Workshop Overview: Funded by the Agency for Healthcare Research and Quality, the goal of the workshop is to convene stakeholders in the molecular imaging and comparative effectiveness research (CER) communities to:

1. Understand the desire for more CER in molecular imaging,
2. Determine the appropriate research methods to address various molecular imaging evidence gaps, and

The result of the workshop will be a CER agenda tailored to the needs of the molecular imaging community.

Day 1

7:00 – 7:30 am  Registration and Breakfast

7:30 – 8:00 am  Introduction and Workshop Overview
Michael Graham, SNM President and Conference Chair

8:00 – 9:45 am  Panel Presentation I: Perspectives on the Need for More CER/
Patients, physicians, payers, and policymakers all desire more CER for molecular imaging. In this session, panelists will describe the evidence various players need to make effective, high-value for healthcare choices.

Moderator: Larry Kessler, ScD
University of Washington

Robert McDonough, MD
Aetna

Marc Boutin, JD
National Health Council

David W. Lee, MD, PhD
GE Healthcare

Leah Hole-Curry, JD
Washington Health Technology Assessment Program

Louis Jacques, MD
Centers for Medicare & Medicaid Services

9:45 – 10:00 am  Break

10:00 – 11:00 am  Panel Discussion I: The Unique CER Needs in Molecular Imaging/
Building on the previous panel presentations, this session will be a facilitated discussion that draws out more specific evidence needs and
evidence gaps that the advanced imaging community should address.

- Same moderator and panelists from Panel Presentation I

11:00 – 12:30 pm Panel Presentations II: Tools and Techniques for Answering CER Questions
CER encompasses a variety of research methods (e.g., systematic reviews, observational registries, pragmatic clinical trials, and data modeling). This session will describe the strengths and weaknesses of different techniques to address the various types of knowledge gaps in molecular imaging.

Moderator: Lou Garrison, PhD
University of Washington

Jean Slutsky, PA, MSPH
Agency for Healthcare Research and Quality (AHRQ)

Sean Tunis, MD
Center for Medical Technology Policy

Jeffrey G. (Jerry) Jarvik, MD, MPH
University of Washington

Brian Bresnahan, PhD
University of Washington

12:30 – 1:45 pm Lunch Break (Morning Wrap-up)

1:45 – 4:00 pm Breakout Session I: Articulating Key CER Questions in Molecular Imaging
Based upon the morning’s discussion, workshop participants will be divided into teams to examine specific evidence gaps and create key questions that can be answered by CER approaches. The result of the breakout session will be a set of draft CER questions, potential research methods to answer those questions, and possible funding sources.

IT/Coordinating – Not Assigned (will participate in all breakouts)
1. Chris Sistrom, MD, MPH
2. Paul Nagy, PhD
3. Eliot Siegel, MD

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## Day 2

### 7:15 – 7:45 am  
**Breakfast**

### 7:45 – 8:00 am  
**Review of Day 1 Progress**

**Michael M. Graham, PhD, MD**  
*University of Iowa*

### 8:00 – 9:00am  
**Keynote Speech I: Nuclear Medicine Going Forward: Challenges and Opportunities**  
The speaker will discuss the need for continued improvement in CER research approaches in nuclear medicine, as well as challenges associated with conducting diagnostic studies and opportunities for developing a meaningful CER agenda in nuclear
medicine and molecular imaging.

Barbara J. McNeil, MD, PhD
Harvard University

9:00 – 9:45 am
Case Study: Evidence in Action: The Recent NOPR Experience/ The speaker will recount the actions that led to the creation of the registry and how that registry was leveraged to improve Medicare coverage for PET imaging.

Barry A. Siegel, MD
Mallinckrodt Institute of Radiology

Bruce E. Hillner, MD
Virginia Common Wealth University Internal Medicine

9:45 – 10:45 am
Keynote Speech II: Demonstrating Value by Leveraging Research Methods in Molecular Imaging/ The speaker will present a broad perspective on the process of developing high-quality CER evidence in medicine and in imaging, as well as its impact on multiple stakeholders. He will highlight the need to design/conduct studies, evaluate findings, learn from CER experiences, and then modify/adapt CER approaches in order to continue to improve methods during the process of gathering comparative health information.

