Research Press Releases

Research Supports Expanding Insurance Coverage of Non-invasive Prenatal Testing

Evidence shows uptake of noninvasive prenatal testing associated with fewer invasive procedures

Sara Knuth | October 8, 2019

Research conducted by the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences provides evidence to support expansion of insurance plan coverage of noninvasive prenatal testing (NIPT), a simple maternal blood draw which screens for fetal chromosomal disorders including trisomy 13 (Patau syndrome), trisomy 18 (Edwards syndrome), and trisomy 21 (Down syndrome), to women under the age of 35.

The research represents a first-of-its-kind published analysis of results from a risk-sharing agreement between biotechnology company Illumina, Inc. and insurer Harvard Pilgrim Health Care to expand coverage of NIPT to pregnant women less than 35 years of age. CU Pharmacy

assistant professor Brett McQueen, Ph.D., is conducting the research in partnership with advisory firm Real Endpoints to evaluate the impacts of the agreement.

As part of the agreement, Harvard Pilgrim Health Care expanded coverage of NIPT to include pregnant women under the age of 35 who are covered by Harvard Pilgrim's health plan. Real Endpoints brought Illumina and Harvard Pilgrim together, helped negotiate the contract between them, and recruited CU Pharmacy to analyze the data.

A CU Pharmacy analysis of health care data during the course of one year showed — for women under age 35 — a 42 percent increase in NIPT tests ordered and a 15 percent decrease in invasive diagnostic tests (chorionic villus sampling and amniocentesis) for trisomy syndromes when health insurer Harvard Pilgrim Health Care expanded NIPT coverage to all pregnant women.

NIPT is a more accurate alternative to other more widely used trisomy screening tests, including nuchal translucency and serum biochemical assays. NIPT's detection rate for trisomy syndromes is more than 99 percent, according to the American College of Obstetricians and Gynecologists.

Poor positive predictive values associated with nuchal translucency and serum biochemical assays can have consequences, potentially leading to invasive procedures that increase the risk of miscarriage. Despite data that support the effectiveness of NIPT, some insurers only cover the testing only for women over the age of 35, and those with high-risk pregnancies.

McQueen presented the results Oct. 4 at the Annual Meeting of the American College of Obstetricians and Gynecologists Districts V, VIII and IX in Maui, Hawaii.

The full findings of the study will be published in 2020 and will include a comprehensive analysis of costs and outcomes related to the expansion of testing in the Harvard Pilgrim Health Care plan.

Evaluation of Coverage Expansion for Non-Invasive Prenatal Testing Through a Performance-Based Risk Sharing Agreement

Skaggs School of Pharmacy and Pharmaceutical Sciences
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Key Finding: NIPT coverage expansion to women under 35 years of age was associated with an increase in NIPT utilization, a decrease in total testing and diagnostic utilization, and a decrease in invasive procedures over the baseline year

Objective

- To estimate the impact of coverage expansion to women under 35 years old on screening utilization, clinical utility, and overall screening program costs

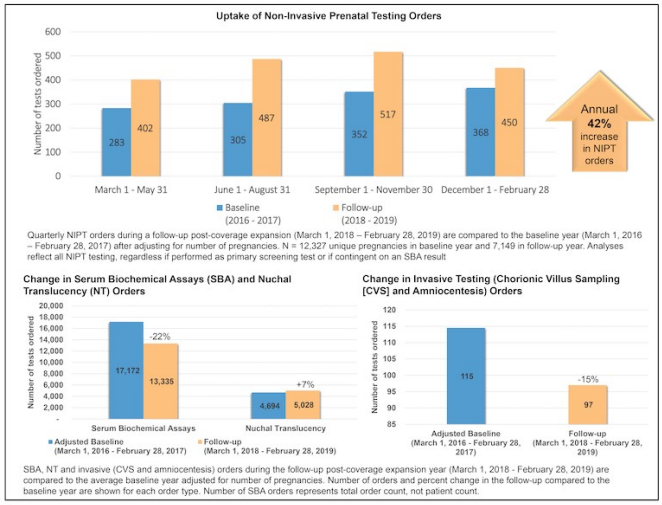
Background

- Illumina and Harvard Pilgrim Healthcare (HPHC) entered into a performance-based risk sharing agreement to expand coverage for cell-free DNA non-invasive prenatal testing (NIPT) to women under 35 years old
- Traditional serum biochemical and nuchal translucency screening approaches are limited by poor positive predictive values and specificity, potentially leading to unnecessary invasive procedures as compared to NIPT

Methods

- Using HPHC claims, we identified women under age 35 years with *at least one pregnancy-related diagnostic or procedure code* from March 1, 2016 to February 28, 2017 (the baseline year) and from March 1, 2018 to February 28, 2019 (the post-coverage expansion year)
- We estimated total NIPT orders, all maternal trisomy screening, diagnostic testing, and invasive procedures (i.e., amniocentesis, chorionic villus sampling) and compared percentage change estimates between baseline and post-expansion year, after adjusting for number of unique pregnancies (i.e., comparing the same number of pregnancies during both time periods)

Results



Quarterly NIPT orders during a follow-up post-coverage expansion (March 1, 2018 – February 28, 2019) are compared to the baseline year (March 1, 2016 – February 28, 2017) after adjusting for number of pregnancies. N = 12,327 unique pregnancies in baseline year and 7,149 in follow-up year. Analyses reflect all NIPT testing, regardless if performed as primary screening test or if contingent on an SBA result

SBA, NT and invasive (CVS and amniocentesis) orders during the follow-up post-coverage expansion year (March 1, 2018 - February 28, 2019) are compared to the average baseline year adjusted for number of pregnancies. Number of orders and percent change in the follow-up compared to the baseline year are shown for each order type. Number of SBA orders represents total order count, not patient count.

Conclusions

- Compared to the baseline year, NIPT coverage expansion for women under age 35 years old was associated with:
  - An increase in NIPT utilization
  - A decrease in total testing (-13% not shown in figures) and diagnostic procedures
  - A decrease in invasive procedures
- Given claims data are not linked with electronic medical records, we were not able to categorize subsequent patient health care utilization for given test findings

Implications

- After adjusting for the same number of pregnancies, coverage expansion of NIPT was associated with decreases in invasive procedures
- Results provide evidence to support expansion of NIPT coverage to women under age 35 years old
- Leveraging real-world data shows promise for assessing health benefit expansions
- Evaluation of the economic impact of the coverage change is ongoing
- Future studies should assess the causal impact of coverage expansion

Harvard Pilgrim Health Care
illumina
real endpoints

Disclosures This study was funded by Real Endpoints and Illumina; data was provided by HPHC

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