ADVANCES IN PRENATAL MOLECULAR DIAGNOSTICS

TRENDS AND IMPLICATIONS IN A RAPIDLY CHANGING LANDSCAPE

SEPTEMBER 23-24, 2013 • BOSTON, MA

COVERAGE INCLUDES:

• Current Options and Considerations for Pregnancy Risk Assessment
• Diagnostic Options, Genetic Counseling, Reimbursement, Patents, Medical Guidelines
• Array-Based Cytogenetic Testing
• Isolation and Analysis of Fetal Cells from Maternal Blood
• Biomarkers of Preeclampsia and Pre-Term Labor

PANEL DISCUSSIONS:

Sequencing-Based Diagnostics of Cell-Free DNA in Maternal Blood
The Future Landscape of Prenatal Molecular Diagnostics

PROGRAM ADVISORS:

Arthur Beaudet, M.D., Chair, Department of Molecular & Human Genetics, Baylor College of Medicine
Diana W. Bianchi, M.D., Executive Director, Mother Infant Research Institute, and Professor of Pediatrics, Obstetrics and Gynecology, Tufts University School of Medicine
Joe Leigh Simpson, M.D., Senior Vice President for Research and Global Programs, March of Dimes Foundation
Ronald J. Wapner, M.D., Director of Reproductive Genetics and Vice Chair of Research, Department of Obstetrics and Gynecology, Columbia University Medical Center

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ABOUT THE CONFERENCE:

In recent years there have been dramatic changes in the field of prenatal diagnostics, both as a result of new technical capabilities and concerns over the risks and limitations associated with traditional diagnostic approaches.

The transition in favor of array-based cytogenetic assays in place of traditional karyotyping is well underway. For higher risk pregnancies the use of sequence-based testing of cell-free DNA in maternal blood is becoming more common, although evidence of genetic abnormalities must then still be confirmed with more invasive procedures. Research aimed at isolation of nucleated fetal cells from maternal blood could provide better answers with lower risk in the future. Advances in single cell sequencing are being applied to pre-implantation diagnostics and could be particularly powerful when combined with fetal cell isolation from maternal blood.

Pre-Conference Short Course*

**SUNDAY, SEPTEMBER 22 | 2:00 PM – 5:00 PM**

**Commercialization Boot Camp: Manual for Success in the Molecular Diagnostics Marketplace**

This workshop will define the priority checklist for executing a successful strategy and operational plan for commercializing molecular diagnostics. It will examine the process of bringing a product to market based on data driven case histories. Financial resources needed to execute the project plan will be measured in the current climate. Participants will learn key requirements for advancing molecular diagnostics through product development. This course will leverage the instructors' years of accumulated experience spanning financial, technical and scientific acumen, as well as overcoming roadblocks on the path to commercial success.

*Instructors: Harry Donikian, Managing Director, Strategy, Precision for Medicine
Elaine Cheung, Business & Corporate Development, Illumina

* Separate registration required

MONDAY, SEPTEMBER 23

**7:45 am Registration and Morning Coffee**

**CURRENT OPTIONS AND CONSIDERATIONS FOR PREGNANCY RISK ASSESSMENT**

**8:50** Chairperson's Opening Remarks
Ronald J. Wapner, M.D., Director, Reproductive Genetics; Vice Chair of Research, Department of Obstetrics and Gynecology, Columbia University Medical Center

**9:00** Prenatal Genetic Diagnosis: Balancing the Options
Ronald J. Wapner, M.D., Director, Reproductive Genetics; Vice Chair of Research, Department of Obstetrics and Gynecology, Columbia University Medical Center

Two emerging technologies have become available for prenatal diagnosis. One is noninvasive testing. It is over 99% accurate in screening for Down syndrome and, it is slightly less accurate in screening for other common chromosomal Aneuploidies. The other, Chromosomal Microarray Analysis, provides the parents with significantly more genomic information, but it requires an invasive test with a 1/300-1/500 risk of pregnancy loss. Patients should be counseled about the availability of both options, so they can make informed decisions about how to evaluate their pregnancy.

**9:30** Medical Decision-Making Models in Prenatal Diagnostics
Kee Chan, Ph.D., Department of Health Sciences, Boston University

This presentation will focus on the medical decision making models used to evaluate the cost and benefits of prenatal testing. Prenatal testing may change due to the lower cost of genome sequencing and the large availability of genomics data compared to a decade ago. Physicians, researchers, and consumers may be challenged with more complex decision-making in assessing predictive risk of prenatal testing for genetic disorders, chronic disease, and late-onset manifestation of disease. Understanding key ethical, legal, social and financial (ELSF) implications of prenatal testing as well as the medical decision making framework may provide guidance for individuals considering genetic testing.