J. Sanford (Sandy) Schwartz, MD
University of Pennsylvania - School of Medicine and The Wharton School

10:45 – 11:00am
Break

11:00 – 12:30 pm
Breakout Session III: Creating Advanced Imaging CER Action Plans/ Based upon Day 1’s breakout session, teams will, further develop their CER questions, research methods, and possible funders to define an action plan for realizing the studies.

• Groups 1-5 from Breakout Session I

12:30 – 1:30 pm
Lunch Break

1:30 – 2:30 pm
Plenary Session: Stating the Advanced Imaging Community’s CER Agenda/ The breakout teams with report out to each other their specific CER action plans. This session will offer opportunities for dialogue across the workshop participants.

• Groups 1-5 from Breakout Session I

2:30 – 3:30 pm
Concluding Remarks and Next Steps
• Michael Graham, PhD, MD and Larry Kessler, ScD
Benefit-Risk Analysis
Risk-benefit analysis is the comparison of the risk of a situation to its related benefits. Exposure to personal risk is recognized as a normal aspect of everyday life. We accept a certain level of risk in our lives as necessary to achieve certain benefits. In most of these risks we feel as though we have some sort of control over the situation. For example, driving an automobile is a risk most people take daily. "The controlling factor appears to be their perception of their individual ability to manage the risk-creating situation." Analyzing the risk of a situation is, however, very dependent on the individual doing the analysis. When individuals are exposed to involuntary risk, risk which they have no control, they make risk aversion their primary goal. Under these circumstances individuals require the probability of risk to be as much as one thousand times smaller then for the same situation under their perceived control. ([http://capita.wustl.edu/ME567_Informatics/concepts/riskben.html](http://capita.wustl.edu/ME567_Informatics/concepts/riskben.html))

Comparative Effectiveness Research (CER)
CER is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. ([http://www.hhs.gov/recovery/reports/plans/nih_cer_plan.pdf](http://www.hhs.gov/recovery/reports/plans/nih_cer_plan.pdf))

Cost-Effectiveness Analysis (CEA)
An economic evaluation in which the costs and consequences of alternative interventions are expressed cost per unit of health outcome. CEA is used to determine technical efficiency; i.e., comparison of costs and consequences of competing interventions for a given patient group within a given budget. ([http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html#CUA](http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html#CUA))

Cost-utility analysis (CUA)
A form of economic study design in which interventions which produce different consequences, in terms of both quantity and quality of life, are expressed as 'utilities'. These are measures which comprise both length of life and subjective levels of well being. The best known utility measure is the 'quality adjusted life year' or QALY. In this case, competing interventions are compared in terms of cost per utility (cost per QALY). ([http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html#CUA](http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html#CUA))

Effectiveness
The contribution which a program makes to individuals' utility or welfare, normally through better health, but not necessarily solely through better health. The contribution which a program makes to individuals' utility or welfare, normally through better health, but not necessarily solely through better health. ([http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html#CUA](http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html#CUA))

Effectiveness can also be assessed at a population, or societal level. Effectiveness is generally measured in real-world settings, under fewer restrictions than in efficacy studies, and is most often assessed in settings closer to normal conditions of treatment. ([http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html#CUA](http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html#CUA))

Efficacy
In medicine, the ability of an intervention (for example, a drug or surgery) to produce the desired beneficial effect in expert hands and under ideal circumstances. The ability of a drug to produce the desired therapeutic effect. ([http://medical-dictionary.thefreedictionary.com/efficacy](http://medical-dictionary.thefreedictionary.com/efficacy))
Efficacy is generally measured in a well-controlled environment (e.g., RCT). Efficacy studies generally have more restrictive inclusion and exclusion criteria compared to effectiveness studies.

**Evidence-Based Medicine**
The term evidence-based medicine refers to the use of current best evidence from scientific and medical research, and the application of clinical experience and observation, in making decisions about the care of individual patients. ([http://www.nlm.nih.gov/nichsr/hta101/ta10104.html#Heading7](http://www.nlm.nih.gov/nichsr/hta101/ta10104.html#Heading7))

**Evidence-Based Radiology**
The role of evidence-based medicine, defined as the integration of best research evidence with clinical expertise and patient values, is becoming increasingly important in health care. Evidence-based practice has 5 basic steps that can be applied to any clinical discipline: (1) formulate an answerable question, (2) find the best current evidence, (3) appraise critically, (4) apply findings to practice, and (5) evaluate performance. Evidence-based radiology (EBR) is a relatively new approach to the practice of radiology based on the principles of evidence-based medicine. Through EBR, radiologists can regularly update their knowledge, deepen their understanding of research methodologies, and use research data in clinical settings more effectively; for patients, EBR ensures that they receive the best current care. Evidence-based radiology can be used to decrease the variability in radiology practice and thus avoid the unnecessary waste of resources. (Journal of the American College of Radiology: JACR. 01/08/2006; 3(7):513-9. ISSN: 1558-349X DOI: 10.1016/j.jacr.2006.01.005)

