Tidsskriftet Tidsskrift for Den norske legeforening

Prenatal testing – universal access?

EDITORIAL

RAGNHILD GLAD

ragnhild.glad@unn.no
Ragnhild Glad, specialist in medical genetics, senior consultant at the Department of Obstetrics and Gynaecology, University Hospital of North Norway, and lecturer at UiT The Arctic University of Norway.
The author has completed the ICMJE form and declares no conflicts of interest.

First trimester prenatal testing is now accessible to women who do not have an elevated risk or need. But the access is not standardised.

In May 2020, the Norwegian Parliament (the Storting) decided to make changes to maternity care in Norway. Access to non-invasive prenatal testing (NIPT) to screen for chromosomal abnormalities by analysing cell-free DNA in maternal blood is now a statutory right for pregnant women with an indication for prenatal diagnostics and for other pregnant women with an increased trisomy risk due to their age. The lower age limit for NIPT is 35 years, which corresponds to an age-related, overall trisomy risk of around 0.5 % (1). Women under the age of 35 are not entitled to NIPT in the public health service, but can have it performed in the private health service. Many private healthcare providers send the blood sample for analysis to laboratories outside Norway. Despite robust counterarguments and warnings from the medical communities, it was decided that both public and private healthcare providers would perform NIPT (2–4).

> *«Highly specialised healthcare personnel have chosen to take up more appealing positions in the private health service rather than work at public maternity clinics»*

This decision has proven to have ripple effects: highly specialised healthcare personnel have chosen to take up more appealing positions in the private health service rather than work at public maternity clinics (Sitras V, Salvesen

KÅ, Johnsen SL, personal communication April 2022). This has exacerbated the shortage of qualified healthcare personnel.

In addition, the health trusts have faced major challenges in establishing a new health service provision without the necessary funding. It was not until May 2021 that a subsidy was received under the revised national budget – six months after the health trusts had been commissioned to establish NIPT.

The introduction of NIPT has created a divide in which younger women, who have the lowest risk but the most pregnancies, have to pay an unnecessarily high price for the same testing that older women receive free of charge at their local hospital. The distinction is even clearer in rural areas, where private NIPT is either difficult to access or non-existent. Major resources have been invested in enabling local hospitals to provide first trimester ultrasound examinations and NIPT. A practical and quality-assured system has been established for patient information, sample taking and handling, DNA analysis, reporting of test results and genetic counselling, which is a regulatory requirement when the analysis reveals abnormal findings (5). It seems illogical that young women do not have access to testing that is now available in the public health service. The medical community's recommendation is therefore for pregnant women under the age of 35 to also be offered NIPT along with their first trimester ultrasound examination at the local hospital, against a fixed charge.

Paid access to public specialist health services would require the outpatient regulations to be revised. The regional health authorities and medical communities have called on the Ministry of Health and Care Services to make the necessary amendments. Facilitating NIPT analysis in the public health service also for those under the age of 35 will reduce the number of unnecessary ultrasound examinations and save resources. Very few pregnant women opt out of first trimester screening in the public health service even if they seek NIPT in the private sector. In fact, there is every reason to believe that pregnant women with concerns will normally welcome both an ultrasound examination and NIPT in the private health service, followed by first trimester screening at the local hospital some weeks later.

> ***«Facilitating NIPT analyses in the public health service, also for the youngest group of women who want this testing, will effectively eliminate the market basis for private actors»***

Facilitating NIPT analyses in the public health service, also for the youngest group of women who want this testing, will effectively eliminate the market basis for private actors and help curb the loss of competence in the health trusts. For many local hospitals in the north of Norway, this will probably be crucial for the future provision of NIPT in the public health service.

The legislative amendments have narrowed the gap between Norwegian women and their European and Scandinavian counterparts, who have had access to NIPT for a long time (6). This has led to a long-awaited harmonisation of a conservative biotechnology law, in line with the expectations of many pregnant

women (7). However, NIPT must be organised in a way that safeguards professional standards and ensures equal access to health services for all pregnant women (8).

REFERENCES

1. UpToDate. 2022. Maternal age-related risk for common fetal trisomies across pregnancy. https://www.uptodate.com/contents/image?imageKey=OBGYN%2F75423 Accessed 28.4.2022.

2. Helsedirektoratet. Forslag til organisering og innføring av tilbud om NIPT og ultralydundersøkelser i første trimester. https://www.helsedirektoratet.no/rapporter/forslag-til-organisering-og-innforing-av-tilbud-om-nipt-og-ultralydundersokelser-i-forste-trimester Accessed 28.4.2022.

3. Helse- og omsorgsdepartementet. Endring av vilkår for bruk av non-invasive prenatal testing (NIPT). Brev av 18. mars 2021. https://www.helsedirektoratet.no/tema/bioteknologi/fosterdiagnostikk/Endring%20av%20vilk%C3%A5r%20for%20bruk%20av%20NIPT.pdf/_/attachment/inline/fa0b7e0d-c042-418c-8d40-48ac1eccd6b5:2efc0ea9d00a797f6c81ba6daa400b474de675a4/Endring%20av%20vilk%C3%A5r%20for%20bruk%20av%20NIPT.pdf Accessed 28.4.2022.

4. Helsedirektoratet. Om godkjenningsordning for private virksomheter som skal tilby NIPT. Svar på oppdrag nr. 56 i tildelingsbrev for 2021. https://www.helsedirektoratet.no/tema/bioteknologi/fosterdiagnostikk/Om%20godkjenningsordning%20for%20private%20virksomheter%20som%20skal%20tilby%20NIPT%20%20-%20endelig.pdf/_/attachment/inline/617799f5-ddbe-4599-bfa7c799d381c99a:39aad8775167b50fa105d308365b840635a2938f/Om%20godkjenningsordning%20for%20private%20virksomheter%20som%20skal%20tilby%20NIPT%20%20-%20april%202021.pdf Accessed 28.4.2022.

5. LOV-2003-12-05-100. Lov om humanmedisinsk bruk av bioteknologi m.m. (bioteknologiloven). Kapittel 4. Fosterdiagnostikk. https://lovdata.no/dokument/LTI/lov/2003-12-05-100 Accessed 28.4.2022.

6. Gadsbøll K, Petersen OB, Gatinois V et al. Current use of noninvasive prenatal testing in Europe, Australia and the USA: A graphical presentation. Acta Obstet Gynecol Scand 2020; 99: 722–30. [PubMed][CrossRef]

7. Sitras V, Ulriksen M, Benth JS et al. Gravide kvinners holdning til fosterdiagnostikk. Tidsskr Nor Legeforen 2020; 140. doi: 10.4045/tidsskr.20.0098. [PubMed][CrossRef]

8. Salvesen KÅB, Glad R, Sitras V. Controversies in implementing non-invasive prenatal testing in a public antenatal care program. Acta Obstet

Gynecol Scand 2022; 101: aogs.14351. [PubMed][CrossRef]

Publisert: 23 May 2022. Tidsskr Nor Legeforen. DOI: 10.4045/tidsskr.22.0273