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ENTERING THE ERA OF GENOMIC MEDICINE: RESEARCH OPPORTUNITIES AND CHALLENGES

Dr. Eric Green

The Human Genome Project’s generation of a reference human genome sequence was a landmark scientific achievement of historic significance. It also signified a critical transition for the field of genomics, as the new foundation of genomic knowledge started to be used in powerful ways by researchers and clinicians to tackle increasingly complex problems in biomedicine. To exploit the opportunities provided by the human genome sequence and to ensure the productive growth of genomics as one of the most vital biomedical disciplines of the 21st century, the National Human Genome Research Institute (NHGRI) is pursuing a broad vision for genomics research beyond the Human Genome Project. This vision includes using genomic data, technologies, and insights to acquire a deeper understanding of genome function and biology as well as to uncover the genetic basis of human disease. Some of the most profound advances are being catalyzed by revolutionary new DNA sequencing technologies; these methods are producing prodigious amounts of DNA sequence data as part of studies aiming to elucidate the complexities of genome function and to unravel the genetic basis of rare and complex diseases. Together, these developments are ushering in the era of genomic medicine.


9p21 DNA VARIANTS ASSOCIATED WITH CORONARY ARTERY DISEASE RISK

Dr. Robert Roberts

Coronary Artery Disease (CAD), is preventable as shown in clinical trials whereby modifying conventional risk factors one can reduce morbidity and mortality by 30% to 40%. It has been recognized for several decades that about 50% of susceptibility for CAD is due to genetic factors. It has been postulated that coronary artery disease will be markedly attenuated, if not eliminated, in the 21st century. Thus, comprehensive prevention will have to include conventional and genetic risk. Personalized Medicine will ultimately seek to tailor prevention and treatment to that of the individual’s genetic variants. Those variants may be analyzed as DNA fragments and in other cases may be reflected by protein biomarkers circulating in the blood. A major barrier to personalized medicine, particularly for common polygenic disorders was the lack of genetic risk variants. In 2005 the technology arrived and by 2007 the first genetic risk variant for coronary artery disease, 9p21, was identified. 9p21, as a risk factor for CAD was rapidly confirmed around the world, followed by the formation of large genome-wide association studies which today have provided over 1200 genetic risk variants for over 160 diseases. For CAD there are now 36 confirmed genetic risk variants, of which over half occurs in more than 50% of the world’s population. The surprising and exciting finding for CAD is that 23 of these 36 variants act independently of known conventional risk factors for CAD (e.g., blood pressure, cholesterol). This scientific observation has significant implications:

- First, comprehensive prevention of CAD will require elucidation and prevention of these independent genetic risk factors.
- Secondly, this implies mechanisms contributing to the pathogenesis of coronary atherosclerosis which are yet to be identified.
- Thirdly, there are likely to be several targets for development of drug therapy following the elucidation of these unknown molecular pathways contributing to CAD.

9p21 will be discussed in detail as an example of a genetic risk factor that occurs in 75% of the world’s population (outside of Africa). We recently discovered that interferon alpha-21 is a biomarker that is elevated in the blood in individuals at risk for 9p21 with existing coronary artery disease. Interferon alpha-21 is likely to be one of several biomarkers that will be discovered and utilized in the future prevention and treatment of coronary artery disease.


THE ETHICS OF HUMAN TISSUES IN RESEARCH

Dr. Michael Christman, Dr. Robert Cook-Deegan, and Dr. Pilar Ossorio

Making meaning of genomic data will require analysis of tissues from many people followed over time. DNA sequencing technology is generating a flood of data in a time of unstable jurisprudence about patent rights over molecules and methods, changing norms of privacy, conflicting impulses about commercialization and financial conflict of interest, and evolving conceptions about ownership and control of data and tissues. How will we struggle through this mess of incoherent policies?


WHOLE GENOME SEQUENCING IN THE CLINICAL SETTING

Dr. Elaine Mardis

This lecture will provide an overview of new DNA sequencing technologies that are driving discovery in human disease, especially cancer. Dr. Mardis will provide fundamental concepts of these technologies and examples of their utility in the clinical diagnostic setting, much of which is originating from their use in basic science discovery. In particular, integrating data from whole genome sequencing with RNA sequencing is providing key insights for individual cancer patients in identifying therapeutic options. Several such examples will be discussed. Further, the use of these techniques for following cancer progression will be presented, as a paradigm for identifying patients who are progressing or developing therapy resistance at earlier stages than currently can be detected by clinical assays.


