NPI Subcommittee on Health & Medicine

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Steve Laderman
Agilent
Photonics in Health and Medicine

Working Group Members

Steve Laderman, Chair  Agilent Technologies
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Tom Baer  Stanford & Entrepreneur
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Jim Mulshine  Rush Medical School
Radislav Potyrailo  GE Healthcare
Jeff Rosner  Life Technologies
Adam Zysk  Diagnostic Photonics
Houston Baker  NIH
Eric Swanson  OCT News

Houston Baker  NIH
Creativity and Contribution

“The creative process works best when it is not too structured, but it must, in the long run, be tamed, harnessed, and hitched to the wagon of man’s needs.”

-William (Bill) Hewlett, cofounder of the Hewlett-Packard Company
Photonics Makes the Invisible Visible

Organs and Tissues

Cells & Their Contents
A Broad Set of Tools & Methods

Some Common Themes:
Precision, accuracy, control, information rich, versatile
Clinical validation, medical value, economic benefit
Economic Impact of Bio Photonics

Pervasive Methods
• Medical and scientific imaging, probes
• Medical Diagnostics
• Bioassays for drug and biomarker discovery
• Biosensors

Growing Application Areas
• Advances in Medical Imaging
• Molecular Medicine (therapeutics, MDx)
• Advances in Surgery
• Point of Care Measurements
• Regenerative Medicine
Technical Barriers Requiring New Research

- Accessible, large libraries of meaningful, annotated image data sets
  - Algorithm development, testing, validation, and dissemination
  - Measurement optimization
  - Standardization of data and of performance
- Size and cost of widely used high performance components, most especially lasers and filters
- Optical devices optimized for metrology/quantitation
- Speed of image acquisition
- Real time and multidimensional visualization
- *In vivo* sensors (including *in vivo* pathology, optogenetics)
- Live cell and noninvasive optical methods
Non-Technical Barriers Requiring Expanding Best Practices

– Application focus -> public/private partnerships:
  • Translational and applied research (e.g., NSF Acceleration of Innovation of Research; Engineering Research Centers)
  • Strategic Roadmaps for Drug Development, Medical Devices, Biomedical Research
  • SBIR

– Regulatory hurdles:
  • Slow, expensive clinical trials -> innovative clinical trials
  • FDA/industry informational forums for emerging technologies

– Human resources
  • interdisciplinary education,
  • retention of trained personnel
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Industry Representative:
James Mulshine
Rush Translational Sciences Consortium
Optics & Photonics: Lighting a Path for the Future
February 28, 2013
Perspective: Tobacco Mortality

- Bubonic Plague (14th century)- 75 million
- Tobacco (20th century)- 100 million
- Tobacco (21st century)- 1 BILLION*

H. Wipfli JM Samet, Clin Pharm Ther 86, 263, 2009*
About 438,000 U.S. Deaths Attributable Each Year to Cigarette Smoking*

- Lung cancer: 123,800
- Coronary heart disease: 86,800
- Chronic lung disease: 90,600
- Other diagnoses: 84,600
- Stroke: 17,400
- Other cancers: 34,700

The National Lung Screening Trial

• The NLST is a prospective randomized controlled trial
• Randomization: Annual CXR vs. CT
• Number of subjects: 53,000
• Number of screening sites: 30 sites, including current PLCO sites (10), and ACRIN sites (20)
• Duration: 3 screening rounds, with follow-up to 2011
• Trial costs $250M and nearly a decade

• NLST had many false positives but not defined diagnostic work up approach

• NELSON used defined diagnostic work up efficiency in NEJM and found a sensitivity of 95%, specificity of 99% using a Siemens Lung Care volume measurement tool*

• Both I-ELCAP and NELSON use a nodule growth criteria to identify clinically significant nodules using quantitative imaging (filter for false positivity)^

*van Klaveren RJ et al NEJM, 2009

^Wagnet et al AJR, 2012
From: Definition of a Positive Test Result in Computed Tomography Screening for Lung Cancer: A Cohort Study—Based on retrospective analysis of 21,000 screening cases from 2006-2010


Frequency of a positive result and cases of lung cancer diagnosed within 12 mo of baseline enrollment.
Need to Define and Standardize

• Imaging Acquisition Quality Control Process
• Image processing quantitative approach
• Invasive work-up process with quantitative approach to define optimal outcomes
• With QIBA obtain FDA qualification of image processing as validated biomarker
Moving To Rapid Learning

• Institute of Medicine (IOM) Roundtable suggested that a new clinical paradigm be developed that takes better advantage of data generated in the course of healthcare delivery

• Data is rapidly analyzed and results are use for modeling new scenarios with improved outcomes

• This approach would speed and improve the development of evidence for real-world decision making for complex management processes

Conclusion:

• Refining components of the process could accelerate improving screening outcomes

Lung Cancer Risk and COPD

• Emphysema was found on 29% of a screening cohort of 9,000 subjects

• After correcting for age and smoking history, emphysema was a significant risk factor for lung cancer hazard ratio = 1.7

• This finding stratifies lung cancer risk in an already defined “high” risk cohort and supports personalized intervention such as smoking cessation

Imaging: The Leading Edge of Innovation

• Tobacco combustion products mediate complex injury of airway including CA and COPD
• CT imaging allows surveillance when clinical intervention can still result in lung cancer cure
• Quantitative characterization of early lesions can refine clinical care-stratify clinically aggressive cases
• Aggregation of cases with known clinical outcomes enables continuous process improvement
• IOM’s “Rapid Learning” leverages digital Electronic Medical Record information enabling transformative biomedical progress by allowing timely reanalysis with imaging and other quantitative tools