CAMBRIDGE HEALTHTECH INSTITUTE'S SECOND ANNUAL

ADVANCES IN PRENATAL MOLECULAR DIAGNOSTICS

TRENDS & IMPLICATIONS IN A RAPIDLY CHANGING LANDSCAPE

NOVEMBER 5-7, 2014, SHERATON BOSTON HOTEL, BOSTON, MA

Conference includes:

• Options and Considerations for Screening and Diagnostics
• SNP and CGH Arrays & Different Sequencing Approaches
• Genetic Counseling, Education and Bioethics
• Clinical Implementation: Guidelines, Reimbursement and Other Factors
• Interpretation and Reporting of Results
• The Potential for Fetal Cell Isolation & Analysis

Panel Discussions:

• Genetic Counselors on Pre- and Post-Testing Issues, Education and Challenges
• Sequence-based NIPT with Leading U.S. Service Providers
• The Future Landscape of Prenatal Molecular Diagnostics
• Facilitated Roundtable Breakout Discussions

Pre-Conference Events:

• Carrier Screening and Pre-Implantation Diagnostics Short Course
• Commercialization Boot Camp: Manual for Success in Diagnostics Workshop

Program Advisors:

Arthur Beaudet, M.D., Chair, Department of Molecular & Human Genetics, Baylor College of Medicine

David Ledbetter, Ph.D., FACMG, Executive Vice President and CSO, Geisinger Health System

Cynthia Morton, Ph.D., William Lambert Richardson Professor of Obstetrics, Gynecology & Reproductive Biology and Professor of Pathology, Harvard Medical School; Director, Cytogenetics, Brigham & Women's Hospital

Joe Leigh Simpson, M.D., Senior Vice President for Research and Global Programs, March of Dimes Foundation

Ronald J. Wapner, M.D., Director, Reproductive Genetics and Vice Chair, Research, Department of Obstetrics and Gynecology, Columbia University Medical Center

Application for 10 hours of CEUs in process
ABOUT THE CONFERENCE:
The field of prenatal diagnostics is undergoing rapid and significant change, as a variety of molecular diagnostics are transforming the type and quality of data that can be provided to pregnant women and their physicians. Array-based cytogenetic analysis can provide more detailed and accurate assessment of many genetic conditions compared with traditional karyotyping, both of which rely on samples obtained using invasive procedures. Since obtaining samples invasively, even in the most proficient hands, does involve some risk to the fetus, there has been tremendous interest in non-invasive testing approaches. Next-gen sequencing of cell-free DNA found in maternal blood has been demonstrated to provide highly accurate assessment of fetal aneuploidies, with quite low false positives and false negatives, in most cases. Best practice guidelines have been modified quite quickly to recommend that such testing be offered to women who are at increased risk of aneuploidies, either because of past history, advanced maternal age or other reasons, and adoption and agreement by insurers to cover such testing has occurred at unprecedented speed. Such tests are not without controversy, however, because they only test for the most common chromosome duplications, and are unable thus far to provide analysis of smaller genetic insertions, deletions and rearrangements. One alternative approach has been research on obtaining circulating fetal cells from maternal blood, which would offer the advantages of being non-invasive, and isolated from confounding maternal DNA, but the challenges of reliably obtaining such rare cells has delayed the prospects for commercialization. This conference will provide an in-depth examination of key issues, technical and practical developments in these areas, and opportunities for discussing some of the issues that will have an impact on how this field continues to quickly evolve in the near future.

ARRIVE EARLY AND MAKE THE MOST OF YOUR TIME IN BOSTON!

PRE-CONFERENCE WORKSHOP*
TUESDAY, NOVEMBER 4
12-5PM
Commercialization Boot Camp: Manual for Success in Diagnostics
Instructors:
• Harry Glorikian, Healthcare Consultant
• Elaine Cheung, Business & Corporate Development, Illumina
• Sandra Statz, Vice President, Clinical, Quality & Regulatory, Exact Sciences Corporation
• Kevin Krenitsky, M.D., Chief Commercial Officer and SVP International Strategy, Foundation Medicine, Inc.

