

Industry's Contribution to Education for Prenatal Genetic Testing

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Chairman, Clinical Advisory Board

CAPS

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Agenda

- Introduction to CAPS
- Key Points
- Industry Role in Education
- Industry Perspective
- Commercial Insurance NIPT Coverage
- Medicaid NIPT Coverage

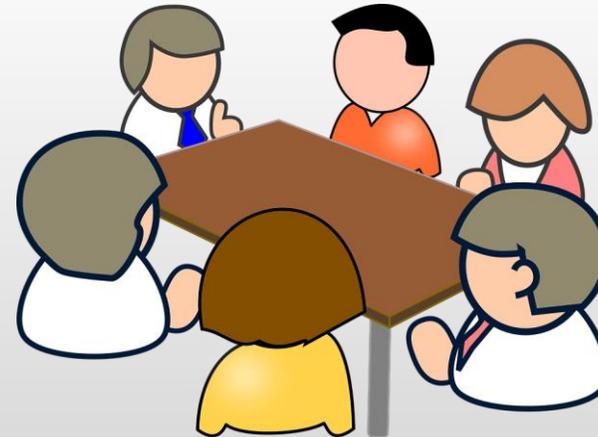
Introduction-CAPS

The Coalition for Access to Prenatal Screening (CAPS) is a collaborative alliance of six leading genetic testing companies in the U.S. (: Illumina, Counsyl, Integrated Genetics (a LabCorp company), Natera, Progenity, and Roche)that seeks to improve access to state-of-the-art prenatal screening using cell-free DNA (cfDNA)-based noninvasive prenatal testing (NIPT)

- accessible to all pregnant women who choose to pursue aneuploidy screening, regardless of their risk factors, income, age or geographic location.
- work together to promote public awareness about the value of this innovative and highly sensitive screening method and to
- advocate for the highest standards of quality, service and education.

Clinical Advisory Board (CAB)

- The CAB provides advice and consults CAPS on non-invasive prenatal screening
- Its role includes, but is not limited to, promoting evidence-based clinical care and attending scientific meetings
- CAB Members:
 - Arnold W. Cohen, MD FACOG (Chair)
 - Jennifer M. Hoskovec, MS, CGC
 - Valerie Rappaport, MD
 - Annelise S. Swigert, MD
 - Thomas Westover, MD, FACOG



- NIPT- the most widely and rapidly adopted molecular diagnostic test in history
 - Previous diagnostics were marketed with equal force with lower uptake - testament to the value NIPT provides to both patients and clinicians.
- Development and Research has been sponsored by industry
- Academic verification of sensitivity, specificity, PPV, NPV and False positive rate has been done by industry
- Peer reviewed publications have all been supported by industry
 - High Risk
 - Average Risk

Clinical Evidence in the General Population

>15 Publications with > 87,000 Average Risk Patients

Author	Date	Journal	N
Nicolaides et al.	Nov-2012	American Journal of Obstetrics and Gynecology	2,049
Dan et al.	9-Nov-2012	Prenatal Diagnosis	1,387
Fairbrother et al.	15-Mar-2013	Prenatal Diagnosis	289
Gil et al.	6-June-2013	Ultrasound Obstetrics & Gynecology	1,111
Song et al.	17-Jun-2013	Prenatal Diagnosis	1,741
Shaw et al.	20-Nov-2013	Fetal Diagnosis and Therapy	101
Lau et al.	10-Feb-2014	Ultrasound Obstetrics & Gynecology	368
Bianchi et al.	27-Feb-2014	New England Journal of Medicine	1,914
Zhou et al.	4-Jul-2014	Prenatal Diagnosis	26
Pergament et al.	Aug-2014	Obstetrics & Gynecology	518

Clinical Evidence in the General Population

Continued

Author	Date	Journal	N
Comas et al.	12-Aug-2014	Journal of Maternal-Fetal & Neonatal Medicine	278
Korostelev et al.	9-Sep-2014	Gynecological Endocrinology	190
Quezada et al.	20-Nov-2014	Ultrasound Obstetrics & Gynecology	2,851
Zhang et al.	8-Apr-2015	Ultrasound in Obstetrics & Gynecology	40,287
Norton et al.	23-Apr-2015	New England Journal of Medicine	15,841
Palomaki et al.	12-Jan-2017	Genetics in Medicine	2691
Caldwell et all.	1-Feb-2017	SMFM Annual Meeting 2017	16,585
		TOTAL	88,227

cfDNA performance in the general obstetric population has been documented in at least **15 studies** covering at least **87,000 subjects**

