



Call for views and evidence on non-invasive prenatal testing

Consultation document

Introduction

The Nuffield Council on Bioethics is considering the ethical issues raised by the increasing availability of non-invasive prenatal testing (NIPT) in the UK. We use the term NIPT to mean all kinds of prenatal genetic testing using fetal DNA from the placenta extracted from a sample of the mother's blood. More information about NIPT can be found at: www.nuffieldbioethics.org/NIPT/background

To inform our deliberations, we would like to hear from as many people and organisations who have an interest in NIPT as possible. The questions in this consultation document may be particularly suitable for people responding on behalf of an organisation and people whose work focuses on the ethical issues raised by NIPT, such as academics working in the field.

When responding, feel free to answer as many or as few questions as you wish, and please use the 'any other comments' section to contribute any views or evidence that do not fit elsewhere. Where possible, please explain the reasons behind your responses and the evidence or experience on which you are basing them.

A shorter online survey that can be completed anonymously by anyone with a personal or professional interest in NIPT is available at: www.surveymonkey.co.uk/r/NuffieldNIPT. If you know someone with learning difficulties who would like to contribute to the Council's project on NIPT, please contact Anna Wilkinson on awilkinson@nuffieldbioethics.org

The Nuffield Council on Bioethics is an independent body based in the UK. The findings and recommendations of our project on NIPT will be published around the end of 2016. Find out more about the Council and the project at: www.nuffieldbioethics.org/NIPT

How to respond

Please complete this form and email it to Anna Wilkinson at: awilkinson@nuffieldbioethics.org.

If you would prefer to respond by post, please send your submission to:

Anna Wilkinson
Nuffield Council on Bioethics
28 Bedford Square
London WC1B 3JS
Telephone: +44 (0)20 7681 9619

Closing date for responses: 25 July 2016

If you have any questions, please contact Anna Wilkinson at the above address. Thank you for taking the time to respond.

Your details

Name	
Organisation	
Email	

Questions

NIPT as part of NHS antenatal care

The UK National Screening Committee (UKNSC) has recommended that NIPT for Down Syndrome, Patau Syndrome and Edwards Syndrome be offered on the NHS to pregnant women whose babies are found to have a high risk of having one of these conditions following the 11-14 week screening tests. The UKNSC has proposed that this should be implemented as part of an evaluation process to understand better how offering NIPT in this way will affect the screening pathway and the choices that women make. The exact specifications of the evaluation are currently being developed. [Find out more.](#)

- 1 If this recommendation was implemented fully into NHS antenatal care, what benefits or concerns might this raise for pregnant women and their partners?
- 2 If this recommendation was implemented fully into NHS antenatal care, what might be the implications for the healthcare professionals involved in offering and providing prenatal screening and testing?
- 3 If this recommendation was implemented fully into NHS antenatal care, it might lead to an increase in the number of terminations of pregnancies with a diagnosis of Down Syndrome, Patau Syndrome or Edwards Syndrome. What benefits or concerns might this raise?
- 4 Do you think the UK National Screening Committee's [criteria](#) for appraising the viability, effectiveness and appropriateness of a screening programme are appropriate for appraising [prenatal](#) screening programmes?

Information and counselling

- 5 How would you rate the information and counselling currently provided [by the NHS](#) to pregnant women and their partners to help them make decisions about [currently available prenatal screening](#) (e.g. using ultrasound) for genetic conditions during pregnancy, if you have experience or evidence relating to this?
- 6 How would you rate information and/or counselling provided [by the NHS](#) about [NIPT](#) available as part of research studies or through the private sector, if you have experience or evidence relating to this?

- 7 How would you rate the information and/or counselling currently provided by private healthcare clinics to pregnant women and their partners to help them make decisions about NIPT, if you have experience or evidence relating to this?
- 8 What information about NIPT and the conditions being tested for do you think should be conveyed to pregnant women and their partners? How do you think that information could best be conveyed and by whom?
- 9 What might be the implications for the NHS of increasing numbers of pregnant women purchasing NIPT through the private sector?
- 10 What benefits and concerns might be raised if pregnant women were able to purchase NIPT directly from providers (e.g. where a kit is sent to the pregnant woman in the post), rather than through a healthcare clinic following a face-to-face consultation?
- 11 A small proportion of NIPT tests will return an inconclusive result, even if repeated. How should healthcare professionals, both in the NHS and in private clinics, deal with inconclusive results?
- 12 What issues are raised by incidental findings that can arise following NIPT (such as genetic abnormalities or cancerous cells in the pregnant woman), both in the NHS and in private clinics?

What should NIPT be testing for

In the future, NIPT may allow pregnant women and their partners to test their unborn babies for a wider range of genetic conditions, including those that develop in adulthood. It may also be possible to find out about non-medical information relating to the behaviour and physical appearance of the future child. It is possible to use NIPT for 'whole genome sequencing', which reveals the complete DNA make-up of the unborn baby. At the moment this is very difficult and expensive, but it may become cheaper and easier in future.

- 13 Should potential parents be able to find out the sex of their unborn baby for non-medical reasons from 10 weeks of pregnancy using NIPT? Please give reasons for your answer.
- 14 What genetic information, if any, do you think parents should be allowed to find out about their unborn baby using NIPT? Please give reasons for your answer.
- 15 What genetic information, if any, do you think parents should not be allowed to find out about their unborn baby using NIPT? Please give reasons for your answer.
- 16 Do you think whole genome sequencing of unborn babies using NIPT should be allowed? Please give reasons for your answer.

Implications for wider society

17 What, if anything, might the increasing availability and use of NIPT mean for people living with genetic conditions? Please provide evidence or examples if possible.

Regulation

18 Is current regulation covering the provision and marketing of NIPT in the UK sufficient and appropriate?

Ethical values

We would like to identify the ethical values that are relevant or important in the context of NIPT. These might include: enabling informed decision making about reproduction, reducing harm, protecting the interests of future children, fair use of public resources, and the promotion of equality among members of society.

19 What ethical values do you think are important or relevant in the context of NIPT?

Any other comments

20 Please tell us anything else you would like to raise in relation to NIPT.

Your response

21 May we include your name/your organisation's name in the list of respondents that will be published in the final report?

- Yes
- No, I/we would prefer to be anonymous

If you have answered 'yes', please give your name or your organisation's name as it should appear in print (this is the name that we will use in the list of respondents in the report):

22 May we quote your response in the report and make it available on the Council's website when the report is published?

- Yes, attributed to myself or my organisation
- Yes, anonymously*
- No

Obtaining consent to publish a response does not commit the Council to publishing it. We will also not publish any response where it appears to us that to do so might result in detriment to the Council's reputation or render it liable to legal proceedings.

*If you select this option, please note that your response will be published in full (but excluding answers to questions 21 onwards in this form), and if you wish to be anonymous you should ensure that your name, and any other identifying information, does not appear in the main text of your response. The Nuffield Council on Bioethics cannot take responsibility for anonymising responses in which the individual or organisation is identifiable from the content of their response.

Using your information

We ask for your email address in order that we can send you a link to the report when it is published and notify you about activities related to this project. Please note that we do not make your email address available to anyone else, and we will not include it with the list of respondents in the report.

23 May we keep your email address for these purposes?

- Yes
- No

24 Would you like to receive our monthly newsletter by email which provides you with information about all of the Council's activities?

- Yes
- No