DIET AND CVD PREVENTION, WHERE SHOULD THE EMPHASIS BE?

Dr. Alice Lichtenstein

Dietary modification for CVD risk reduction has centered on dietary fat — type and quality. A substantial body of evidence indicates that type of fat is more important than quality of fat within current levels of total fat intake (25% of energy [E] to 35%E). Regarding type of fat, recent controversy has arisen over the value of limiting intake saturated fatty acids, historically a major target of dietary approaches to reduce CVD risk. The available data addressing this issue will be explored. Also, additional factors that should be taken into consideration when interpreting data from human intervention trials and extrapolating those data to risk reduction recommendations will be discussed. Examples of such factors include energy balance and dietary patterns.


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  Akershus University Hospital
- **Phillip Barter, MD**
  University of Sydney
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  Harvard Medical School
- **Kári Stefánsson, MD**
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  McGill University Health Center
- **David Morrow, MD**
  Harvard Medical School
- **K. Srinath Reddy, MD**
  Public Health Foundation of India

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Generous corporate funding for this program has been received from the Committee of Cardiovascular Pharmacology of the Chinese Pharmacological Society, Denka Seiken Co., Ltd., Health Diagnostic Laboratory, Inc., Randox Cardiology, Roche Diagnostics, and Siemens Healthcare.
The seventh edition of Pediatric Reference Intervals is a valuable reference providing instant and accurate reference intervals for over 250 chemistry and hematology analytes in an alphabetized, user-friendly format. Changes to this edition include:

- New analytes in the Chemistry section, including C-peptide, haptoglobin, and insulin;
- New analytes in the Hematology section, including hemoglobin A, hemoglobin A2, hemoglobin F, immature platelet fraction, and reticulocyte hemoglobin equivalent;
- Addition of reference intervals for steroids, free thyroxine, and free triiodothyronine measured by tandem mass spectrometry; and
- Addition of reference intervals employing new platforms such as the Abbott Architect® ci8200 and the Roche cobas® 6000 analyzer.

Pediatric Reference Intervals provides the following information:

- Age- and sex-related reference ranges;
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Tuesday, August 28, 2012 ~ 2:00-3:30 pm Eastern U.S. Time

For the first time in history, ACS and USPSTF have released consistent guidelines for cervical cancer screening. Previously, the USPSTF had indicated that the evidence was insufficient for it to recommend the combined use of cervical cytology and high-risk human papillomavirus (HPV) DNA testing (“co-testing”). Now, both groups include recommendations for co-testing in women age 30–65 years, stating that they should either be screened by cytology every 3 years or by co-testing every 5 years.

The groups’ willingness to lengthen the time between screenings when co-testing is performed speaks to the medical community’s confidence in today’s HPV testing technologies. A variety of molecular assays are now available for detecting HPV, and labs performing these assays in-house must determine which technology best fits their HPV testing needs.

During this program, experts will address:

- What the current guidelines for cervical cancer screening are and how they predict risk
- The major applications of HPV testing and the role it plays in these guidelines
- What it means to have a “clinically validated” HPV test
- The advantages and limitations of using today’s FDA-cleared HPV testing technologies
- Why traditional method validation protocols won’t work with new HPV testing technologies

Program Faculty:

Mark H. Stoler, MD, Professor of Pathology, Cytology and Gynecology; Associate Director of Surgical Pathology and Cytopathology; and Director, Gynecological Pathology Fellowship Program, University of Virginia, Charlottesville, VA

Frederick S. Nolte, PhD, Professor, Director of Clinical Laboratories, and Director of Molecular Pathology, Department of Pathology & Laboratory Medicine, Medical University of South Carolina, Charleston, SC

This program is approved by AACC for 1.5 Category 1 ACCENT credit hours, and supported by an educational grant from Roche Diagnostics.

Stay current with the latest developments in HPV testing. Register today!