**10:00** Reimbursement Issues for Prenatal Diagnostics: How Do the Payers Look at This Field
Robert C. McDonald, M.D., MBA, President, Aledo Consulting

This conference applies substantial focus on the technological aspect of pre-natal testing. Technologically, the field is in a state of rapid evolution. Likewise, the reimbursement of prenatal testing is in a state of rapid evolution. This discussion will review several reimbursement trends regarding laboratory services, in general, molecular diagnostic tests, more specifically, and prenatal diagnostic testing, in particular.

**10:30** Coffee Break

**11:00** How the Changing Patent Landscape Will Impact the Future of Prenatal Molecular Diagnostics
Tara Rachinsky, Ph.D., Counsel, Intellectual Property, Fox Rothschild LLP

In recent years, the legal landscape regarding intellectual property protection for molecular diagnostics has altered dramatically. The controversy over patent protection for DNA sequences continues. The recent decision by the Supreme Court in Mayo v. Prometheus has called into question the patentability of many diagnostic methods. In the wake of these changes, legal battles are being waged over the ownership of certain prenatal diagnostic technologies. The outcome of these legal controversies will undoubtedly impact the future of prenatal molecular diagnostics.

**11:30** How Has the Integration of Non-Invasive Prenatal Testing Changed Current Standard of Care, and What’s Next?
Diana W. Bianchi, M.D., Executive Director, Mother Infant Research Institute; Professor of Pediatrics, Obstetrics and Gynecology, Tufts University School of Medicine

An overview of the technical and practical issues that affect integration of noninvasive prenatal testing using maternal plasma sequencing of cell-free DNA will be presented. New aspects of maternal and fetal biology that are being discovered through implementation of the test will be reviewed. Speculation as to what will be the future applications of noninvasive prenatal testing in the immediate future will also be discussed.

**12:00 pm** Luncheon Presentation *(Sponsorship Opportunity Available)* or Lunch on Your Own

**ARRAY-BASED CYTOGENETIC TESTING**

**1:25** Chairperson’s Remarks
David Ledbetter, Ph.D., FACMG, Executive Vice President and CSO, Geisinger Health System

**1:30** Array CGH vs. Classical Cytogenetics in Prenatal Diagnostics
Ashita Patel, Ph.D., Department of Molecular and Human Genetics, Baylor College of Medicine

The data presented will compare the array CGH results to classical cytogenetics in about 3500-4000 prenatal cases. The data show that array CGH should be the first line test with classical cytogenetics as an adjunct test to pick up balanced rearrangements. With increasing medical
cost and decreasing reimbursements, it is important to provide appropriate and efficient testing. These data would also highlight some of difficult counseling issues with array CGH in prenatal testing, i.e. the interpretation of variants of unknown clinical significance.

2:00 High Density SNP Arrays for Prenatal Cytogenetic Analysis
Sponsored by Affymetrix
Stuart Schwartz, Ph.D., FACMG, Strategic Director, Cytogenetics, Laboratory Corporation of America
Cytogenetic diagnostic tools have evolved quickly over the past five years, particularly in the pediatric setting. Hear how a leading expert in Cytogenetics has embraced high density SNP arrays to provide comprehensive, clinically relevant information for prenatal diagnosis. Drawing from a vast case load, Dr. Schwartz will present multiple cases highlighting the relevant data uncovered by these SNP arrays. For optimal utilization of this important new technology, collaboration between laboratory, physicians and counselors is essential.

2:30 Clinical Validation of Prenatal Microarrays in Prospective High-Risk Pregnancies
M. Anwar Iqbal, Ph.D., Director, Cytogenetics and Microarray CGH Lab, Department of Pathology and Laboratory Medicine, University of Rochester and Medical Center
Only a small proportion (~3.3%) of pregnancies with fetal anomalies detected by ultrasound show an abnormal karyotype due to the low resolution of techniques used in classical cytogenetics. Determining clinically significant microdeletions and microduplications across the whole genome in abnormal fetuses may provide genetic etiology. The objective of this study was to determine the efficiency of microarray comparative genomic hybridization (aCGH) in detecting clinically significant imbalances in high risk pregnancies with a normal karyotype.

3:00 Refreshment Break with Exhibit and Poster Viewing

3:45 Prenatal Counseling Issues Regarding CNVs: Clinical Variability and “Incomplete Penetrance”
David Ledbetter, Ph.D., FACMG, Executive Vice President and CSO, Geisinger Health System
Significant clinical variability is associated with all chromosomal disorders, including recently described CNV disorders. To provide accurate prenatal counseling regarding CNVs, more data is needed on a) the full phenotypic spectrum of CNVs from cohorts with biologically defined cases and b) the influence of other genetic and environmental factors on clinical variability, such as maternal age, behavioral and psychiatric. With improved data from such studies, genetic counseling in the context of CNVs will become more accurate and allow couples to make informed reproductive decisions.

