited diseases, gene disorders that have arisen afresh (*de novo*) at conception and a number of other types of gene alterations. It is not possible currently to offer NIPD for conditions where the mother is a carrier of the

genetic condition in question. NIPD for recessively inherited conditions is currently being researched and developed.

- 3 The UK Genetic Testing Network has approved NIPD for a number of specific conditions for clinical practice in the NHS. These tests are offered to high risk pregnant women, for example those with a family history of a condition or an indication for testing, as an alternative to invasive testing. There is increasing demand for NIPD to inform decisions about pregnancy management, for reassurance in early pregnancy and/or for information only.

Non-invasive prenatal testing

- 4 cffDNA can also be analysed for the presence of aneuploidies, such as trisomy disorders (Down Syndrome (T21), Patau Syndrome (T13) and Edwards Syndrome (T18)). This method does not target specific genes but evaluates total chromosomal presence. cffDNA comes from the placenta and may continue to be released from the placenta of a vanishing twin, which means that discordant results can arise by the detection of confined placental mosaicism. In addition, when performing non-invasive prenatal testing (NIPT) for aneuploidies all the cell free DNA in maternal plasma is analysed – maternal and fetal – and so maternal rearrangements may be detected. For these reasons, NIPT for aneuploidies is considered a screening test and an invasive test is required to provide a diagnosis following a positive result.
- 5 NIPT can usually be carried out from 10 weeks of pregnancy, which is when cffDNA levels are high enough to be detected. This can be later for obese women who have lower levels of cffDNA. Testing is not likely to be possible any earlier in the foreseeable future. NIPT can result in incidental findings for the mother, such as chromosomal rearrangements and, rarely, maternal tumours.
- 6 In January 2016 the UK National Screening Committee proposed an evaluative approach to offering NIPT for aneuploidies to pregnant women whose babies are found to have a greater than 1 in 150 chance of developing these conditions following the combined test at 10-14 weeks. Details of whether and how the tests will be rolled out and provided across the UK have not yet been released.
- 7 The main benefits of offering NIPT as part of the NHS Fetal Anomaly Screening Programme is expected to be more accurate information for

pregnant women about the risk of aneuploidies without any risk to the fetus, and a potential reduction in the number of invasive diagnostic tests carried out and the number of pregnancies lost from procedural related miscarriage. NIPT for aneuploidies is widely considered to be a more sensitive screening test than that which has previously been available.

- 8 Research on NIPT has mainly been carried out in high risk populations, i.e. pregnant women who have been shown through initial testing to have a higher than 1 in 150 chance of carrying a baby with aneuploidy. The RAPID (Reliable Accurate Prenatal Non-Invasive Diagnosis) study is a five-year UK national programme funded by the National Institute for Health Research that aims to evaluate NIPD and NIPT. Preliminary findings show that NIPT for aneuploidies has high levels of sensitivity and a high positive predictive value (PPV) in high risk pregnant women. Uptake of follow-on testing (invasive testing or NIPT) in high risk women after initial screening was found to be higher when NIPT was offered, which led to higher detection of aneuploidies and a fall in invasive testing. Of the pregnancies detected by NIPT in the study as being affected by Down Syndrome, a number of women chose to continue with the pregnancy.
- 9 Other research studies have shown NIPT offers similarly high levels of sensitivity in low risk pregnancies, although the PPV is lower – around 50 per cent – meaning that more than half of positive NIPT results may generate false alarms. There is also a 1 to 12 per cent failure rate of NIPT (i.e. when the test fails and produces no result) which needs to be considered.
- 10 The RAPID investigators conclude that NIPT could be implemented into the NHS maternity pathway as a second tier test for high risk women and improve the screening performance at no additional cost. The sensitivity of NIPT for microdeletions, triploidy and unbalanced translocation syndromes is not currently known however, and therefore is not recommended for clinical application.
- 11 Different providers of NIPT (currently, mainly commercial providers) use different methods. Some methods provide the sequences obtained from all chromosomes, whereas others only sequence the chromosomes of interest, which leads to fewer false positive results. Turnaround times and failure rates vary between different providers.
- 12 Research on stakeholder views on NIPT found that women and partners welcome safer, earlier testing. Many want NIPT for reassurance, to facilitate

decision making and to allow time to prepare for the birth of an affected child. People reported that they are concerned about the potential negative impact on informed choice as NIPT is 'just a blood test' in pregnancy, whether the removal of risk may remove the 'excuse' to decline, and potential peer pressure. It was suggested that many will take what trusted health professionals offer.