PRE-CONFERENCE SHORT COURSE*
WEDNESDAY, NOVEMBER 5
8:30AM-12:15PM
Carrier Screening and Pre-Implantation Diagnostics
• Next-Generation DNA Sequencing-Based Tests for Reproductive Medicine
  Mark Umbarger, Ph.D., Director, Research and Development, Good Start Genetics
• Expanded Carrier Screening - Clinical Experience & Practical Implementation
  Gabriel A. Lazarin, MS, CGC, Director, Genetic Counselors, Counsyl
• More Balanced Whole-Genome Amplification for Single Cell Applications
  Sunney Xie, Ph.D., Department of Chemistry, Harvard University
• Universal Approach to PGD for Single Gene and Chromosomal Disorders with and without HLA Typing
  Svetlana Rechitsky, Ph.D., Laboratory Director, Reproductive Genetics Institute
• Experience and Results with ultraPGD based on Biopsy of Day Five Embryos
  Mark Hughes, Ph.D., Laboratory Founder, Genesis Genetics

* Separate registration required
Invasive Prenatal Screening (NIPS) and Expanded Carrier Screening (ECS) will be discussed. Challenges in reimbursement, an important factor in the adoption of prenatal molecular pathology tests, will also be discussed. The process by which coverage policy is determined will be presented. “Standard of Care” will be considered vis-a-vis Implementation of technology in Prenatal Care. Barriers that surround utilization of these technologies and solutions for improving acceptance into clinical practice will be discussed.

3:10 Barriers and Promises: Solidifying the Role of Next-Gen Technology in Prenatal Care
Anthony Gregg, M.D., Department of Obstetrics & Gynecology, University of Florida

Current professional practice guidelines and policy statements surrounding Non-Invasive Prenatal Screening (NIPS) and Expanded Carrier Screening (ECS) will be presented. “Standard of Care” will be considered vis-a-vis Implementation of newer technology into clinical practice. Barriers that surround utilization of these technologies and solutions for improving acceptance into clinical practice will be discussed.

2:10 Barriers and Promises: Solidifying the Role of Next-Gen Technology in Prenatal Care
Joe Leigh Simpson, M.D., Senior Vice President, Research & Global Programs, March of Dimes

Technological advances in prenatal genetic diagnosis continue to evolve, increasing diagnostic accuracy and broadening indications. However, unanimity does not exist, as witnessed by reticence to interrogate “low risk” pregnancies by NIPT. Is the bar raised higher than traditionally set for example for serum analyte and ultrasound screening? Conversely, is NIPT appropriate as the de facto sole test given information on many other clinically significant conditions not being sought? This introductory talk will enumerate the major recent advances in prenatal genetic diagnosis, and explore their implementation.

3:40 Refreshment Break with Exhibit and Poster Viewing

1:30 pm Chair’s Opening Remarks
Joe Leigh Simpson, M.D., Senior Vice President, Research & Global Programs, March of Dimes

3:10 Ethical Issues Related to Prenatal Screening and Diagnostics
Vardit Ravitsky, Ph.D., Bioethics Program, School of Public Health; Director of the Ethics & Health Branch, Centre de Recherche en Ethique, University of Montreal

Prenatal testing provides pregnant women with valuable information that expands their options, thus promoting reproductive autonomy. For decades, however, these technologies have been raising complex ethical and social challenges. The current introduction of NIPT is likely to intensify them. Will the ease of testing and the absence of risk of miscarriage erode the recognition that informed consent is important prior to testing and increase the pressure on women to test? If or when NIPT is validated for use in low-risk pregnancies, how will the healthcare system cope with the need to offer counseling to many more women? How can women and clinicians stay informed regarding a technology that is constantly evolving? And finally, will the integration and routinization of NIPT reduce dramatically the number of individuals with Down syndrome and increase the discrimination and stigmatization of such individuals and their families?

