Clinical implementation of NIPT into routine OB care

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Women with pregnancies considered high risk due to ultrasound abnormalities, family history, advanced maternal and/or paternal age should discuss their risks with their doctor and genetic counselor to determine which tests are appropriate for their situation.
DNAFirst Study

Integrating NIPT into routine care

The clinical utility of DNA-based screening for fetal aneuploidy by primary obstetrical care providers in the general pregnancy population

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Objective: To assess the clinical utility of cell-free DNA (cfDNA)-based screening for aneuploidies offered through primary obstetrical care providers to a general pregnancy population.

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DNAFirst Study

- Statewide program examining utility of NIPT
- What was the ease of switching from MSS to NIPT?
  - Education of provider, patient education, uptake of screening after education, understanding of the results
- Reinforces that NIPT can be used as a first-line screening regardless of risk
DNAFirst Trial Details

• OB practice offered NIPT to a general pregnancy population
• 2,681 women screened through 72 providers
• Average Maternal age was 31
  — 79% of women younger than 35
• Pre-test counseling provided by the women’s physicians, nurse midwives and nurses/educators
• Providers were given a short (10-20 minute) in-service education to prepare them for pre-test counseling
DNAFirst Trial Results

*Results ease concerns around the education and counseling requirements some thought would hinder widespread NIPT use*

- In a patient survey conducted following the study:
  - Most correctly recalled that NIPT was not diagnostic
  - 99% reported that the reason for screening was discussed
  - 98% would recommend NIPT to a friend

- In a provider survey conducted following the study:
  - 83% believed they and their staff were adequately prepared to implement NIPT in their practice, without more extensive education
DNAFirst Takeaways

- Evaluated a straightforward protocol for provider and patient education about NIPT as a primary screen
- Outcome data proves that pre-test counseling requirements can easily be fulfilled by physicians, nurse midwives, and office nurses/educators
- Patients showed similar understanding of screening compared to other similar studies with MSS
- Reinforces that NIPT can be used as a first-line screening regardless of risk
Patient Screening Timeline

First OB appt

First trimester

Second trimester

Intake, video, education materials
Most babies are born healthy, but about 3% have birth defects or other genetic conditions.
Testing is available if you want to learn more.

Testing during pregnancy is available to learn more.

Any woman *may* have this testing, but no woman *has* to have it.
Some tests are diagnostic, others are screening

Diagnostic testing gives definitive answers, but have a small risk of loss.

Screening tests evaluate if the pregnancy is at high or low risk.
NIPT is one type of screen that gives a high or low risk for certain chromosome abnormalities from information found in mom’s blood.

Non-invasive prenatal testing is one option.
Patient Screening Timeline

First trimester
- First OB appt
- Intake, video, education materials
- Early ultrasound

Second trimester
Patient Screening Timeline

- **First trimester**
  - First OB appt
  - 9+ weeks

- **Second trimester**
  - Intake, video, education materials
  - Early ultrasound
  - Blood draw
Patient Screening Timeline

First trimester
- First OB appt
- Intake, video, education materials
- Early ultrasound
- Blood draw
- Results

9+ weeks
- Optional post-test GC info

Follow up
- Low risk: routine OB care
- High risk: discuss diagnostic testing

Second trimester
Putting the clinical pieces together

First trimester ultrasound:
- Gestational age
- Major anomalies
- Nuchal translucency

- Pregnancy History
- NIPT
- AFP
  - Anatomic survey
- Family History
Putting the clinical pieces together

- Increased risk identified: MFM referral
- No increased risks identified: Routine prenatal care
Efficient integration into general OB care

- Genetic information sessions with board-certified genetic counselors
  - Pre &/or Post test
- Patient friendly resources
- Algorithm to discuss and document choices
- Customer support
The test has been developed and its performance characteristics determined by the CLIA-certified laboratory performing the test. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). Although FDA does not currently clear or approve laboratory-developed tests in the U.S., certification of the laboratory is required under CLIA to ensure the quality and validity of the tests.

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