Education

- Companies provide physician NIPT education,
 - medical affairs groups
 - sales force
- Education based on Professional Organizations Guidelines and Peer Reviewed Journal publications
 - Examples: Office brochures, websites, webinars, presentations at scientific conferences, educational grants to private educational providers and professional organizations, peer-reviewed publications
- Physicians play a key role in educating patients
- Companies also support programs aimed directly at patient education
 - Initially for high Risk
 - moved to average risk

Industry Supports Society Partnership & Educational Programs

Coalition for Access to Prenatal Screening

The goal of the Perinatal Quality Foundation Genetic Education Modules (GEM) is to facilitate communication between providers and patients by providing baseline knowledge and common resources for support.



gem Genetic Education Modules

Innovative pre-test education for routine prenatal genetic testing

- Reduces clinic time spent on routine education
- Facilitates patient - provider discussions
- Provides resources and records of patient education

GEM helps providers comply with ACOG/SMFM standards regarding prenatal genetic testing.

GEM helps providers comply with ACOG/SMFM standards regarding prenatal genetic testing.

Providers and staff can earn credentialing and CME, plus stay up-to-date through webinars, newsletters, reference guides, and more...

- Testing at-a-Glance
- Compare Tests
- Risk Profiler and Test Detection Tool
- Values Calculator
- Discussion Planner

Founding Supporters of GEM



Industry & society partnership to promote education for routine prenatal genetic testing

Society Partnership & Educational Programs

Coalition for Access to Prenatal Screening



Various Presentations on NIPT for All patients

ACOG District presentations

- Non Invasive Prenatal Testing (NIPT) for all patients in an Obstetrical practice
- Interactive workshops on prenatal aneuploidy screening

Emerging Technology Session

iTalk Unplugged: Building a Comprehensive NIPT Program.

(View point of Physician, genetic alliance and patient advocates)

Donor lounge sponsorships

- Non Invasive Prenatal Testing (NIPT) for all patients



Various presentations on NIPT & expanded panels

- Chromosomal Mosaicism in Structurally Abnormal Fetuses
- Expanding NIPT with the Power of NGS



Educational TV Segments on NIPT



Live Global Quarterly Webinars

Implementing NIPT into a Busy OB Practice

Industry Supports Patient Education Videos

Coalition for Access to Prenatal Screening

Understanding prenatal genetic testing options



Understanding carrier screening testing options



Industry Perspective

- Companies continue to be active in new research that has a goal of providing comprehensive Prenatal Genetic Testing NON-INVASIVELY
- Companies continue to be active in patient and provider education around NIPT
 - Efforts have included providing educational and/or research grants to professional organizations (ACOG, ACMG, NSGC, SMFM, PQF) and many academic institutions