5:00 Genetic Counselor’s Panel Discussion on Pre- and Post-Testing Issues, Education and Challenges

Pregnant women now face a growing range of screening and diagnostic options. Genetic Counselors are on the front line providing education and explanations to women, so that they are well-informed for choosing between these options, what results could show, what they can’t, and also providing explanations and guidance once results are obtained.

- Mary-Frances Garber, Executive Director, New England Regional Genetics Group
- Andrew Faucett, Director, Policy & Education, Office of the CSO, Geisinger Health System
- Jacquelyn Halliday, Senior Genetic Counselor, Women’s & Infants Hospital of Rhode Island
- Elizabeth Balkite, Independent Genetic Counselor

Genetic Counselor CEUs: This event has been submitted to the National Society of Genetic Counselors (NSGC) for approval of Category 1 CEUs. The American Board of Genetic Counseling (ABGC) accepts CEUs approved by NSGC for purposes of recertification. Approval for the requested CEUs and Contact Hours is currently pending.

6:15 Close of Day One
THURSDAY, NOVEMBER 6

INVASIVELY-OBTAINED SAMPLES: MICROARRAYS AND SEQUENCING

9:00 am Chair’s Remarks

9:05 The Obstetrician’s Dilemma: So Many Choices, So Little Time
Ronald Wapner, M.D., Director, Reproductive Genetics; Vice Chair, Research, Department of Obstetrics & Gynecology, Columbia University Medical Center
Over the past five years, the number of genetic tests available to obstetricians and their patients has exploded, yet the time available to counsel their patients remains severely limited. How we integrate these tests into obstetrical care and the appropriate counseling is an issue that needs immediate attention. This talk will explore the various options and define the issues that must be addressed to allow appropriate implementations.

9:35 Microarray Analysis of Over 15,000 Prenatal Samples: Detection of both Copy Number and Copy Neutral Changes
Stuart Schwartz, Ph.D., Strategic Director, Cytogenetics, Laboratory Corporation of America
The findings of over 15,000 prenatal tests utilizing SNP microarray analysis will be reviewed. This data illustrates the utilization not only for ultrasound abnormalities, but also for patients referred for AMA and patients identified with chromosomal anomalies that need better clarification. These studies have not only illustrated the importance of the detection of the gain or loss of chromosomal material, but also the importance of copy-neutral loss of heterozygosity (uniparental disomy or identity by descent). It has also demonstrated the usefulness of examining the SNP alleles for detection of maternal cell contamination, twin-twin contamination, as well as mosaicism and whole genome homozygosity.

10:05 Understanding Clinical Variability Associated with Copy Number Variants
Christa Martin, Ph.D., FACMG, Director and Senior Investigator, Autism & Developmental Medicine Institute, Geisinger Health System
The interpretation of copy number variants (CNVs) detected in the prenatal setting will be discussed. Participants will learn how the use of evidence-based processes, along with CNV data from publically available databases, can be used to classify CNVs as pathogenic. Other key points will include a discussion of incomplete penetrance and variable expressivity in the context of determining the phenotypic effects of a CNV.

10:35 Coffee Break with Exhibit and Poster Viewing

11:15 Next-Gen Sequencing of Fetal de novo Balanced Chromosome Rearrangements Informs Prenatal Diagnosis
Cynthia Morton, Ph.D., William Lambert Richardson Professor of Obstetrics, Gynecology & Reproductive Biology and Professor of Pathology, Harvard Medical School; Director, Cytogenetics, Brigham & Women’s Hospital
Approximately 20% of de novo balanced chromosome rearrangements detected in the prenatal setting are recognized to have an untoward fetal outcome. Conceptuses with de novo rearrangements found to be unbalanced by aCGH analysis are reasoned to be at risk for an abnormal phenotype due to dysregulation or disruption of a gene(s) at the breakpoints, necessitating nucleotide resolution analysis for optimal genetic counseling. Experience in diagnosing and interpreting de novo balanced rearrangements by next-gen sequencing in a series of prenatal cases will be presented.