**Health Technology Assessment**
Health technology assessment is the systematic evaluation of properties, effects or other impacts of health technology. The main purpose of HTA is to inform policymaking for technology in health care, where policymaking is used in the broad sense to include decisions made at, e.g., the individual or patient level, the level of the health care provider or institution, or at the regional, national and international levels. HTA may address the direct and intended consequences of technologies as well as their indirect and unintended consequences. HTA is conducted by interdisciplinary groups using explicit analytical frameworks, drawing from a variety of methods. HTA can be used in many ways to advise or inform technology-related policymaking. ([http://www.nlm.nih.gov/nichsr/hta101/ta10104.html#Heading7](http://www.nlm.nih.gov/nichsr/hta101/ta10104.html#Heading7))

**Meta-Analyses**
Meta-analysis is the statistical procedure for combining data from multiple studies. When the treatment effect (or effect size) is consistent from one study to the next, meta-analysis can be used to identify this common effect. When the effect varies from one study to the next, meta-analysis may be used to identify the reason for the variation. ([http://www.meta-analysis.com.html](http://www.meta-analysis.com.html))

**Pragmatic Clinical Trials**
Clinical trials for which the hypothesis and study design are developed specifically to answer the questions faced by decision makers are called pragmatic or practical clinical trials (PCTs). The characteristic features of PCTs are that they (1) select clinically relevant alternative interventions to compare, (2) include a diverse population of study participants, (3) recruit participants from heterogeneous practice settings, and (4) collect data on a broad range of health outcomes. ([http://www.ncbi.nlm.nih.gov/pubmed/14506122](http://www.ncbi.nlm.nih.gov/pubmed/14506122))

**Randomized Clinical Trial**
A study in which the participants are assigned by chance to separate groups that compare different treatments; neither the researchers nor the participants can choose which group. Using chance to assign people to groups means that the groups will be similar and that the treatments they receive can be compared objectively. At the time of the trial, it is not known which treatment is best. It is the patient's
choice to be in a randomized trial.  
( http://www.cancer.gov/dictionary/?CdrID=45858 )

**Patient Safety**
A definition for patient safety has emerged from the health care quality movement that is equally abstract, with various approaches to the more concrete essential components. Patient safety was defined by the IOM as “the prevention of harm to patients.” Emphasis is placed on the system of care delivery that (1) prevents errors; (2) learns from the errors that do occur; and (3) is built on a culture of safety that involves health care professionals, organizations, and patients. The glossary at the AHRQ Patient Safety Network Web site expands upon the definition of prevention of harm: “freedom from accidental or preventable injuries produced by medical care.”  

**Systematic Literature Reviews**
Systematic reviews retrieve, appraise and summarize all the available evidence on a specific health question. They are designed to reduce the effect of the reviewers' own bias, and a full protocol should be written to define and guide the process. The appropriate resources should be in place before undertaking a review. The steps of the review are: frame the question and choose appropriate methods; identify relevant work; extract relevant data on outcomes and quality; summarize the evidence; and, interpret the evidence. Reviews that combine valid, homogeneous studies of treatments that are relevant to health care, in patients who are typical, can provide good evidence to guide health care decisions.  
(http://www.ncbi.nlm.nih.gov/pubmed/15907679)

**Health Promotion Glossary**
This Health Promotion Glossary was prepared on behalf of WHO by Don Nutbeam, WHO Collaborating Centre for Health Promotion, Department of Public Health and Community Medicine, University of Sydney, Australia. A pre-publication of the glossary was prepared as a resource document for the Fourth International Conference on Health Promotion, *New Players for a New Era: Leading Health Promotion into the 21st Century*, Jakarta, Indonesia, 21-25 July 1997. The pre-publication was subsequently revised to account for the outcomes from that Conference, specifically the Jakarta Declaration on Leading Health Promotion into the 21st Century.  
(http://www.who.int/hpr/NPH/docs/hp_glossary_en.pdf)
Panel and Keynote Speaker Bio-Sketches