4:15 PANEL DISCUSSION: Sequencing-Based Diagnostics of Cell-Free DNA in Maternal Blood
Moderator: Subhashini Chandrasekharan, Ph.D., Research Assistant Professor, Duke Institute for Genome Sciences & Policy; Panelists: Sucheta Bhatt, M.D., Director, Genetics, Verinata Health, Inc, Mathias Ehrich, M.D., Vice President, Research & Development, Sequenom, Inc, Ken Song, CEO, Ariosa Diagnostics, Inc, Zach Demko, Ph.D., Senior Director, Research & Development, Natera, Inc, Daixing Zhou, Ph.D., CEO, Berry Genomics Co., Ltd.

5:45 Welcome Reception with Exhibit and Poster Viewing
TUESDAY, SEPTEMBER 24

ADVANCES IN ISOLATION AND ANALYSIS OF FETAL CELLS

8:00 am Morning Coffee

8:30 Chairperson’s Remarks
Joe Leigh Simpson, M.D., Senior Vice President, Research and Global Programs, March of Dimes Foundation

8:35 Thinking about Selecting between Cell-Free and Fetal Cell Analysis, Now and in the Future
Joe Leigh Simpson, M.D., Senior Vice President, Research and Global Programs, March of Dimes Foundation
Recovering fetal cells from maternal blood has been a vision for decades, long prior to the more recent advances using cell-free fetal DNA. In the early 1990’s our group and then others achieved prenatal detection of fetal trisomy using nucleated fetal red blood cells. Although a collaborative NICHD-funded trial generated 74% sensitivity for trisomy 21 (Bianchi, Simpson, Jackson et al 2002), informative results were not consistently achieved. Cell sorting technologies used in these studies were updated, but consistency was still lacking until recently. Now, trophoblasts and other embryonic cells can be recovered that are not admixed with maternal cells. Purity of sample has great potential for not only embryonic cytogenomic evaluation but also interrogating for a wide range of embryonic disorders. Analysis of the embryonic transcriptome should always be more facile.

9:05 Options for Analysis of Single Fetal Cells
Arthur Beaudet, M.D., Chair, Department of Molecular & Human Genetics, Baylor College of Medicine
Our objective is to develop a noninvasive prenatal diagnosis that is as complete as can be accomplished at present with invasive testing and ultimately to detect especially de novo seriously deleterious point mutations and CNVs. Cell-based analysis has far better potential to achieve these goals compared to analysis of cell free fetal DNA. Two goals must be achieved to accomplish these objectives; first, fetal cells must be reliably recovered noninvasively, and second, genetic analysis must be performed on single cells. The two most attractive cell types are fetal nucleated red blood cells and trophoblasts. The most attractive methods for analysis of single cells start with whole genome amplification followed by array comparative genomic hybridization (CGH) and/or next generation sequencing. We have compared multiple methods for whole genome amplification of single cells including the MALBAC method followed by array CGH.

9:35 Life at the Single Molecule Level: Single Cell Genomics
Xiaoliang (Sunney) Xie, Ph.D., Department of Chemistry and Chemical Biology, Harvard University
As the primary cause for failure in human pregnancy and genetic disorders, aneuploidy increases drastically with women’s age, and leads to low success rates of in vitro fertilization (IVF). To select ovum or embryo without aneuploidy in IVF, preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) have been implemented with PCR, FISH, SNP and CGH arrays, but are limited in accuracy and resolution, thus often giving high false positives and negatives. Here we demonstrate highly accurate genome-wide PGS using multiple annealing and looping based amplification cycle (MALBAC) for single cell whole genome amplification and sequencing of oocytes and 8-cell embryos. By sequencing the two polar bodies of each oocyte, we deduced the ploidy of the female pronucleus, phased the maternal genome, and inferred the oocyte haplotype. In so doing, we show the proof of principle for selecting an embryo free of aneuploidy, particularly for women with recurrent implantation failure and miscarriages, as well as of maternal genetic diseases associated with point mutations.