11:45 Invasive and Non-Invasive Prenatal Diagnostics Using Whole-Genome Sequencing and Convergent Genomic Profiling
Michael Talkowski, Ph.D., Center for Human Genetic Research, Massachusetts General Hospital and Harvard Medical School
Technology has had a dramatic impact in prenatal genetic diagnostics, particularly for congenital anomalies where de novo structural variations (SV) represent a major source of risk but are not considered by cell-free fetal DNA (cfDNA) studies that primarily detect aneuploidy. Results of prenatal clinical diagnosis from whole-genome sequencing (WGS) using large-insert ‘jumping libraries’ at a cost and timeline comparable to karyotyping or microarray will be presented. A series of real-time clinical sequencing and integrative genomic interpretation of fetal DNA sequencing of de novo balanced SVs following amniocentesis, as well as detection of a balanced inversion from cfDNA sequencing will be shared. These studies emphasize the unique challenges facing development of a comprehensive prenatal genetic screening strategy that accesses the entire pathogenic mutational spectrum but minimizes risks to the fetus.

12:15 pm Noninvasive Prenatal Testing: Past, Present and Future
Martin Chavez, M.D., Chief, Maternal Fetal Medicine, Winthrop University Hospital
This presentation will cover the goals and current indication for the use of NIPT. It will also review the current society guidelines and the issues related to clinical implementation of NIPT, with emphasis on pretest and post test considerations. The presentation will also cover the future expansions.

12:45 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own
NON-INVASIVE SEQUENCED-BASED PRENATAL TESTING (NIPT)

2:00 Chair’s Remarks

2:05 The Influence of Genomic SNP Array Testing and NIPT on the Diagnostic Yield in Pregnancies without Fetal Ultrasound Anomalies
Malgorzata Srebniak, Ph.D., Department of Clinical Genetics, Erasmus Medical Center
After initially applying SNP array only in fetuses with ultrasound abnormalities, since July 2012, we routinely perform the HumanCytoSNP-12 (Illumina) array with a 0.5Mb resolution in cases without fetal ultrasound anomalies. More than 1400 cases without fetal ultrasound anomalies have been analyzed and we will show the frequency of abnormal array results. The introduction of NIPT in Europe led to a decrease in the number of prenatal invasive procedures. Since 2014 for patients with advanced maternal age or abnormal first trimester screening we have offered a choice between invasive testing with high resolution and NIPT for trisomy 13, 18 and 21. Based on our own data we will show the influence of genomic SNP array testing and NIPT on the diagnostic yield in pregnancies without fetal ultrasound anomalies.
2:35 Fetal CNV Detection Directly from Circulating Cell-Free DNA in Maternal Blood Using a Modified Array CGH Approach
John Anson, Ph.D., Executive Vice President R&D, Oxford Gene Technology
Array comparative genome hybridisation (aCGH) is widely employed to detect CNVs in both post- and pre-natal scenarios, the latter following an invasive sampling procedure such as amniocentesis. We have developed a procedure to enable this routine methodology to be deployed in a non-invasive prenatal testing scenario. This has been achieved by a combination of a novel sample preparation procedure, coupled with dedicated array design and analysis approaches. This novel aCGH approach will be exemplified using data obtained from maternal blood samples from high risk pregnancies obtained in standard clinical settings.

3:05 Microarray-Based Invasive Prenatal Diagnosis in the Era of NIPT
Trilochan Sahoo, M.D., FACMG, Director, Cytogenetics, CombiMatrix
The immense value of microarray-based cytogenetic testing for prenatal diagnosis has been established. The high uptake of NIPT using cfDNA predicts a diminishing role for invasive prenatal testing. A comprehensive analysis of clinically significant outcomes from both avenues will be presented to support the important role of microarray testing in prenatal diagnosis.

3:20 Encouraging Broad Uptake of Prenatal Screening Tests through a Regulated in vitro Diagnostic Product Strategy
Stephen Little, Ph.D., CEO, Premaitha Health
Premaitha is a molecular diagnostics company with a non-invasive prenatal test (NIPT) available for clinical laboratories to run the test in-house. Dr Little will discuss some of the hurdles and solutions involved in translating next generation sequencing technology into an in vitro diagnostic product suitable for use in the clinical environment.