Whole genome sequencing

- 13 There are reports of whole genome sequencing (WGS) being carried out in a few high risk pregnancies. It is very time consuming and costly, as most of the cfDNA in maternal blood comes from the mother, and requires sequencing of the mother, father and the baby. The availability of WGS on a larger scale is thought to be some way off. However, studies (e.g. the PAGE study) are developing WGS for use in fetuses with structural abnormalities, such as limb or heart abnormalities.

How could NIPT affect uptake of screening?

- 14 Participants who work with pregnant women reported rising demand for private NIPT because of its non-invasive nature. The uptake of NIPT in the NHS is likely to depend on to whom it is offered, e.g. all women or just certain populations. Where NIPT has been available as a second tier test on the NHS as part of pilot studies, uptake was high, which led to increased detection of aneuploidies. A proportion of women turned down the offer of NIPT. Some participants speculated that offering NIPT may result in an increase in the number of terminations taking place overall, but could reduce the number of late terminations, as problems are more likely to be picked up before the 18-20 week scan. This would need to be monitored following implementation.
- 15 As uptake of NIPT as a second tier test may be higher than uptake of invasive testing, introduction of NIPT in the NHS screening programme may allow increased access to information by pregnant women and their partners. This brings issues about choice and informed consent into the foreground.
- 16 Uptake is known to vary in different regions. The reasons are not known but could be related to the demographics of different areas or to differences in how the tests are offered, packaged and presented by healthcare professionals.

How do we achieve equity, informed consent and protect those who do not want NIPT?

- 17 Several participants were of the view that, if NIPT for some disorders under certain conditions is deemed to enhance reproductive decision making and reduce the risks of miscarriage following invasive testing, then all women meeting these criteria should have access to NIPT. The cost of NIPT has a bearing on whether it will be available on the NHS.
- 18 The way NIPT is rolled out is important. Previous prenatal screening tests have been introduced unequally across the country, creating confusion among women about whether they had had the test or not. There was concern that the process of rolling out NIPT across the UK could be unfair as some women would be able to access the test sooner than others.
- 19 Participants agreed that pregnant women should be able to make a genuine, informed and free choice about whether to have NIPT or not, and then about what to do with that information with regards her pregnancy. The counselling and information available to and accessed by pregnant women is likely to determine the extent to which they are making genuine choices. There is concern that women are not given adequate information about the tests that are already performed in the NHS prenatal screening programme, and that many do not realise what they have agreed to. This is illustrated by the very high initial uptake of screening for Duchenne muscular dystrophy in Wales, which raised questions about whether women were making a genuine choice. When the way the test was offered was tweaked, the uptake rate dropped and levels of satisfaction with the process increased.
- 20 The provision of information and consent process in the RAPID study was much more detailed than it is likely to be when NIPT is rolled out across the UK. The UKNSC produces standard leaflets for healthcare professionals to use and carries out extensive training and education programmes on counselling and consent processes. However, evidence suggests that this is not carried out adequately in practice by all healthcare professionals. This has long been a concern for all types of screening programmes and is a challenge for all areas of medical practice where informed consent is sought. There are also reports of women not being counselled adequately when they have sought NIPT in the private sector.

- 21 It was suggested that midwives in some regions are unhappy with the combined test due to the low detection rate and that they may be more likely to encourage pregnant women to have NIPT when it becomes available. Whether women are asked, in effect, to opt in or opt out of prenatal testing may have an effect on their attitudes towards the tests and on uptake. Offering a test on the NHS sends a message in itself – i.e. if the state is willing to pay for it then women may feel they should have it. In the Netherlands, pregnant women have to pay for prenatal testing.
- 22 There are concerns about the potential routinisation of NIPT and that women may be criticised for choosing not to take the test if it is deemed the default option, or even for not aborting an affected baby. Although the fetal anomaly screening programme is not described as a public health programme, the Nuffield Council on Bioethics' 2007 report on public health was highlighted as providing useful guidance on how making a particular measure the default option can make it difficult for people to opt out, depending on how 'sticky' that default is.
- 23 Several participants suggested that an extensive education programme for healthcare professionals is required in order to enable pregnant women to make a genuine choice. Healthcare professionals should be able to spend an adequate amount of time discussing the implications of NIPT with pregnant women, and should understand that there is a spectrum of how informed women are when making a decision – it is not simply the case that they are informed or not informed. In addition, healthcare professionals should understand that making a decision about whether or not to continue with a pregnancy is not made more trivial in some way because the test is easier or available earlier.
- 24 It will be important that pregnant women understand the high rate of false positives that occur with NIPT for aneuploidies and the need for diagnostic testing following a positive result. If this is not understood, the anxiety caused by a positive result is likely to be very high. Studies in other countries (China and the US) have reported instances of women having abortions based on a NIPT result alone. In addition, women should be aware that NIPT can provide incidental findings that can have consequences for them and their relatives.
- 25 Ensuring pregnant women are making informed choices will be a challenge given that they already receive a lot of information and are asked to make several decisions at their booking appointment. They are known to access