**Brian W. Bresnahan, Ph.D.** is a Research Assistant Professor supporting the Departments of Radiology at the University of Washington (UW) Medical Center and Harborview Medical Center, both in Seattle, Washington. He is the principal health economist for the UW Comparative Effectiveness, Cost and Outcomes Research Center (CECORC). He has a doctorate in economics, worked in the pharmaceutical/biotechnology industry for seven years, and specializes in health economics, health policy, and outcomes research. Dr. Bresnahan has a wide range of experience in conducting clinical and patient-reported outcome studies, health outcomes and health services research, cost-effectiveness analysis, retrospective database analysis, and economic modeling. Following his industry experience, he spent 2.5 years as a post-doctoral fellow in the Pharmaceutical Outcomes Research and Policy Program (PORPP) at UW. Currently, he also serves as a co-Chair of the SNM's CER Working Group, which is part of the PET Utilization Task Force. His research interests include comparative effectiveness and cost-effectiveness studies, approaches to improving hospital and radiology quality, and studying alternative approaches to assessing value in health and healthcare.

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**Marc M. Boutin, Esq.** is the executive vice president and chief operating officer of the National Health Council, an organization that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers.

Boutin has been actively involved in health advocacy, policy, and legislation throughout his career. He currently serves on the Advisory Board, Council for American Medical Innovation; Advisory Board, Coalition Against Major Diseases; and Advisory Board, Partnership to Fight Chronic Disease. He is a member of the AHRQ Effective Healthcare Program Stakeholder Group and the eHealth Initiative Leadership Council, and a panel expert for the NIH-funded grant on Protecting Privacy in Health Research.

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**Lou Garrison, PhD** is Professor in the Pharmaceutical Outcomes Research & Policy Program in the Department of Pharmacy and Adjunct Professor in the Department of Global Health at the University of Washington, where he joined the faculty in 2004. For the previous 12 years, he worked as an economist in the pharmaceutical industry. Most recently, he was Vice President and Head of Health Economics & Strategic Pricing in Roche Pharmaceuticals, and was based in Basel, Switzerland, in 2002-4. He oversaw
the development of the economic and pricing strategies, and research plans for all Roche compounds. Prior to this, he was Director of the Project HOPE Center for Health Affairs. In eight years there, he worked on a wide variety of health policy issues, including studies of health care reform both in the U.S. and overseas. Before this, he worked at the Battelle Human Affairs Research Centers in Seattle, where he carried out studies of the adequacy of physician manpower supply and the cost-effectiveness of kidney and heart transplantation. He received a B.A. in economics from Indiana University, and a Ph.D. in economics from Stanford University. Dr. Garrison's research interests include national and international health policy issues related to regulatory risk-benefit analysis, insurance, pricing, reimbursement, and risk-sharing agreements, as well as the economic evaluation of pharmaceuticals, diagnostics, devices, surgical procedures, and vaccines, particularly as related to organ transplantation, renal disease, influenza, measles, and cancer. From 2007-9, he served on the Board of Directors of the International Society for Pharmacoeconomics and Outcomes Research.

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Michael M. Graham, PhD, MD is currently Professor of Radiology and Radiation Oncology at the University of Iowa School of Medicine, Director of the Division of Nuclear Medicine, and a leader of the Tumor Imaging Program at the University’s Holden Comprehensive Cancer Center. He has been active in the Society of Nuclear Medicine, as chair of the Computer Council, Brain Imaging Council, and Academic Council, as President of the Pacific Northwest Chapter, as a member of the Board of Directors, and is immediate past president of SNM. His research interests are in quantitative PET, with recent emphasis in head and neck PET-CT imaging. His major areas of focus at SNM are in the Clinical Trials Network and in Comparative Effectiveness Research.

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Bruce E. Hillner, MD is general internist and cancer researcher. He is an Eminent University Scholar and Professor of Medicine at the Virginia Commonwealth University and the Massey Cancer Center in Richmond, VA.

He is an internationally recognized expert in outcomes research in oncology, especially breast cancer. Has addressed a variety of ‘outcomes’ issues including technology assessment, patterns of care, quality of care indicators, costs and, most commonly, cost-effectiveness analysis. He has >100 peer reviewed publications.

He is also Chair of the National Oncology PET Registry. His current academic goals are to use his
methodological and oncology clinical expertise as the national health focus shifts to Comparative Effective Research.