3:35 Refreshment Break with Exhibit and Poster Viewing

4:15 What do Patients Want? Understanding the Challenges of the Clinical Implementation of NIPT
Ruth Farrell, M.D., Department of Obstetrics & Gynecology, Cleveland Clinic
NIPT has rapidly been integrated into prenatal care both in the United States and abroad. This raises key questions about how to ensure that pregnant patients have the information and resources they need to make informed choices about NIPT, including if to use the test and how to interpret its findings. This presentation will discuss the self-reported educational needs and preferences of pregnant women at the forefront of this new test.

4:45 Facilitated Breakout Discussion Groups
To enhance networking opportunities and take advantage of the expertise and experience of attendees, this session will provide each attendee with the chance to select one of the following topics for facilitated discussion with other attendees particularly interested in the same topic. Topics for discussion include:
- Pre-Testing & Post-Results Genetic Counseling
  Subhashini Chandrasekharan, Ph.D., Institute of Genome Sciences & Policy, Duke
- The Potential for Substituting New Tests for Karyotyping
  Cynthia Morton, Ph.D., William Lambert Richardson Professor of Obstetrics, Gynecology & Reproductive Biology and Professor of Pathology, Harvard Medical School; Director, Cytogenetics, Brigham & Women’s Hospital
- Exome Sequencing of Invasively-Obtained Samples
  Ignatia Van den Veyver, M.D., Professor Maternal-Fetal Medicine and Genetics, Baylor College of Medicine
- Comparing NIPT via Sequencing and Targeted Microarrays
  Adam Wolfberg, M.D., MPH, Associate Director, Medical Affairs, Ariosa Diagnostics
- Detecting Deletions with NIPT
  Arthur L. Beaudet, M.D., Chair, Department of Molecular & Human Genetics, Baylor College of Medicine
- The Potential for Commercialization of Fetal Cell Isolation for NIPT
  Regen Drouin, M.D., Ph.D., Division of Genetics, Department of Pediatrics, Faculty of Medicine and Health Sciences, University of Sherbrooke, Canada
- Strategies for Analysis and Reporting of Genetic Results
  Moderator TBA
- Expanding NIPT Screening for Lower Risk Patients
  Moderator TBA

5:45 Networking Reception with Exhibit and Poster Viewing
6:45 Close of Day Two
NIPT is being rapidly adopted worldwide. Going forward tests may include a broader range of genetic conditions and may also be used in “average” risk pregnancies and new noninvasive prenatal tests are being commercialized. Effective and ethical use of these tests will require integrating perspectives of different stakeholders involved. Findings from ongoing research to assess stakeholder experiences and views about factors that affect clinical implementation of NIPT will be presented. Issues related to intellectual property, reimbursement, and regulatory oversight of NIPT will be discussed, with a special focus on challenges for implementing NIPT in developing world settings.

9:05 The Challenge of Introducing Non-Invasive Prenatal Testing (NIPT) in a National Healthcare System
Brigitte Faas, Ph.D., Department of Human Genetics, Radboud University Medical Centre, Nijmegen, Netherlands
Offering NIPT to pregnant women with an increased risk for fetal aneuploidies is supported by statements of different societies and NIPT is offered almost worldwide now. However, just as with array analysis, the incorporation in routine prenatal care may differ from country to country, as may the reimbursement by the health care systems, which may be private or not. In this presentation, the steps towards implementation of NIPT in a national health care system will be highlighted.