Barriers to Use of NIPT

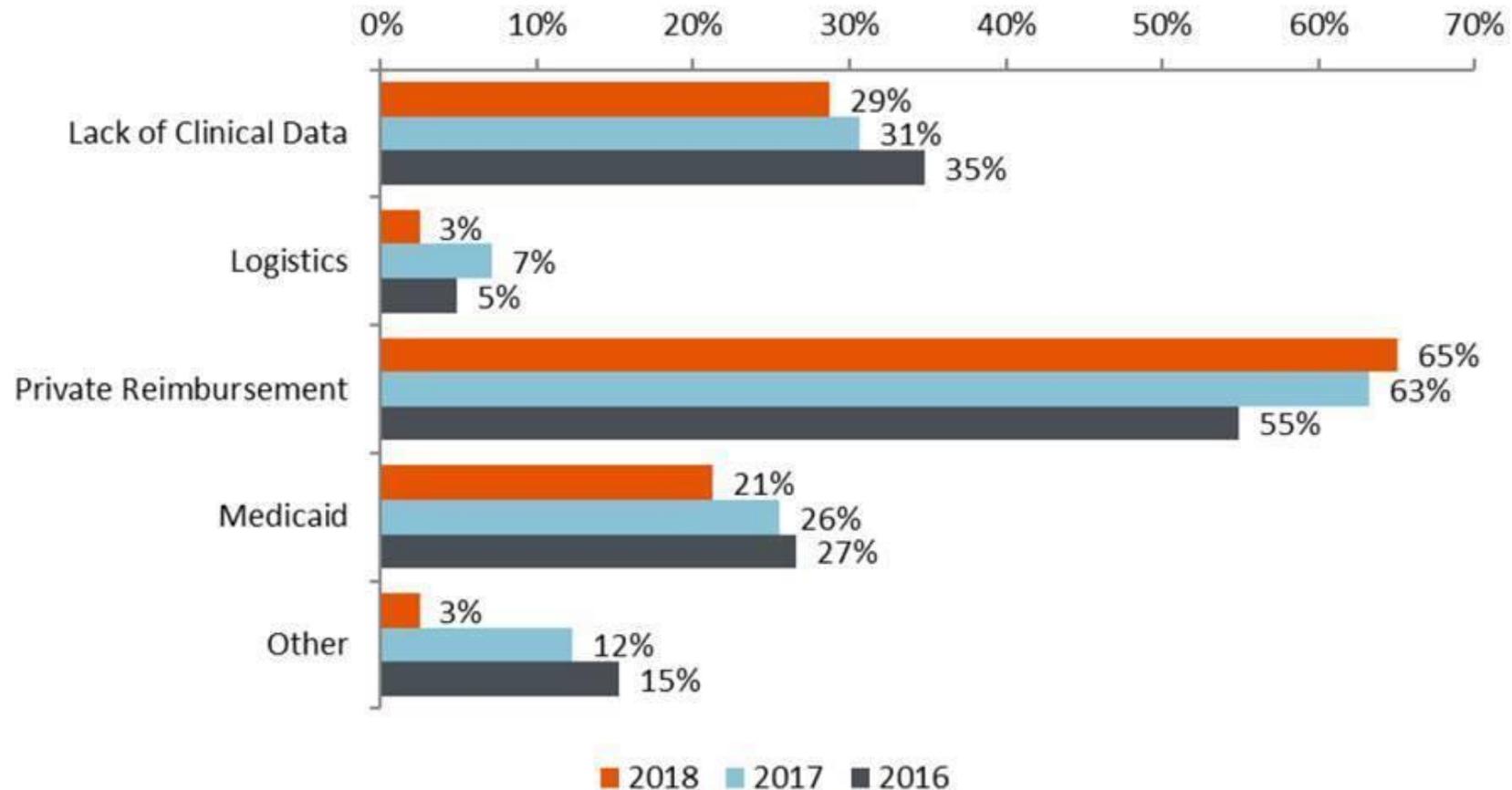
Conflicting Professional organization opinions

- Organizations' endorsement of invasive procedures (i.e. CVS, amnio), while not fully supporting a validated noninvasive blood test
- Organizations' reliance on data obtained by invasive testing as the "Gold Standard"
- Organizations' endorsement of counselling for all available options for prenatal genetic diagnosis
- Disconnect between Organizations' endorsement and availability of counselors
- Organizations' support of Patient Autonomy in decision making but not payment coverage
- Organizations' reluctance to support insurers coverage policies that would allow patients access to NIPT
- Organizations' reluctance to understand the significance of a 10x lower false positive rate that will decrease need for invasive testing and risk to the pregnancies
- Commercial insurance variation in coverage policies
 - High Risk
 - Average Risk
- Medicaid variation in coverage policies
 - High Risk
 - Average Risk
- Lack of explicit endorsement by the largest organizations (ACOG)
- Lack of explicit endorsement by SMFM

Reasons Precluding NIPT Use by OBGYNs

Exhibit 8

Reasons For Avoiding NIPT In Average Risk Mothers – Comparison To 2016-2017



- Eager to learn about how to do better and further improve education efforts and access to appropriate prenatal genetic testing
- Eager to promote expanded content in non-invasive testing technology
- Eager to collaborate to ensure availability to the appropriate testing to all