10:05 Coffee Break with Exhibit and Poster Viewing

10:45 CGH Microarray Analysis of Fetal Cells Isolated from Maternal Blood
Bharavri Parikh, PhD, CEO and Co-Founder, CellScape Corp
CellScape has developed a process suitable for collection and whole genome molecular analysis of fetal cells from maternal blood. The process includes a gentle approach to blood processing and enrichment, algorithms and optical methods to differentiate fetal cells from maternal ones, and the use of chromosomal microarrays to assess copy number variants which can cause cytogenetic syndromes relevant for prenatal testing.

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5:45 Welcome Reception with Exhibit and Poster Viewing
TUESDAY, SEPTEMBER 24

ADVANCES IN ISOLATION AND ANALYSIS OF FETAL CELLS

8:00 am Morning Coffee
1:15 Non-Invasive Prenatal Diagnosis through Genetic Analysis of Trophoblastic Cells, Isolated by ISET
Prof. Patrizia Paterlini-Brechot, Ph.D., Chief Scientific Officer, RareCells, and Department of Cell Biology & Oncology, University Paris Descartes

Trophoblasts are cells of epithelial origin thus consistently larger than leukocytes. We show that a highly efficient system of cell sorting by size (ISET; Isolation by Size of Epithelial Cells) is able to extract trophoblastic cells from blood and from cervical samples allowing their genotyping and genetic analysis. Trophoblastic cells are expected to provide the optimal DNA substrate for non-invasive prenatal diagnosis. In fact, they carry fetal DNA not mixed with maternal DNA, they are available at a very early term of pregnancy (from the 5th week of gestation, thus earlier than the current term for chorionic villus sampling), and their collection and analysis is easy, rapid and cheap. Results of a clinical validation study and potential implications of using trophoblasts and ISET for non-invasive prenatal diagnosis will be discussed.

11:45 A Workflow for the Isolation and Molecular Characterization of Individual Circulating Fetal Cells in Non-Invasive Prenatal Diagnosis
Francesca Fontana, Ph.D., R&D Biology Project Leader, Silicon Biosystems S.p.A.

Fetal cells circulating in maternal blood hold the promise to enable non-invasive prenatal diagnosis (NIPD); however, a trustful workflow comprising their identification, isolation and genetic analysis is still needed. A workflow for fetal cells isolation based on DEPArray™, a fluorescent image-based sorting platform will be presented. Results showing the achievement of the goal of isolating multiple, 100% pure cells with single cell resolution from enriched suspensions will be described. In addition, with Ampli1™Whole Genome Amplification for single-cells, we show that it is possible to confirm fetal origin by DNA fingerprinting, carry out array Comparative Genomic Hybridization as well as analysis of point mutations. The above capabilities can be the cornerstone for enabling 1) the set-up and validation of a dependable enrichment and staining method and 2) further bring this workflow into a routine clinical practice.

12:15 pm Development of an Automated Agilent Microarray System to Detect Aneuploidy in Single Cells
Lian Liu, M.D., CEO, PacGenomics

The aim of this study was to develop a reliable, cost effective and automated Agilent microarray hybridization and bioinformatics pipeline for aneuploidy detection. The ploidy detection results derived from the PacGenomics-developed Agilent pipeline has a 100% concordance with BlueGnome, NimbleGen platforms and Corell cell line reports, respectively. The turn-around time is 13 hours, 4 hours shorter than NimbleGen. The PacGenomics-developed Agilent hybridization and automated pipeline is a reliable and less time-consuming tool for aneuploidy detection.

BIOMARKERS FOR EARLIER ASSESSMENT OF PREGNANCY COMPLICATIONS: PREECLAMPSIA

1:15 Chairperson’s Remarks
Matthew Cooper, Ph.D., CEO, Carmenta Biosciences

1:20 Highly Sensitive and Specific Serum Test for Risk of Preeclampsia
Matthew Cooper, Ph.D., CEO, Carmenta Biosciences

Carmenta Bioscience is currently developing a diagnostic test for preeclampsia, a condition impacting 5% of pregnancies and a leading cause of death in mothers and newborns in the US. Clinical symptoms of preeclampsia (hypertension and proteinuria) do not present in mothers until later in pregnancy, often unexpectedly and too late for preventative measures, resulting in complications such as preterm birth and death. Carmenta’s serum-based, multiplexed protein test can accurately detect preeclampsia enabling doctors to prescribe lifestyle, dietary, and pharmacological interventions demonstrated to improve clinical outcomes and yield economic benefit.
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Points North via I-93: Heading southbound on Interstate 93 Boston, take Exit 23, Purchase Street and move into the left lane. At the top of the ramp, take a left turn onto the Evelyn Moakley Bridge/Seaport Boulevard. Follow Seaport Boulevard for approximately .8 miles, the Seaport Boulevard entrance to the Seaport Garage will be on the right, after the Seaport Boulevard/B Street intersection.

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