



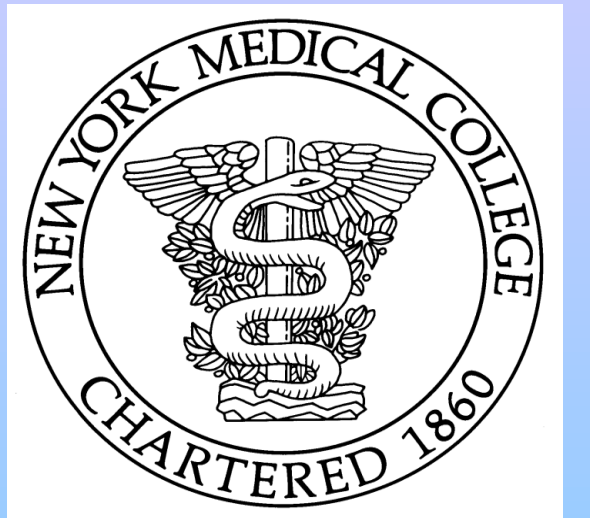
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Identification of Deficits in the Informed Consent Process for Non-Invasive Prenatal Testing (NIPT)

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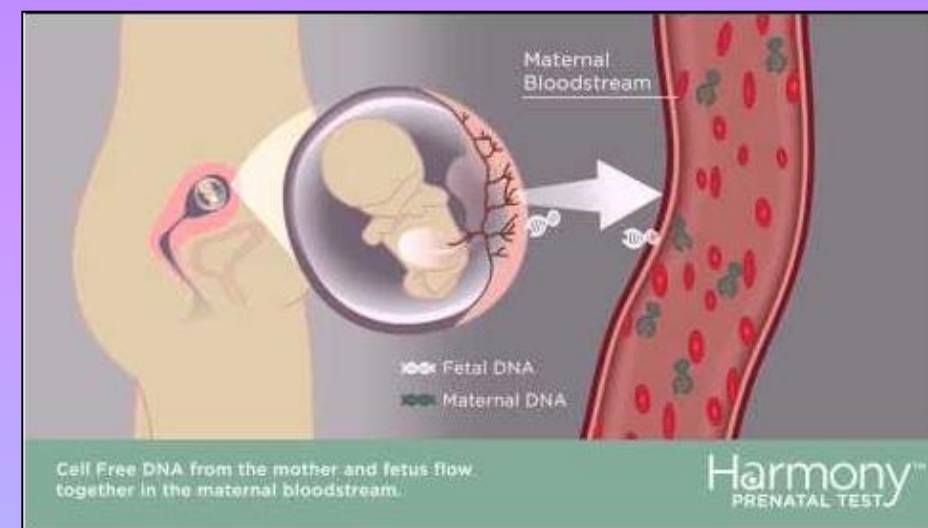


Project Goal

Our project goal is to review the literature available on NIPT, including how the testing protocol is used in medical practice, the accuracy associated with the results of the testing, the modifications to the informed consent process, and the actions families and healthcare providers have chosen in response to the results.

Background

The informed consent process is a method of documenting that the associated risks/benefits/limitations and alternatives to a procedure have been discussed with a patient without introducing the provider's personal biases. Informed consent for invasive prenatal testing has understandably focused on the risk of infection, miscarriage, and fetal injury. However, less attention has typically been paid to additional factors that can impact a patient's decision-making process. Discussion of these more comprehensive factors (i.e., culture, religion, etc.) during the informed consent process could help healthcare professionals ensure potential parents make the most appropriate and healthy decisions for their families.



http://article.wn.com/view/2012/02/06/Aria_Diagnostics_Announces_Name_of_New_NonInvasive_Prenatal/