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Leah Hole-Curry, JD directs Washington State’s Health Technology Assessment program since its creation in 2006. The HTA program is a leading state effort to purchase high-quality health care that is proven safe, effective, and cost-effective. The program relies on independent evidence reports and a committee of current practitioners to guide state purchasing decisions of medical technologies.

From 2001 to 2006, Ms. Hole-Curry provided regulatory consulting and project management to state Medicaid agencies and the federal Department of Health and Human Services (Medicaid, Office of HIPAA Standards, Office for Civil Rights) as a consultant with Fox Systems, Inc. She focused on HIPAA (Health Insurance Portability and Accountability Act) and information technology projects. She was consulted as an authority on HIPAA implementation by local, state, and federal entities; spoke nationally and regionally on HIPAA impacts, especially for public agencies; participated in workgroups and chaired a national workgroup.

Ms. Hole-Curry began her commitment to improving quality and safety of public health systems working for the Departments of Social and Health Services and Labor and Industries in Washington, providing contract management and regulatory compliance guidance.

Prior to working in the public health care field, she practiced land use, real property, and business law in Olympia, WA for several years. She received her JD, Magna Cum Laude, at Seattle University School of Law in 1997 and a B.A. from Evergreen State College. She lives in Olympia with her daughter and lab mix dog, and spends free time on her boat, or wishing she was on her boat.

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Jeffrey G. (Jerry) Jarvik, MD, MPH
Larry Kessler, ScD was appointed as Professor and Chair of the Department of Health Services at the University of Washington, School of Public Health in January 2009. In this role he directs over 60 faculty members who provide education in a wide variety of health services disciplines leading to degrees in public health, including a Ph.D. program, Masters of Public Health, Masters of Health Administration, and a recently developed undergraduate major in public health. The Department also contains four centers, three concerned with different aspects of public health research and the fourth is the Northwest Center for Public Health Practice.

Prior to joining the faculty at UW, he spent 30 years working for the federal government, first at the National Institute of Mental Health, then at the National Cancer Institute, and most recently at the US Food and Drug Administration’s Center for Devices and Radiological Health. He obtained his degree in Operations Research from the Johns Hopkins School of Public Health in 1978.

In September, 2002, Dr. Kessler was appointed Director of the Office of Science and Technology at the FDA’s Center for Devices and Radiological Health. In this position, he directs the efforts of the laboratories of CDRH and the Standards Coordination Program. The Office became the Office of Science and Engineering Laboratories in a reorganization effort designed to better integrate OSEL into the function and mission of CDRH. OSEL plays a crucial role in identifying key scientific questions and solutions concerning device safety and effectiveness.

In June, 1995, he first joined the FDA’s Center for Devices and Radiological Health as the Director of the Office of Surveillance and Biometrics. Under his leadership, the Office has implemented the MDR regulation for user reporting; has developed a program for reducing the burden on industry for repetitive reporting; and has completed a pilot program to develop a sentinel system for user facility reporting of adverse events. In addition, he has helped develop a new program encouraging the application of a wide variety of new statistical methods, with a focus on Bayesian methods, for the device review process. From 1996 through 2001, he has served as chair of Study Group 2 of the Global Harmonization Task Force, concentrating on postmarket vigilance and surveillance.

In 2007, Dr. Kessler became chair of the Global Harmonization Task Force for 1-1/2 years until July 2008. In this position, he instituted a new policy of routine conference calls for the Steering Committee, had the website revamped to be more user friendly, expanded the reach of GHTF to Asia and Latin America, and held a Steering Committee meeting outside the boundaries of the original five founding members during which there was a joint meeting between the Steering Committees of GHTF and the Asian Harmonization Working Party.

For the period from September 2001 through August 2002, Dr. Kessler took a position as a visiting scientist at the Fred Hutchinson Cancer Research Center, working on research projects involving prostate cancer trends, the National Emphysema Treatment Trial, and studies of colorectal and lung cancer.

From 1984 to June 1995, Dr. Kessler served as chief of the Applied Research Branch at the National Cancer Institute (NCI). The Applied Research Branch, an interdisciplinary research unit within the NCI's
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David W. Lee, PhD performs health economics and outcomes research studies that demonstrate the value of medical imaging to patients, healthcare providers and payers. David’s work is routinely presented at scientific meetings such as the American College of Obstetrics and Gynecology and the International Society of Pharmacoeconomics and Outcomes Research. He has also authored a number of studies that appear in several peer-reviewed journals. He is also co-chair of the Value of Imaging Research Coalition

Prior to joining GE Healthcare in 2005, David served as a senior consultant with ValueMedics Research, provided independent health economics consulting services, served as Director of Health Economics at GD Searle (now Pfizer), and was a health policy analyst with the American Medical Association.

