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THE IMPACT OF BIOMARKERS ON THE DIAGNOSIS OF ALZHEIMER’S DISEASE
Dr. John Trojanowski

In this study, we review progress by the Penn Biomarker Core in the Alzheimer’s Disease Neuroimaging Initiative (ADNI) toward developing a pathological cerebrospinal fluid (CSF) and plasma biomarker signature for mild Alzheimer’s disease (AD) as well as a biomarker profile that predicts conversion of mild cognitive impairment (MCI) and/or normal control subjects to AD. The Penn Biomarker Core also collaborated with other ADNI Cores to integrate data across ADNI to temporally order changes in clinical measures, imaging data, and chemical biomarkers that serve as mileposts and predictors of the conversion of normal control to MCI as well as MCI to AD, and the progression of AD. Initial CSF studies by the ADNI Biomarker Core revealed a pathological CSF biomarker signature of AD defined by the combination of Ab1-42 and total tau (T-tau) that effectively delineates mild AD in the large multisite prospective clinical investigation conducted in ADNI. This signature appears to predict conversion from MCI to AD. Data fusion efforts across ADNI Cores generated a model for the temporal ordering of AD biomarkers which suggests that Ab amyloid biomarkers become abnormal first, followed by changes in neurodegenerative biomarkers (CSF tau, F-18 fluorodeoxy-glucose-positron emission tomography, magnetic resonance imaging) with the onset of clinical symptoms. The timing of these changes varies in individual patients due to genetic and environmental factors that increase or decrease an individual’s resilience in response to progressive accumulations of AD pathologies. Further studies in ADNI will refine this model and render the biomarkers studied in ADNI more applicable to routine diagnosis and to clinical trials of disease modifying therapies.


THE CHANGING AND CHALLENGING HEALTHCARE LANDSCAPE
Dr. Gail Wilensky

With the passage of the Patient Protection and Affordable Care Act, all providers of services to people receiving coverage from Medicare and Medicaid can expect to be affected—both in the near term and over time. These changes include smaller updates in payment, greater demand for services, more scrutiny on quality and medical appropriateness, and greater attention to fraud. More dramatic changes may occur if some of the pilots included in the legislation are widely adopted—pilots that involve the bundling of payments across providers during a given episode of illness or that incentivize more cooperative behavior between physicians and hospitals. Whatever the specific changes that result, greater accountability and greater emphasis on value are likely to be a part of our collective future.


HUMAN INDUCED PLURIPOTENT STEM CELLS DERIVED FROM EPISOMAL VECTORS
Dr. James Thomson

Human Embryonic Stem (ES) cell lines are capable of unlimited undifferentiated proliferation and yet maintain the ability to contribute to advanced derivatives of all three embryonic germ layers. Human induced pluripotent (iPS) cells share these defining characteristics of human ES cells, but are derived from somatic cells, not from early embryos. Our initial screens identified four factors (Oct4, Sox2, Nanog, Lin28) as sufficient to reprogram human fibroblasts to iPS cells. A limitation of this initial work was the use of lentiviral vectors to introduce the reprogramming factors, as these vectors integrate into the genome leaving the transgene present, potentially disrupting endogenous genes. More recently we have described methods for deriving human iPS cells with episomal vectors that do not require integration of the reprogramming transgenes into the genome. This talk will discuss the derivation and properties of human iPS cells, the challenges facing the use of human pluripotent stem cells in transplantation therapies, and will describe the use of these cells in drug discovery, toxicity testing, and modeling human genetic diseases.

**WEDNESDAY, JULY 22 • 8:45 am – 10:45 am**

**INFLAMMATION, hsCRP, AND CARDIOVASCULAR PREVENTION: A PARADIGM SHIFT**  
Dr. Paul Ridker

In the recently completed Justification for Use of Statins in Prevention: An Intervention Trial Evaluating Rosuvastatin (JUPITER) trial, which was conducted with 17,802 primary-prevention patients with LDL cholesterol concentrations <3.37 mmol/L (<130 mg/dL) and high-sensitivity C-reactive protein (hsCRP) concentrations 2 mg/L, random allocation to treatment with 20 mg rosuvastatin was associated with a 54% reduction in the incidence of myocardial infarction, a 48% reduction in stroke, a 47% reduction in the need for angioplasty or bypass surgery, a 43% reduction in venous thrombosis, and a 20% reduction in all-cause mortality. These effects were consistent in all of the evaluated subgroups, including among women as well as men, among minority populations, at all levels of Framingham risk, and among those with and without metabolic syndrome. Within the JUPITER trial, as had previously been shown in high-risk patients with acute coronary ischemia and among those with stable coronary disease, the clinical benefits of statin therapy compared with placebo were greatest among patients who reduced not only their LDL cholesterol concentration but also their hsCRP value. On the basis of these data, an advisory panel to the US Food and Drug Administration recently voted in favor of expanding the labeling for statin therapy to include those with low LDL cholesterol and increased hsCRP. Furthermore, 2009 guidelines from the Canadian Cardiovascular Society—the first national guidelines to appear since publication of the JUPITER trial data—now explicitly endorse hsCRP screening among “intermediate risk” patients, including those with low LDL cholesterol concentrations (3). The concept that low-LDL, high-hsCRP patients are at a higher than anticipated vascular risk and thus good candidates for statin therapy has also recently been confirmed in the multiethnic Atherosclerosis Risk in Communities (ARIC) study, in which patients with low LDL cholesterol values but high hsCRP concentrations had a substantially higher vascular risk than those with low values for both LDL cholesterol and hsCRP, despite both groups having identical Framingham risk scores. These data are almost identical to those reported in the Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexasCAPS) trial, in which lovastatin was highly effective at reducing cardiovascular event rates among patients with LDL cholesterol concentrations <3.89 mmol/L (<150 mg/dL) and hsCRP concentrations >2 mg/L, but showed no clinical benefit among those with LDL cholesterol values ≥3.89 mmol/L (<150 mg/dL) and lower hsCRP concentrations, despite a substantial reduction in LDL cholesterol. While these studies establish the clinical utility of hsCRP in practice, ongoing and future work will directly test the inflammatory hypothesis of atherosclerosis.