information from a variety of sources on the internet and in the media that can be biased and inaccurate. Pregnant women need to have ready access to evidence-based, unbiased information about all types of prenatal testing. It should also be recognised that pregnant women and their partners make decisions based on a wide range of factors, and not solely on the information that is provided to them by healthcare professionals.

- 26 However, women's ability to understand risk and make decisions during pregnancy should not be underestimated. The level of risk and uncertainty families are willing to accept in the genetic information they receive about their future child will vary. It was suggested that evidence from the adoption arena about the level of risk that families are willing to accept when it comes to genetic testing of children might provide a useful comparison.
- 27 A further issue to consider is that pregnancies affected by aneuploidies often end in miscarriage. Early detection of these conditions means parents can be faced with a difficult decision about whether to terminate the pregnancy or continue without intervention. Parents who chose to terminate the pregnancy may feel the emotional burden of that decision. For parents who decide to continue with the pregnancy and it ends in miscarriage, the reason for miscarriage would be known which can be helpful for parents and the medical team. Offering NIPT as a second tier test on the NHS is unlikely to result in detection of trisomy disorders any earlier than the current screening programme. However, detection of disorders that are likely to end in miscarriage should be noted as a potential cost of earlier testing if this becomes more common in future.

How could NIPT affect what is tested for?

- 28 The RAPID researchers conclude that the evidence on the sensitivity and predictive value of NIPT for aneuploidies in high risk women supports its implementation in the NHS fetal anomaly screening programme, and that the evidence does not support the implementation of NIPT for any other conditions, such as those caused by microdeletions, at the current time.
- 29 However, the development and availability of NIPT technology raises questions about how the landscape of prenatal testing may change, and what will be tested for in future. NIPT accessed privately, for example, makes it possible to find out the sex of a fetus much earlier than is currently possible in the current NHS prenatal testing programme. In the RAPID study, a targeted

method for detecting aneuploidies was used and the sex of the fetus was not determined or revealed.

- 30 Some commercial providers already offer a package of tests from 10 weeks of pregnancy that includes tests for additional disorders, even though they have low or unknown levels of sensitivity. Most companies also offer sex determination. Whole genome sequencing using NIPT is possible, although currently it is expensive.
- 31 A key challenge in the expansion of the conditions and genetic factors tested for using NIPT is the interpretation of data. If the success of NIPT is measured against how many pregnant women are able to make genuine, informed choices that are right for them and their families, then the provision of hard-to-interpret, potentially misleading information will not be helpful. There is also the danger that offering NIPT for conditions where there is a high rate of false positives will increase rather than decrease the number of invasive diagnostic tests being carried out.
- 32 Although pregnant women and their partners often want as much information as possible, conveying clearly different levels of risk and probability and the problems in interpreting some information can be extremely difficult. Some methods offered by providers of NIPT, such as those that sequence only the chromosomes of interest, may better suit than others the idea that families should not have access to information that is hard to interpret or misleading. Healthcare providers need to understand the different methods available.
- 33 NIPT can result in incidental findings about the mother, such as chromosomal rearrangements and, rarely, tumours. In the Netherlands, where the government is considering whether NIPT should be introduced as a first tier or second tier test, how to deal with incidental findings is a particular concern. Using targeted methods that only test for aneuploidies would not give rise to incidental findings.
- 34 Whole genome sequencing of fetuses is technically possible and raises questions about the rights of the future child or adult to an open future and the right not to know about their genetic make-up. Besides this, it is, at the current time, still very difficult and time consuming to interpret most genetic information and so there is great uncertainty around the health or other implications of most genetic factors. There are also concerns about whether other actors,

such as insurance companies, will have access to genetic information gained prenatally.