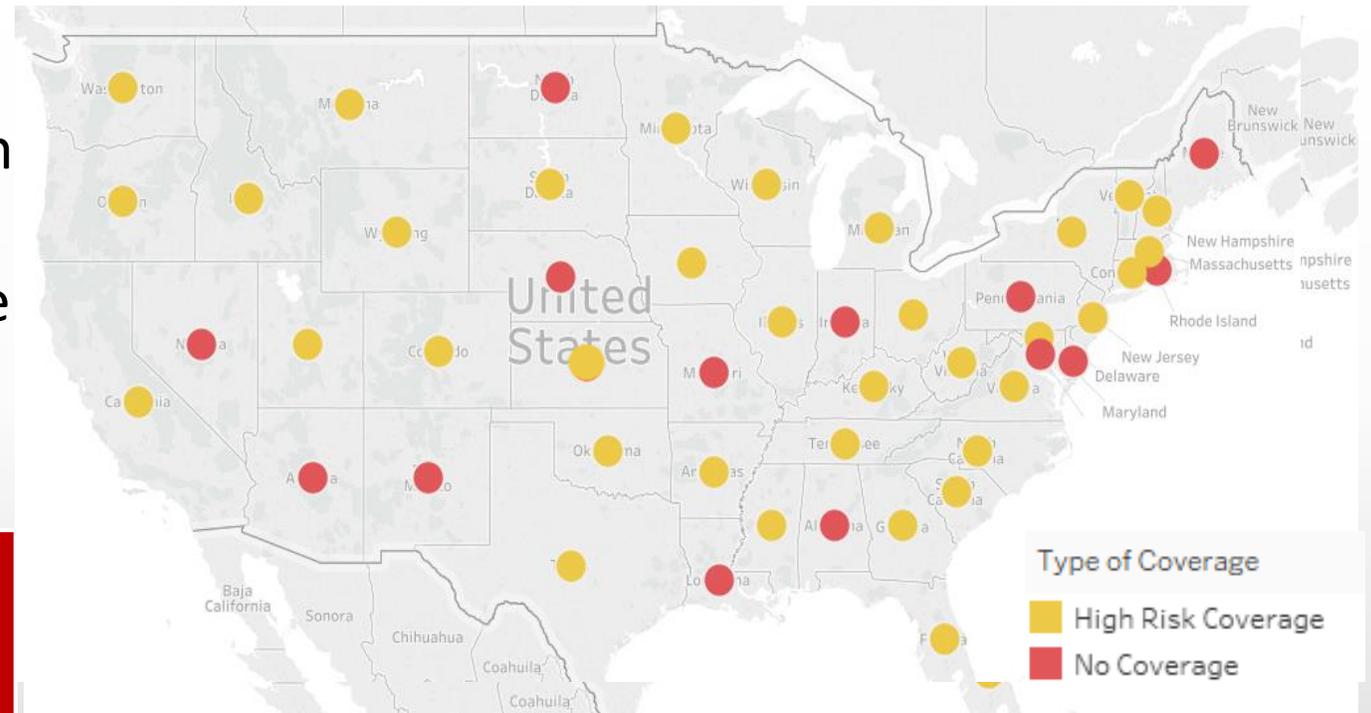
Commercial Payer Coverage

Current commercial payer coverage of NIPT (average risk):

- 37 commercial plans, encompassing **107.9 million** people, cover NIPT
- Major insurers providing coverage include Cigna and Anthem
- 2018 policy changes by WellMark and Blue Cross Blue Shield Tennessee
- However, several major insurers (and ALL state Medicaid) do not cover NIPT for average-risk patients
 - Divergent professional society opinions
 - Lack of explicit endorsement by the largest organizations (ACOG)
 - Leaves some of the most vulnerable populations without access to optimal management (disparity in care)

Medicaid Coverage

- **37** states cover NIPT (CPT Codes 81420 & 81507) for roughly 61 million Medicaid patients, for high risk pregnancies only
- The remaining 12.3 million people on Medicaid are from one of the 13 states + DC not covering NIPT



13 States + DC that Do not Cover NIPT:
Alabama, Arizona, Delaware, District of Columbia, Indiana, Louisiana, Maine, Missouri, Nebraska, Nevada, New Mexico, North Dakota, Pennsylvania, Rhode Island