Free fetal DNA for non-invasive prenatal diagnosis (NIPD): ethical aspects

16 June 2008

By Dr Zuzana Deans and Dr Ainsley Newson, Centre for Ethics in Medicine, University of Bristol

Dr Phillipa Brice's accompanying commentary highlights how non-invasive testing of free fetal DNA (ffDNA) in pregnancy could transform women's experiences of antenatal screening and prenatal diagnosis. NIPD is already available for foetal sex, rhesus D blood type and some Mendelian inheritance such as achondroplasia, with tests for aneuploidy detection and Down syndrome being developed. These tests will not pose a risk to the pregnancy and could provide women and couples with definitive information earlier than current methods. The advantages over 'traditional' prenatal screening and diagnosis seem obvious - so is NIPD ethically problematic?

Unsurprisingly, a pithy 'yes' or 'no' answer to this question is impossible and would undermine the opportunity for a rich and important discussion of how the ethics of NIPD might depart from 'traditional' testing in pregnancy. But in short, expectations are that NIPD can be conducted ethically if the right conditions are in place, and it is laudable that those working in this field are liaising so closely with ethicists to address emerging concerns as this technology develops.(1)

An initial question is whether this technology gives rise to any new ethical questions over and above existing screening, diagnostic or assisted reproductive technologies. Existing debates in prenatal diagnosis, such as the disability rights critique, will continue to be relevant and may be exacerbated. So too will issues of the 'seriousness' threshold for offering PND and the routinisation of testing. Whilst NIPD does not depart too far from these existing issues, there may be important changes to the moral landscape of testing.

If offered widely (for suitable conditions), NIPD will effectively become a screening test with a definitive outcome, akin to HIV (human immunodeficiency virus) testing in pregnant women, but one that may lead to termination. We need to decide which method of consent is appropriate and be mindful that a major justification for declining prenatal diagnosis (risk to the pregnancy) will be removed. Overall termination rates may also increase. Women will need sound and unbiased information about NIPD and will require time to reflect before deciding about testing.

Women are generally expected to enter into prenatal testing as fully consenting individuals. While at face value this may seem an obvious condition for ethical conduct, achieving informed consent or following an informed choice may not be as straightforward as it first appears. This may be especially true in the context of NIPD. Research shows that there are different attitudes between cultures as to whether women, couples or health professionals should make decisions about prenatal testing (2). This arguably calls into question the emphasis on respect for individual autonomy so common in Northern European nations. Our research is asking whether autonomous decision-making for NIPD might better be understood in a feminist (relational) way, recognising social relationships as a fundamental part of what it is for an individual to make an autonomous decision.

NIPD could also be used for non-medical ends, such as sex determination and paternity testing. Indeed, internet-based providers of both are already available. Whilst a full exploration of these issues is not possible here, such applications should be monitored. For example, one major concern is that sex determination may be used to reinforce stereotyped gender expectations or sex discrimination. Prenatal paternity testing to inform the interested parties may be acceptable, but procuring this test to terminate if the 'wrong' biological father is discovered is more challenging.

These concerns mean that procedures and regulation for NIPD should be considered. Prenatal diagnosis currently involves clinical services as gatekeepers but NIPD will only require a blood test - should this be regulated by the market or more formally? Any new guidelines should be consistent with current practice and should not unduly restrict professional autonomy.

Ethical analysis of NIPD should go hand in hand with economic and clinical evaluations, not to mention empirical research with pregnant women, couples and health professionals. This multi-disciplinary approach will help address important questions such as educational and informational needs, and psycho-social indications. We are currently working with the SAFE Network (3) and the Public Health Genetics Foundation to deliberate ethical issues. NIPD is certainly not without ethical pitfalls, but early identification and deliberation will ensure a constructive role for NIPD to facilitate pregnant women to make well informed decisions in pregnancy, with good informational support.

SOURCES & REFERENCES

1) Newson AJ (2008) Ethical aspects arising from non-invasive fetal diagnosis.
Semin Fetal Neonatal Med. 13(2):103-8

2) van den Heuvel A, Dormandy E, Chitty L, Newson A, Ma R, Masturzo B, Pajkrt E & Marteau T. 'Is informed choice in prenatal testing universally valued? A population based survey in Europe and Asia' (submitted)

3) SAFE Network