9:35 Experiences with Logistics and Technology Introduction in the Canadian Non-Invasive Prenatal Testing Domain
Philip R. Wyatt, M.D., Ph.D., Medical Director, GD Specialized Diagnostics
In Canada, introduction of new health care services generally requires government appointed committees’ review and approval before they can be covered by the universal coverage system of each province and territory. Services not covered can be paid for directly by patients. Our lab began offering NIPT on a patient self-pay basis in May 2012, and has subsequently made it available across Canada. The province of Ontario recently agreed to fund NIPT on a preapproved basis. In the first 2 years, over 4000 samples have been received from women identified as being at “high risk” and thus eligible for invasive prenatal testing. In this presentation, the steps towards implementation of NIPT in a national health care system will be highlighted.

10:05 An International Perspective on Implementation of NIPT
Megan Allyse, Ph.D., The Institute for Health and Aging, The University of California, San Francisco
NIPT is now available in more than 60 countries worldwide and an increasing number of stakeholders have information about or experience with noninvasive testing. Based on a family of studies by the Prenatal Information Research Consortium (PIRC), a variety of stakeholder views and perspectives on the utility, value and barriers to the use of NIPT will be presented. Data available from several studies in the United States and the UK, as well as Hong Kong, China and Argentina will be discussed.

10:35 Coffee Break with Exhibit and Poster Viewing

FETAL CELL ISOLATION AND ANALYSIS

1:45 Chair’s Remarks

1:50 NIPT with Fetal Cells: Will We Ever Get There?
Arthur L. Beaudet, M.D., Chair, Department of Molecular & Human Genetics, Baylor College of Medicine
Fetal cells were first described in the blood of pregnant women in 1979. Since that time, there have been many academic and commercial attempts to detect cytogenetic abnormalities in the fetus by recovering and analyzing these cells. Although single cells can now be analyzed by array CGH and by next-generation sequencing, no group has launched a routine clinical test using a cell-based method to detect cytogenetic abnormalities including various deletion syndromes. Two of the more promising cell types are trophoblastic cells and fetal nucleated red blood cells. We have worked with many collaborators in attempts to recover and analyze either of these two cell types. Results obtained over the last year will be presented.
2:20 NIPT Using Fetal Cells: Some Key Steps to Get There
Regen Drouin, M.D., Ph.D., Division of Genetics, Department of Pediatrics, Faculty of Medicine and Health Sciences, University of Sherbrooke, Canada
There are two major reasons to use fetal cells in maternal blood (FCMB) instead of cell-free fetal DNA: 1) obtaining pure fetal DNA material to allow specific characterization of the fetal genome, and 2) obtaining the whole fetal genome of the fetus and not just fragments of it. Specifically labeled FCMB can be localized on slides using an automated scanning system to recover 5 to 7 cells. Next, DNA is extracted, amplified and analyzed using QF-PCR or any other analysis methods.

2:50 Advances in the Isolation and Analysis of Trophoblastic Cells for Non-Invasive Prenatal Diagnostics
Patrizia Paterlini-Brechot, M.D., Ph.D., Professor of Cellular & Molecular Biology, University of Paris Descartes (France)
Trophoblastic cells can be isolated non-invasively from blood and from the cervix at very early terms of pregnancy. Their fetal DNA is not mixed with maternal DNA and can be efficiently used for prenatal, early and non-invasive paternity test and for non-invasive prenatal diagnosis (NI-PND). Furthermore, high throughput sequencing of the DNA from fetal cells can pave the way to “gene panels” for extensive NI-PND.

3:50 Refreshment Break

4:15 Closing Panel Discussion: The Future Landscape of Prenatal Molecular Diagnostics
- Arthur Beaudet, M.D., Chair, Department of Molecular & Human Genetics, Baylor College of Medicine
- Cynthia Morton, Ph.D., William Lambert Richardson Professor of Obstetrics, Gynecology & Reproductive Biology and Professor of Pathology, Harvard Medical School; Director, Cytogenetics, Brigham & Women’s Hospital
- Joe Leigh Simpson, M.D., Senior Vice President, Research & Global Programs, March of Dimes
- Ronald Wapner, M.D., Director, Reproductive Genetics, Vice Chair, Research, Department of Obstetrics & Gynecology, Columbia University Medical Center

5:15 Close of Conference
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Additional Registration Details
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