

## Guidance for manufacturers and healthcare providers

# Information to include on your website and patient leaflets about non-invasive prenatal testing (NIPT)

The Nuffield Council on Bioethics has published a report on the ethical issues raised by the increasing use of NIPT. It concluded that pregnant women and couples should have access to NIPT, but only when they are able to make informed choices about whether to have testing or not. The Council recommended that NIPT manufacturers and private hospitals and clinics that offer NIPT should provide accurate, balanced and non-directive information about the benefits and limitations of NIPT and about the conditions being tested for. Potential customers should be provided with this information before they agree to testing.

The UK Code of Non-broadcast Advertising requires that advertisements must be legal, decent, honest and truthful, and that they must not be misleading, harmful or offensive. Websites and patient leaflets that are directly connected with the supply or transfer of goods or services, including NIPT, are considered to be advertisements.

This leaflet sets out the information that if included on your website and in your patient materials we believe will ensure you are providing balanced, accurate and non-directive information about NIPT.

Find out more at: [www.nuffieldbioethics.org/NIPT](http://www.nuffieldbioethics.org/NIPT)  
Or contact the Nuffield Council on Bioethics:  
E: [bioethics@nuffieldbioethics.org](mailto:bioethics@nuffieldbioethics.org)  
T: +44 (0)20 7681 9619

# Essential information

## 1. How does the test perform?

- State whether the test is being offered as a screening test or a diagnostic test and what this means.
- Give a clear picture of how the test performs **for each genetic condition being tested for** in easy to understand language.
- This should include, at a minimum, the sensitivity and positive predictive value of the tests you offer, presented in an accessible and jargon-free way. For example:

*“The test for Down’s syndrome is 96% accurate in most pregnant women. This means the test will identify 96 out of 100 women who have a baby with Down’s syndrome. The test is even more accurate in women with a higher than normal chance of having a baby with Down’s syndrome.”*

*“Although the test is very accurate, sometimes it shows a positive result when the baby does not in fact have Down’s syndrome. Around 20% (1 in 5) of positive results are false in this way.”*
- Without the positive predictive value, the sensitivity data could be misinterpreted as meaning that women with a positive result have a 96% chance of having a baby with the condition tested for. Similarly, stating very low false positive rates (“0.1%”) could give the impression that the test is as good as diagnostic.
- Most studies show that NIPT is more sensitive in populations of women who have been identified as having a higher chance of having a fetus with the condition, compared to general populations of women. Be clear about this and, if you only cite one figure, use the sensitivity figure that relates to the population of women you are marketing your test to.
- Do not imply the test can diagnose conditions, nor that it can rule out conditions.
- Claims about test performance should be based on recent, peer-reviewed, high quality clinical data that you could provide if asked.

## 2. Follow-up testing is needed to get a definite diagnosis

- Prominently state that women with a positive result will need to have another test if they would like a definite diagnosis, because of the chance of a false positive NIPT result. You could mention that the follow-up tests are invasive and carry a small risk of miscarriage.
- Be clear that follow-up testing is entirely up to the woman.
- Do not imply that NIPT is a replacement for invasive testing.

## 3. The possibility of a ‘failed’ test

- Be clear that sometimes NIPT fails to produce any result at all. State the proportion of women that you expect to get an inconclusive result from the test you are offering.
- Explain what will happen in the event of a failed test (such as a free repeat test or a refund).

## 4. Describe genetic conditions without causing offence

- Provide information about the genetic conditions being tested for and do so without causing offence. Down's syndrome is a variable condition and the majority of families report high satisfaction with life. People with Down's syndrome and their families are likely to find the following language offensive.

*"Find out the **risk** that your baby suffers from Down's syndrome."*

*"NIPT has a lower false positive rate, meaning less women will need invasive testing when they actually have a **normal baby**."*

Instead, use neutral language, such as:

*"Find out the **chance** that your baby has Down's syndrome."*

AVOID	USE
High risk result	High chance result
Low risk result	Low chance result
Baby suffering from Down's syndrome	Baby with Down's syndrome
Normal baby	Baby without a genetic condition

- If in doubt, check your language with a patient organisation, such as the UK Down's Syndrome Association.
- Include hyperlinks to reliable information about the conditions being tested for, such as the NHS Choices website and patient support groups.

## Information to include as a matter of good practice

### 1. The implications of testing

- Women should be made aware that having NIPT may lead to some difficult decisions in the event of a positive result, such as whether to have diagnostic testing and, if the diagnosis is positive, whether to continue the pregnancy or have a termination.
- Stating that NIPT will 'offer reassurance' or 'give peace of mind' is misleading, given that some women will receive a positive result.

### 2. The services you offer

- Explain what kind of pre- and post-test counselling the customer can expect to receive from you to help them decide whether to have the test or not, and to

help them interpret and consider their test results.

- Describe how the results will be given and how long it will take to receive them.
- If you are a hospital or clinic, state whether you offer follow-up diagnostic testing and whether this is included in the price of NIPT.

### 3. Secondary findings

- Be clear if the NIPT tests you offer can reveal information about the pregnant woman's genetic makeup and cancerous tumours.
- Describe your company policy for testing for and returning secondary findings about the woman.

## Seek certification from NHS England's Information Standard scheme

Organisations that achieve the Information Standard are demonstrating their commitment to trustworthy health and care information. We encourage you to meet the scheme's Principles and Requirements as far as possible and to join the scheme, which is free of charge.

The Information Standard quality mark indicates that your information production process has undergone a rigorous assessment. This provides assurance that the information you produce is evidence based and that people can understand and use it.

Benefits for organisations of joining the scheme and displaying the quality mark include:

- Enhanced credibility and reputation
- Increased public confidence in the health information you provide
- Potential to reduce chance of litigation
- Increased competitive advantage

Organisations wishing to join the scheme must be able to demonstrate, with supporting evidence, how they meet a number of requirements relating to information production, including user understanding and involvement, and regular review.

Find out more about The Information Standard:  
[www.england.nhs.uk/tis](http://www.england.nhs.uk/tis)

Or contact The Information Standard team:  
E: [england.theinformationstandard@nhs.net](mailto:england.theinformationstandard@nhs.net)  
T: +44 (0)1138 253 002