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Robert McDonough, MD is head of Clinical Policy Research and Development for Aetna, where he is responsible for developing Aetna's clinical policies. He is cochairman of Aetna's Pharmacy and Therapeutics Committee, is a member of the Medicare Evidence Development and Coverage Advisory Committee, and has served on several Institute of Medicine Committees. He has special interests in preventive health services, technology assessment, and outcomes research. He is former senior analyst and project director with the Health Program of the Congressional Office of Technology Assessment. He is a graduate of Duke University School of Medicine and School of Law (J.D.), and has a masters degree in policy analysis from Duke's Sanford Institute of Public Policy. He completed an internship in internal medicine at Stanford University School of Medicine, and is a Fellow of the American College of Legal Medicine.

Robert McDonough, MD
Aetna Clinical Policy Unit
Barbara J. McNeil, MD, PhD is the Ridley Watts Professor and was the founding Head of the Department of Health Care Policy at Harvard Medical School in 1988. She is also a Professor of Radiology at Harvard Medical School and at Brigham and Women's Hospital. She continues to practice nuclear medicine one day a week at the BWH. She was interim dean of Harvard Medical School in summer, 2007.

Dr. McNeil received her A.B. degree from Emmanuel College, her M.D. from Harvard Medical School, and her Ph.D. from Harvard University. She is a member of the Institute of Medicine of the National Academy of Sciences and the American Academy of Arts and Sciences. Dr. McNeil is also a member of the Blue Cross Technology Evaluation Commission; she is a member of the Medicare Evidence Development Coverage Advisory Committee (MedCAC), having previously served as its chair and vice chair. She serves as an advisor for several other federal and private organizations and also sits on the public board of Edwards Lifesciences (EW).

Dr. McNeil’s original career involved research in decision analysis and cost-effectiveness analysis. More recently, her work has focused on quality of care and technology assessment. Her research involves relationships with payers, providers and the federal government. Her largest ongoing study compares quality of care in the VA system with that in the private setting for patients with cancer.

The Department of Health Care Policy at HMS is the largest research policy unit at Harvard University with over twenty faculty members working on issues related to cost, quality and access in the health care system.

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Barry A. Siegel, MD is currently Professor of Radiology and Medicine at Washington University School of Medicine, Director of the Division of Nuclear Medicine at Mallinckrodt Institute of Radiology, and a member of the University’s Alvin J. Siteman Cancer Center. His current research efforts are focused on uses of positron emission tomography for cancer diagnosis and staging, as well as predicting and monitoring the tumor response to therapy. He also has been heavily engaged in the development and conduct of multicenter clinical trials in the arena of cancer imaging through his involvement in the American College of Radiology Imaging Network. For the last five years, he has devoted much of his time to the development and operation of the National Oncologic PET Registry.

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Jean Slutsky has directed the Center for Outcomes and Evidence (COE), Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services since June 2003. Prior to Ms. Slutsky’s appointment as director of COE, she served as acting director of the Center for Practice and Technology Assessment at AHRQ. Most recently, Ms. Slutsky has implemented a comparative effectiveness research program that includes evidence synthesis, evidence generation, and evidence translation and implementation. The Effective Health Care Program is authorized under Section 1013 of the Medicare Modernization Act.

Ms. Slutsky oversees the Evidence-based Practice Center program; Technology Assessment Program; extramural and intramural research portfolios concerning translating research into practice, outcomes and effectiveness research, including pharmaceutical outcomes, and cost-effectiveness analyses; and the National Guideline, Quality Measures, and QualityTools Clearinghouses. She is a member of the editorial board of Implementation Science.

Prior to becoming acting director of the Center for Practice and Technology Assessment, Ms. Slutsky, served as project director of the U.S. Preventive Services Task Force, an internationally recognized panel of experts who make evidence-based recommendations on clinical preventive services.

Ms. Slutsky received her Bachelor of Science degree at the University of Iowa, a Masters of Science in Public Health (Health Policy and Administration) from the University of North Carolina at Chapel Hill, and trained as a Physician Assistant at the University of Southern California.