**Come Prepared:** Ridker P. Statin Therapy for Low-LDL, High-hsCRP Patients: From JUPITER to CORONA. *Clinical Chemistry* 2010;56:505-507.

**THURSDAY, JULY 29 • 12:30 pm – 2:00 pm**

**SYSTEMS MEDICINE, TRANSFORMING TECHNOLOGIES AND THE EMERGENCE OF P4 MEDICINE: PREDICTIVE, PERSONALIZED, PREVENTIVE AND PARTICIPATORY**  
Dr. Leroy Hood

The challenge for biology in the 21st century is to view it as an informational science. This view leads to the conclusion that biological information is captured, mined, integrated and finally executed by biological networks. Hence the challenge in understanding biological complexity is that of deciphering the operation of dynamic biological networks across the three time scales of life—evolution, development and physiological responses. Systems approaches to biology are focused on delineating and deciphering dynamic biological networks. I will outline the contemporary state of systems biology and then focus on its application to disease. In particular I will discuss in detail a model system we have studied—prion disease in mice. This systems approach provides a powerful new approach to understanding disease mechanisms—and suggests new strategies for diagnosis and therapy. I will discuss in some detail our systems approach to blood diagnostics. Then I will focus on a series of emerging technologies that will transform the landscape of medicine—next generation DNA sequencing, new approaches to protein analysis, mathematical tools will transform medicine over the next 5-20 years from its currently reactive state to a mode that is predictive, personalized, preventive and participatory (P4 medicine). P4 medicine will alter the commercial landscape of healthcare (companies at every strata will have to rewrite their business plans) and it will lead to a dramatic reduction eventually in the cost of healthcare—to the point that we will be able to export P4 medicine to the developing world and, indeed, it will become the very foundation of global medicine. This should lead to a universal democratization of healthcare that was unthinkable even a few years ago.

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**Fact:** Because serology cannot distinguish between active and passive infection, it cannot be used as a test for eradication.²

**Fact:** The ¹³C urea breath test (UBT) is recommended by both the AGA and ACG.¹,³

**Fact:** The UBT is the most reliable non-endoscopic test to document eradication of *H. pylori* infection.¹

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4. Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress *H. pylori*. Ingestion of these within 2 weeks prior to performing the BreathTek UBT may give false negative results.
5. A false positive test may occur due to urease associated with other gastric spiral organisms observed in humans such as *Helicobacter heilmannii*.
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7. A false positive test could occur in patients who have achlorhydria.
8. If particulate matter is visible in the reconstituted Pranactin®-Citric solution after thorough mixing, the solution should not be used.

**Limitations:**
1. The BreathTek UBT should not be used until 4 weeks or more after the end of treatment for the eradication of *H. pylori* as earlier post-treatment assessment may give false negative results.
2. The performance characteristics for persons under the age of 18 have not been established for this test.
3. The specimen integrity of breath samples and reference gases stored in breath bags under ambient conditions has not been determined beyond 7 days.
4. A correlation between the number of *H. pylori* organisms in the stomach and the BreathTek UBT result has not been established.
5. The predicate device (Meretek UBT®) was standardized in asymptomatic healthy volunteers and subsequently validated in clinical trials limited to patients with documented duodenal ulcer disease.
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Antinuclear Antibody Screening: Issues and Answers

Wednesday, September 22, 2010 ~ 2:00-3:30 pm Eastern U.S. Time

The antinuclear antibody (ANA) test is the mainstay for screening for a number of autoimmune disorders, which affect approximately 13-22 million people in the US. The immunofluorescence (IF) ANA Assay has long been considered the gold standard for the detection of ANAs. This method uses cell lines, in particular HEp-2 cells, which contain approximately 100 to 150 autoantigens and can provide both a pattern and a titer to assist in diagnosis.

In recent years, enzyme immunoassays (EIA) and solid phase multiplex immunoassays have been introduced for ANA screening. These assays can process specimens more quickly and at less cost than the traditional IF technique. However, they are less sensitive for some conditions because they can detect only specific autoantibodies that are directed against autoantigens included in the assay. Further, the composition of the EIA and multiplex assays varies from as few as 8-12 antigens to a much larger number when extracts from HEp-2 cells and/or chromatin material is included.

The decision as to which of the tests to use to screen patient serum for the presence of autoantibodies is highly controversial. This program will provide both the laboratory’s and the rheumatologist’s perspective on the pros and cons of different methodologies used to screen for ANAs. Key components of each technology will be reviewed, including false positives and false negatives. Strategies to overcome these limitations and improve screening, diagnosis and test result communications will be discussed.

Attend and you will know:
• Why the American College of Rheumatologists considers the immunofluorescence ANA assay to be the gold standard for ANA screening
• The importance of standardization of ANA laboratory testing and results
• How to compare the different methodologies currently available
• How to evaluate which testing method is best for your lab
• What to include with your ANA test results to ensure proper test interpretation

The Experts:
David Keren, MD, Medical Director, Warde Medical Laboratory, Ann Arbor, MI
Donald Bloch, MD, Associate Physician, Massachusetts General Hospital, Assistant Professor of Medicine, Harvard Medical School, Boston, MA
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