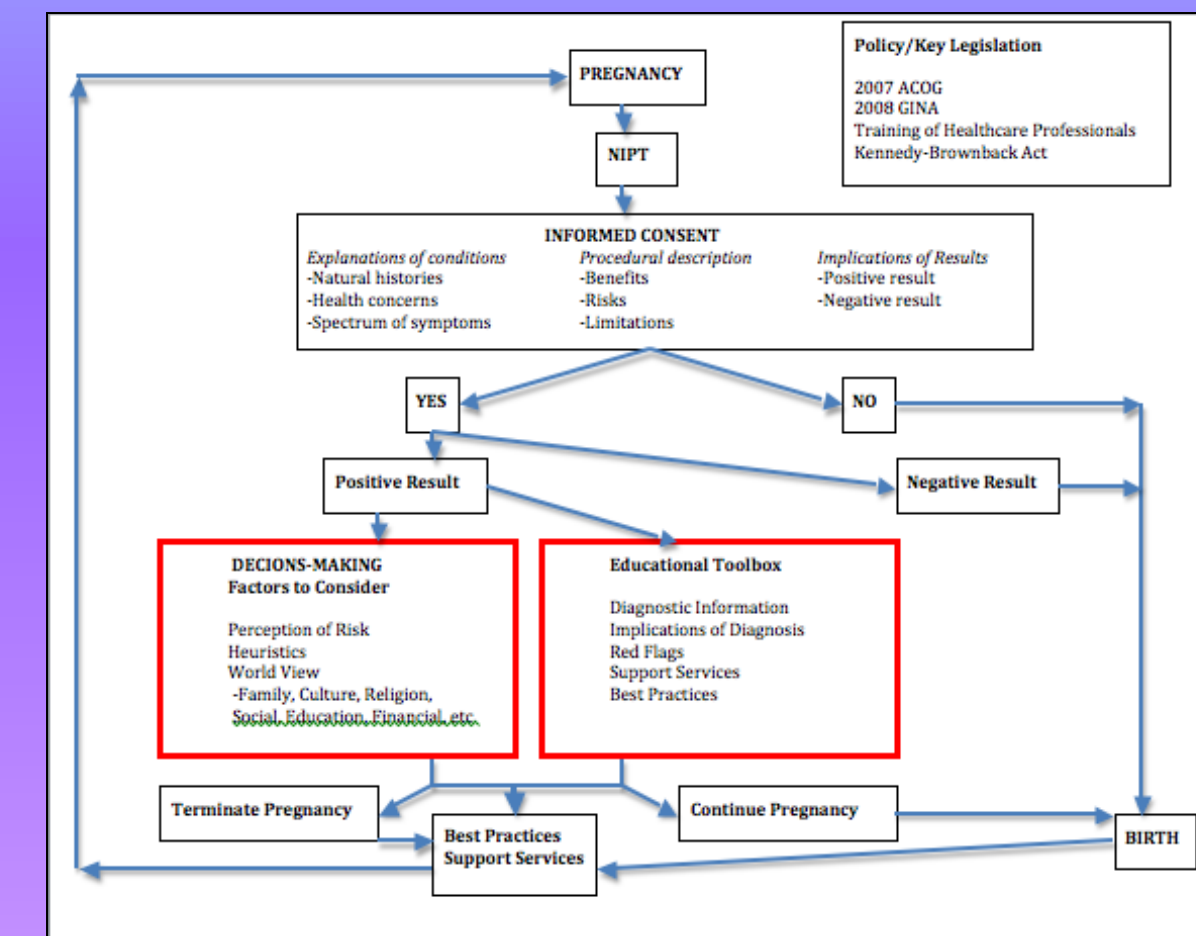
Non-invasive prenatal testing (NIPT) is a blood test that can currently detect the presence of fetal trisomies 13, 18 and 21 with high accuracy (~99%). While currently considered a "screening" test, the accuracy rate is nearing that of the diagnostic amniocentesis and chorionic villus sampling testing methods, which have an associated risk of miscarriage. With the introduction of NIPT, there is no longer a risk of miscarriage, but it presents a serious risk of misinformed consent regarding whether or not to undergo testing. The American College of Obstetrics and Gynecology (ACOG) Committee Opinion recommends offering this testing to women at increased risk of aneuploidy.

Community Partners

Brian Skotko, MD, MPP – Medical Geneticist, Mass General Hospital
Harold Kleinert, EdD – National Center for Prenatal and Postnatal Down Syndrome Resources

Methods

- Discussion
- Brainstorming
- Flowchart
- Literature Review
- Interviews with Experts
- Revision of Goals



Literature Review

Two examples of articles that were reviewed:

- Zuzana Deans & Ainsley J. Newson. *Should Non-Invasiveness Change Informed Consent Procedures for Prenatal Diagnosis?*
- Greer Donley, Sara Chandros Hull, & Benjamin E. Berkman. *Prenatal Whole Genome Sequencing: Just Because We Can, Should We?*

"If these tests are someday replaced by the new blood test, many women may be told out of the blue not simply that they're at risk, but that in fact their baby almost surely has Down syndrome, Greely says. 'They're going to jump directly to the final answer, which is not necessarily something they wanted to get,' Greely said. So the new test poses a challenge to the medical establishment about how to assure that women get adequate counseling to make an informed choice, he said." - The Today Show, 6/12/11

"We have a fleet of physicians who are saying they're untrained, unprepared and sometimes knowingly inserting their own personal bias," he said. "How are women today able to make a truly informed decision?" - Brian Skotko

Results

Major factors that may influence a patient's decision to undergo prenatal testing were identified and explored.

Evaluation of Decision-Making Factors/Perception of Risk

- Heuristics
- Religion
- Culture
- Socio-economics
- Education
- Age
- Other Children
- Exposure to individuals with disabilities

The significance and objectives of this project were written up in "The Paragraph" and interviews with experts in the field of genetics confirmed that informed consent pre-NIPT is lacking.

Highlights from Expert Opinions

- Brian Skotko, MD, MPP
 - No pre-test information
 - Patients do not want pre-test information
- Blythe Crissman, MS, CGC
 - Lack of informed consent
 - Suggested a broad-based survey to assess population-based knowledge about Down syndrome

Conclusions/Discussion

Based upon an extensive literature review, and in depth discussion with key community partners, it has become apparent that the broad realm of informed consent necessary before NIPT, is neglected in terms of supporting families in identifying the most appropriate course of action for their individual circumstances. Recommendations need to be made to support an appropriate standard of care for health care professionals involved in NIPT, in particular a flexible framework of information and guidance measures to be adjusted to the individual needs and priorities of the subject family.

Next Steps

- Revised goal: to fill in identified gaps in the informed consent process for NIPT
- Continue literature review
- Continue communication with community partners and other experts to monitor the emerging issues
- Survey healthcare professionals about their knowledge of NIPT and what they would like to know about NIPT and informed consent
- Develop recommendations to be considered as an appropriate standard of care