What implications could NIPT have for disabled people?

- 35 The UN Convention on the Rights of Persons with Disabilities sets out the equal human rights and place in society of people with disabilities. It has been suggested that screening for conditions such as Down Syndrome could be in conflict with the Convention, but as a fetus is not legally a person the argument does not hold. The use of NIPT does, however, raise questions about how society views people with disabilities. There is concern that NIPT could lead to higher uptake and the potential routinisation of screening, which may exacerbate difficulties that people with disabilities and their families already face, such as stigmatisation, lack of advocacy, and reluctance to provide places for children with Down Syndrome in mainstream schools. If earlier, easier and safer testing is available and a woman chooses to continue with an affected pregnancy or not have the test at all, there may be a perception that any problems she and her family encounter down the line are their fault and that society should not take any responsibility. The increasing commodification of people was also raised as a concern. On the other hand, public awareness and discussion of NIPT may promote discussion and raise the profile of people with disabilities and the challenges they face.
- 36 It is widely agreed that women should be able to make autonomous reproductive choices, but the context within which these choices are made is important. Decisions about whether to have testing or continue with affected pregnancies are made in a complex way, and not usually in the consultation room. Potential parents are influenced by many factors, including their views on abortion, perceptions of how the world treats disabled people, their financial position, and levels of confidence in the ability of the NHS to provide appropriate care.
- 37 Concerns were raised about a lack of clear, balanced information available to potential parents about disability and the lives of people with disabilities. For example, it was suggested that pregnant women and their partners are often presented with only the medical effects of Down Syndrome. Multidimensional information about Down Syndrome, including the social aspects and an up-to-date picture of what life is like for people with Down Syndrome would give potential parents a fuller picture of the condition. It is also important to understand the range of impairment experienced by people with disabilities;

there are not simply the options of a healthy child and a disabled child. It was noted that while the accuracy of prenatal testing for conditions such as Down Syndrome has improved, it is also the case that the lives of people with disabilities has improved.

- 38 Many women continue with pregnancies after they receive a diagnosis. For these women, knowing their baby has Down Syndrome early in pregnancy can help in the planning and care of the baby. For example, early inductions can improve outcomes, as can giving birth in a specialist centre and preparing for postnatal surgery. Offering NIPT as part of the NHS screening programme may lead to more cases of aneuploidies being detected and potentially more women and future children being helped in these ways for those who choose to continue with their pregnancy. Effective medical interventions during pregnancy – in-utero therapy – for Down Syndrome are not generally available at the current time.
- 39 Questions were raised, however, about whether NIPT should be offered on the NHS where there was no potential health benefit, and the tests were being carried out for ‘information only’.
- 40 NIPT, or any kind of prenatal screening test, generates information about conditions the fetus has or might develop. There are concerns about the implications for the future child and their right to an open future of testing prenatally for an increasing range of genetic factors and conditions.

What are the issues raised by commercially available NIPT?

- 41 By the end of 2014, it was estimated that more than 1 million commercial NIPT tests had been carried out worldwide in more than 90 countries. Invasive testing has declined significantly globally.
- 42 Commercial companies have been driving the demand for NIPT for aneuploidies and other conditions, and are likely to continue to do so. This has created challenges for the NHS, in terms of considering equity of access to NIPT and in dealing with women who have access NIPT privately and then go to the NHS for follow-up information or care.
- 43 There is no support from the commercial sector in developing NIPD for monogenetic disorders, possibly because of the lack of commercial potential

of such tests. One company was known by a participant to have discontinued a test because it was not commercially viable.