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- Understanding the Sources of Error and Limitations in Point-of-Care Testing
- Point-of-Care Testing Beyond the Hospital
- Developing Effective Strategies to Achieve Quality POCT Results
- New Technologies in Point-of-Care Testing

Hear keynote speaker Maurice O’Kane, MD of Altnagelvin Hospital in Londonderry, UK discuss the current and emerging quality perspectives in point-of-care testing.

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Clinical labs now have a new option for quality control (QC) compliance programs based on risk management principles.

Risk management principles can improve laboratories’ QC programs by evaluating regulatory requirements, information provided by the manufacturer, information pertaining to the laboratory environment, and medical requirements for the test result. The result is a QC plan designed specifically for the particular combination of measuring system, laboratory environment, and clinical application.

In this program you will hear from CLSI guideline developers and world leaders in the field of QC. Through case studies they will share with you how they have implemented effective QC plans using risk management principles to improve the practice and safety of laboratory medicine.

After attending you will be able to:
- Describe the CLSI document EP23 and understand risk management’s role in QC
- Develop a QC plan for moderate complexity POCT and central lab-based tests
- Identify benchmarks for monitoring the effectiveness of a QC plan after implementation
- Use EP23 to refine an existing QC plan for a testing process not performing up to expectations

The Experts:
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James H Nichols, PhD, Professor of Pathology, Tufts University School of Medicine; Medical Director, Clinical Chemistry, Baystate Health, Springfield, MA; Chairholder, CLSI EP23 Document Development Committee

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Clinical Chemistry is pleased to announce a special upcoming theme issue on Cancer edited by Drs. Eleftherios P. Diamandis, Robert C. Bast and Carlos Lopez-Otin titled, “Conquering Cancer in Our Lifetime: New Diagnostic and Therapeutic Trends.” Clinical Chemistry, published by the American Association for Clinical Chemistry, is the most highly cited forum for peer-reviewed, original research in the fields of clinical chemistry and laboratory medicine.

The purpose of this issue is to highlight recent advances in diagnosis and therapy of cancer and will include diverse themes such as cancer genomics, proteomics, chemoprevention, early diagnosis, biomarker discovery and validation, drug resistance, cancer stem cells, cancer epigenetics, antiangiogenic therapies, mechanisms of cancer metastasis, and the tumor microenvironment.

Clinical Chemistry invites authors to submit original articles related to cancer to be considered for publication in this special issue. Manuscripts are most likely to be favorably received if they address novel technologies to diagnose, treat or prevent cancer or its complications.

Potential topics of interest include:

- Discovery and validation on novel biomarkers for early diagnosis, prognosis, and monitoring of cancer therapies
- Role of cancer genomics, proteomics, and epigenetics in personalized medicine
- Mechanisms of cancer metastasis and the tumor microenvironment
- Cancer chemoprevention
- Drug resistance and how it can be overcome
- The cancer stem cell hypothesis and its application to diagnostics and therapeutics
- Cancer subclassification by using genomics, proteomics, metabolomics, and other omics
- Novel approaches for therapeutics, diagnosis and monitoring, such as circulating cancer cells, and circulating free DNA and micro-RNAs

Be a part of this exciting issue. Submit now!

Submissions must be received through our online submission system at http://submit.clinchem.org. We welcome submissions after July 1, 2012, but cannot guarantee the inclusion of late submissions for the Special Issue. Your cover letter should express your interest in submitting your paper for consideration for the Cancer theme issue. Journal guidelines for submission apply as described in the Information for Authors on the submission website.
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- Aug 14 – Biomarkers for Chronic Kidney Disease: Urine Albumin and Multi-markers
- Sept 11 – Biomarkers for Acute Kidney Injury: Now and the Future

**THYROID DISEASE SERIES:**
- Oct 9 – Perspectives in Thyroid Testing: Pros and Cons of Immunoassay and Mass Spectrometry
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Lembcke et al., 2011: "Fast, robust and reliable method for the determination of 1,25(OH)$_2$ vitamin D."
[AB SCIEX Poster, ASMS conference, June 5-9]

Yuan et al., 2011: "An LC-MS/MS-based method [...] suitable for clinical testing. Both D$_3$ and D$_2$ were quantified with high selectivity and sensitivity."

He et al., 2011: "This off-line purification approach is very specific and robust. No interference or ion suppression was observed."
[ThermoScientific Poster, ASMS conference, June 5-9]

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