



NIPT in The Netherlands June 2014

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www.vumc.com/researchcommunitygenetics

Prenatal Downscreening 2013 NL

- Information on **combined test** for all pregnant women
- Permission for screening focusses on trisomy **21,18,13**
- Risk estimate based on maternal age, nuchal translucency, two biochemical markers
- If risk \geq **1:200**: diagnostic test: **amniocentesis** or chorionic villi sampling, followed by foetal genotyping
- Uptake 27%

Direct **indication** for prenatal diagnostics:

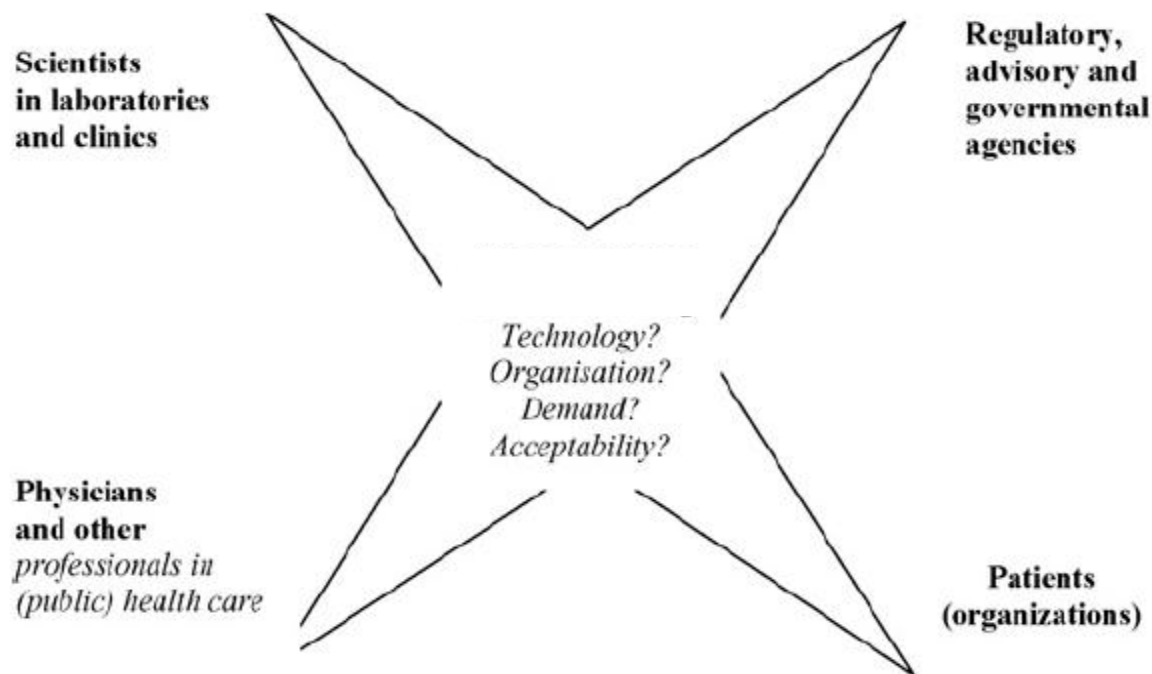
- Maternal age \geq 36 y
- Previous child with chromosomal anomaly
- Carrier balanced translocation

2011 publications

- Some Dutch co-authors to Lo group (Oudejans, van Vugt, Go)
- Early discussions: this could be implemented into prenatal screening practice fast...
- Consortium with OB/GYN, clinical geneticists, midwives, etc.

Implementation & Organisation?

– Attune between parties



Achterbergh et al. Health Policy 2007; 83: 277-286.

KEY STAKEHOLDERS			
Society <ul style="list-style-type: none">- patient support groups- community groups- general public	Medicine <ul style="list-style-type: none">- patients and families- health professionals- researchers	Industry <ul style="list-style-type: none">- biotechnology- pharmaceutical- biomedical	Government <ul style="list-style-type: none">- health sector- other sectors

Andermann et al. Journal of Health Services Research & Policy 2010; 15: 90-97.

Request permission Population Screening Act: March 2013

- VUmc on behalf of national consortium
- For implementation of NIPT for pregnant women with increased risk for trisomy 21, 13 en 18 in The Netherlands
- End March 2013 to Ministry of Health (VWS)
- 17 May 2013 to Health Council
- 2x Correspondence to ask for clarification
- Some scientific questions – therefore treated as research project – TRIDENT: Trial by Dutch Laboratories for Evaluation of Non-invasive prenatal testing.
- Mid December 2013: Health Council report # 35.

After Health Council Report – December 2013

- Minister VWS responded same day
- Health Care Insurance Board: NIPT is risk estimating test, not final diagnostic test, therefore for women <36 jaar not in basic health care package.
- Who will pay?

Relation with neighbouring countries

- Untill end 2013 NIPT-t21 not implemented in public health care, first in Belgium (KGC Leuven, 460€)
- Commercial offers in Belgium (GENDIA), Germany (Lifecodexx), etc.
- 70 women per week to België (GENDIA)

April 2014 and further

- 8 University Medical Centres offer NIPT after increased DS risk based on combined test (>1:200)
- Some UMCs sent samples to other UMCs lab (Leiden->Amsterdam)
- In the first 40 days, around 350 women opted for NIPT in UMCs.
- TRIDENT will evaluate after first 1000 samples – after summer?
- Report to ministry of Health before end 2014
- WBO Permission for 2 years, most likely further request for WBO permission

Questions for future

- Lower cut off for Down's screening? (To scale up to larger target group & increase sensitivity, see www.gr.nl)
- For all pregnant women?
 - Covered by health insurance?
- Other serious disorders included?
- The role of commercial parties?