
Why do we have an age threshold for free NIPT testing?

INVITERT KOMMENTAR

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All prenatal diagnostics should be organised by the public health service and should be the same for all pregnant women.

The Norwegian Biotechnology Act defines prenatal diagnostics as examinations to obtain fetal genetic information or to detect or exclude a disease or fetal abnormality. Amniocentesis, chorionic villus sampling (CVS), non-invasive prenatal testing (NIPT) and prenatal ultrasound examination in pregnancy weeks 11 to 14 are regarded as prenatal diagnostics, while ultrasound examination in the second trimester is not considered to be prenatal diagnostics (1). It is difficult to understand this distinction, which is likely due to historical reasons.

NIPT gives genetic information about the fetus by analysing cell-free placental DNA found in the maternal blood. In Norway, this test is approved for examining fetal rhesus status, trisomy testing for trisomy 21, 18 and 13, testing

for hereditary single-gene disorders, and testing for fetal sex if it is likely that the fetus has a hereditary sex-linked disease [\(1\)](#). It is also possible to examine copy number variations, which is not approved in Norway.

The specialist health service offers some pregnant women NIPT for trisomies free of charge. This comprises pregnant women over the age of 35 years at their estimated due date and women at increased risk of fetal abnormalities.

Pregnant women under the age of 35 years can pay for such testing in the private health service. Nordklev et al. have questioned the fairness of a practice where some women are offered the test free of charge while others have to pay for it. In their study, published in the current issue of the Journal of the Norwegian Medical Association, they asked pregnant women under the age of 35 years for their opinion [\(2\)](#). Three out of four answered that NIPT should be offered to all pregnant women in the public health service free of charge.

«There are several reasons why the authorities have set a threshold of 35 years of age, and one may be financial considerations»

There are several reasons why the authorities have set a threshold of 35 years of age, and one may be financial considerations. NIPT is offered in most Western countries, but availability and the patient's own cost vary [\(3\)](#). The test is expensive, and laboratory costs are between NOK 4 000 and 5 000. Pregnant women under the age of 35 must pay NOK 6 000 for the test at a hospital, and NOK 8 000–10 000 in the private health service [\(4\)](#). Nordklev et al.'s survey showed that many women had an extra ultrasound examination outside the public health service. Examinations with no medical indication represent poor utilisation of medical knowledge and healthcare resources [\(4\)](#).

The likelihood of fetal trisomy increases with age. The age threshold is set at 35 years, but there is no great difference in risk for women who are 34 or 36 years old.

Both sensitivity and specificity are over 99 % for trisomy testing with NIPT [\(5\)](#). The high sensitivity means that a negative test result is very reliable. But even when the false positive rate is less than 1 %, a positive result is uncertain when the test is administered in an unselected population with low incidence. In women aged 35 years or older, the positive predictive values are estimated to be 97 %, 88 % and 67 % for trisomies 21, 18 and 13, respectively. Corresponding values for women in the age range 20–29 years are 73 %, 51 % and 28 %, respectively [\(6\)](#). A false positive test is usually caused by placental trisomy even though the fetus has normal chromosomes. Consequently, a positive test result must be confirmed by amniocentesis.

Previously, Norway had a restrictive practice when offering prenatal diagnostics. In order to avoid screening out some groups, identifying all fetal abnormalities has been regarded as undesirable [\(7\)](#). Trisomy 21 has been in particular focus [\(8, 9\)](#). This is probably a main reason for not offering everyone NIPT free of charge. Many fetuses with trisomy 21 have heart defects or intestinal obstruction, and this can be diagnosed with ultrasound. However, the degree of intellectual disability cannot be predicted.

«Organising all prenatal diagnostics, including free NIPT, in the public health service will result in fairer and more equal services»

Society's desire to avoid screening out some groups must be balanced against women's right to information and their right to autonomy. Nordklev et al's study shows that women want information. Organising all prenatal diagnostics, including free NIPT, in the public health service will result in fairer and more equal services. It will also be easier to obtain an overview of how prenatal diagnostics is managed in Norway. Most importantly, society should also provide support to those who choose to give birth to children with genetic abnormalities. This will reduce the challenges and increase the quality of life of the children and their parents.

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