- 44 Some companies offering NIPT have been found to be providing misleading information. For example, NIPT is sometimes presented as a way of ensuring a 'healthy baby'. The evidence for NIPT for aneuploidies is good, but more research is needed on the use of NIPT for other conditions. Many private clinics only offer to test for aneuploidies, in line with current guidelines. However, others are offering tests for additional conditions, perhaps because there is a demand from parents for more information and because it is a competitive market. However, these tests have serious limitations. In addition, it is recommended that NIPT should always be offered in conjunction with a dating scan, but some companies offer NIPT on its own.
- 45 Potential parents may be accessing NIPT privately because they believe they will obtain information about their pregnancy quicker. However, as NIPT can only be carried out from 10 weeks and the results usually take two weeks, and the NHS combined test takes place between 10 and 14 weeks, there is not the huge time difference that people often imagine. Those who have accessed NIPT privately may receive results that they do not understand or do not know how to deal with, and so access NHS care afterwards. However, current guidance to regional NHS genetics centres states that their role is not to support people who have accessed genetic tests privately and people must pay for any related counselling.
- 46 Other genetic tests are available to buy direct-to-consumer and it was suggested that it is only a matter of time before people are able to by-pass the clinics and send off their own blood sample to access NIPT. There are concerns about the counselling, information and support that will be provided to customers if NIPT is available direct-to-consumer. The Human Genetic Commissions published a report on direct-to-consumer genetic testing in 2007 and the Government's response was broadly that the market would regulate itself.
- 47 There is debate and negotiation ongoing in Europe about criminalising direct-to-consumer genetic tests. The outcome may affect the regulatory environment for direct-to-consumer genetic testing across Europe. In some countries there are already laws on this and people can be fined for accessing direct-to-consumer genetic tests. In the US, companies like 23andme can no longer claim that their tests provide health-relevant data.

- 48 Privately-funded research may not reveal publicly the full data it generates due to commercial sensitivities, which may create problems for the advancement of science and transparency in this area.

What are the global benefits and challenges of NIPT?

- 49 Many of the implications of NIPT apply to people across the globe, although there will be specific issues raised in different regions or populations. Fetal sex determination, for example, will raise different issues within different cultural contexts, and NIPT may offer particular benefits to pregnant women in rural areas as they are not required to go to specialist facilities. It is important not to generalise.
- 50 People may travel abroad to access NIPT, and it is likely that people in the UK were doing this before NIPT became available here in October 2012.

What could the Nuffield Council on Bioethics usefully contribute in this area?

- 51 Several participants suggested that there were not clearly any new ethical issues raised by using NIPT as a second tier test for aneuploidies as part of the NHS Fetal Anomaly Screening Programme. However, practical issues that may arise in relation to implementation and the potential for further technical developments in NIPT mean that a framework for thinking through the ethical issues would be helpful. It was suggested that the Council could:
- Write up and publish the outcomes of today's discussion.
 - Promote better understanding among the general public of genetic information.
 - Conduct further work to examine:
 - The implications of likely future developments in NIPT, such as increased sensitivity of testing for other conditions and the availability of whole genome sequencing. What is it legitimate to test for and reveal? How do we decide when it is right to include more conditions in NIPT? Do we have a right to remain ignorant and not to choose? Is it ethical not to offer testing once the technology is available? Should the NHS be

providing NIPT for parents who use it for ‘information only’? How do we balance enhancing the autonomy of pregnant women with paternalism of the state and protecting the interests of future children, noting the recent change in the UK law on consent following the Montgomery v Lanarkshire Health Board case in the Supreme Court?¹ How does the healthcare context affect these questions? What is the relationship between NIPT and pre-implantation genetic diagnosis? What is the influence of the commercial sector on the development of NIPT, for example in relation to tests for rare conditions that might not be commercially viable? Are legislative changes required?

- How NIPT for aneuploidies should be implemented in the NHS Fetal Anomaly Screening Programme, particularly in relation to issues of equity of access, education of healthcare professionals, counselling and support for pregnant women, the potential for increase in terminations, and monitoring how people use the information they obtain from testing.
- The range of candidate outcome measures that could be used to evaluate success with NIPT, in order to facilitate constructive debate. Measures currently used include the number of babies with aneuploidies detected, the number of miscarriages or terminations avoided and the number of tests used.

Follow-up note

After considering the discussions that took place at the roundtable meeting, in March 2016 the Nuffield Council on Bioethics decided to set up a Working Group to consider in more depth the ethical, legal and regulatory implications of recent and potential future developments in NIPT. Up-to-date information can be found at: www.nuffieldbioethics.org/NIPT

¹ Montgomery v Lanarkshire Health Board (2015) UKSC 11. Available at: www.supremecourt.uk/decided-cases/docs/UKSC_2013_0136_Judgment.pdf

Annex A Participants

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