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Sean Tunis, MD, MSc. is the Founder and Director of the Center for Medical Technology Policy, an independent non-profit entity focused on improving the value of clinical research for decision making by engaging a range of experts and stakeholders in study design and implementation. He advises numerous domestic and international health care agencies and organizations on issues of comparative effectiveness, evidence based medicine, clinical research and technology policy.

Through September of 2005, Dr. Tunis was the Director of the Office of Clinical Standards and Quality and Chief Medical Officer at the Centers for Medicare and Medicaid Services (CMS). In this role, he had lead responsibility for clinical policy and quality for the Medicare and Medicaid programs, which provide health coverage to over 100 million US citizens. Dr. Tunis supervised the development of national coverage policies, quality standards for Medicare and Medicaid providers; quality measurement and public reporting initiatives, and the Quality Improvement Organization program. As Chief Medical Officer, Dr. Tunis served as the senior advisor to the CMS Administrator on clinical and scientific policy. He also co-chaired the CMS Council on Technology and Innovation

Dr. Tunis joined CMS in 2000 as the Director of the Coverage and Analysis Group. Before joining CMS, Dr. Tunis was a senior research scientist with the Technology Assessment Group, where his focus was on the design and implementation of prospective comparative effectiveness trials and clinical registries. Dr. Tunis also served as the Director of the Health Program at the Congressional Office of Technology Assessment and as a health policy advisor to the U.S. Senate Committee on Labor and Human Resources, where he participated in policy development regarding pharmaceutical and device regulation.

He received a B.S. degree in Biology and History of Science from the Cornell University School of Agriculture, and a medical degree and masters in Health Services Research from the Stanford University School of Medicine. Dr. Tunis did his residency training at UCLA and the University of Maryland in Emergency Medicine and Internal Medicine. He is board certified in Internal Medicine and holds adjunct faculty positions at Johns Hopkins and Stanford University Schools of Medicine.

Sean Tunis MD, MSc.
Center for Medical Technology Policy
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Overview: The speaker will discuss the need for continued improvement in CER research approaches in nuclear medicine, as well as challenges associated with conducting diagnostic studies and opportunities for developing a meaningful CER agenda in nuclear medicine and molecular imaging.

Barbara J. McNeil, MD, PhD
Harvard University
Boston, MA

Dr. McNeil will present background information related to health policy and healthcare trends as well as her perspective on the current state of CER in nuclear medicine in 2010. Dr. McNeil will briefly overview previous CER studies in nuclear medicine (traditional and routine work) and provide suggestions for the future, including needs and approaches. She will discuss the following:

- Rising costs of health care, in general and specific to imaging
- Changes in the U.S. payment system
- CMS and its stricter criteria for coverage
- Comparative Effectiveness Research (CER) in general and its impact on physicians
Overview of Session: Patients, physicians, payers, and policymakers all desire more CER for molecular imaging. In this session, panelists will describe the evidence various players need to make effective, high-value for healthcare choices.

**Moderator:** Larry Kessler, ScD  
*University of Washington*  
Seattle, WA

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**Robert McDonough, MD**  
*Aetna*  
Hartford, CT

Overview of Presentation: Advanced molecular imaging has the potential to improve health outcomes, but its costs and potential risks has engendered heightened scrutiny by managed care organizations and other policymakers. This presentation will focus on how is comparative effectiveness research findings are used in a managed care organization. The processes managed care organizations have in place to evaluate the comparative effectiveness of medical technologies, and the criteria used by managed care organizations in that evaluation, will be described. The presentation will explain the role of opinions and evaluations by national medical associations, consensus panels, governmental agencies, and other technology evaluation bodies in the assessment of medical technologies. The challenges to managed care organizations in evaluating the comparative effectiveness of advanced molecular imaging technologies will be discussed, using positron emission tomography as an example.

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**Louis Jacques, MD**  
*Centers for Medicare & Medicaid Services*  
Baltimore, MD

Overview of Presentation: When discussing the opportunities and challenges of the health care system, one must not overlook the end user – the patient. Evidence-based medicine, as defined by Dr. David Sackett, integrates clinical expertise with the best evidence and individual patients’ predicaments, rights, and preferences to support making the best health care decisions. Unfortunately, patients demonstrate a great deal of skepticism about the application of evidence-based health care. We have an opportunity at this time to structure the comparative effectiveness research agenda in a way to address the health care needs of individuals – in particular people with chronic diseases and disabilities – and bring greater value to the overall health care system.

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**Marc Boutin, JD**  
*National Health Council*  
Washington, DC
David W. Lee, MD, PhD  
*GE Healthcare*  
Waukesha, WI

**Overview of Presentation:** This presentation will explore the unique opportunities and challenges that comparative effectiveness research (CER) presents for equipment manufactures. In principle, CER has the potential to affect what new technologies will be developed, the regulatory approval process, the likelihood of securing reimbursement, and the adoption curve of radiologists and referring physicians. Industry could also have a role in shaping and enabling CER, and CER may yield new collaborative models for manufacturers and academia for generating CER. Finally, the discussion will explore the challenges CER presents to manufacturers who compete in the global economy.

Leah Hole-Curry, JD  
*Washington Health Technology Assessment Program*  
Olympia, WA

**Overview of Presentation:** This presentation will outline legislation related to molecular imaging in the Washington Health Technology Assessment Program specifically with regards to the Advanced Imaging Management Legislation. In addition, the process on how important questions are identified and the most effective way to get questions answered will explored.

**Challenges:**

1. There is a lack of consensus among stakeholders about the evidence needed to permit conclusions about the comparative effectiveness of a advanced molecular imaging on health outcomes.

2. There is a need for improved methods of prioritizing and efficient development of evidence necessary to inform decision-making by managed care organizations and other policymakers.

3. Implementing the results of comparative effectiveness research pose a challenge to managed care organizations and other policymakers, especially where the findings of comparative effectiveness research call for reducing the use of an established technology.

4. Industry is often focused on the next generation of technology, which often becomes available before the results of a CER study of current technology is completed. Rapid technology advancement is a recognized challenge in diagnostic tests.

5. Determining a sustainable funding source will be the key to establishing a long-term CER enterprise. If all stakeholders are not included in the funding, study design, analysis, and interpretation, this creates challenges with long-term CER relationships and continued funding.

6. Imaging is just one of many upstream inputs for physician and patient decision making about treatment. It is therefore challenging to identify its effect on ultimate patient centered clinical outcomes.

7. The interpretation of imaging is largely seen as an art despite initiatives toward standardization of methods and devices.
Opportunities:
1. The American Recovery and Reinvestment Act provides a new source of funding for comparative effectiveness research.

2. Comparative effectiveness research findings have the potential to be used by managed care organizations to improve the value received from our investment in healthcare.

3. As a whole, comparative data on imaging effectiveness is limited. Encouraging more CER studies to address a changing marketplace will likely lead to modifications in the technology development process (i.e., more comparative data) or a plan to evaluate product effects under post-marketing restrictions with public or private payers.

4. The advanced imaging community is more organized and clearly definable than many others.

5. Imaging output is readily shared by electronic means, providing an opportunity for more standardized interpretation and archiving for secondary study.

Panel Discussion Topic: Building on the previous panel presentations, this session will be a facilitated discussion that draws out more specific evidence needs and evidence gaps that the advanced imaging community should address.

BIG Study Questions:
1. What are the limitations and constraints of a study similar to NOPR and how coverage with evidence development will be done in the future?

2. Pragmatic Trials/Studies – More flexible trials?
Overview: CER encompasses a variety of research methods (e.g., systematic reviews, observational registries, pragmatic clinical trials, and data modeling). This session will describe the strengths and weaknesses of different techniques to address the various types of knowledge gaps in molecular imaging.

Moderator: Lou Garrison, PhD  
University of Washington  
Seattle, WA

Moderator Overview:
1. Present an overview of the session and introduce the panelists.
2. Provide a few broad comments from a health economist’s point of view.
3. Address the need to establish an approach to priority setting in health care.

Jean Slutsky  
Agency for Healthcare Research and Quality (AHRQ)  
Rockville, MD

Presentation Overview: "An AHRQ Perspective on CER and Methodology Considerations"
1. Provide an AHRQ overview of comparative effectiveness research initiatives
2. Discuss role of imaging within CER and challenges of surrogate endpoints and linking to outcomes.
3. Discuss role of patient registries and systematic reviews (in general and imaging specific).
4. Provide qualities/characteristics of higher-quality CER studies vs. lower-quality studies.
5. Briefly discuss newly implemented AHRQ web-based CME credit opportunity in CER.

Sean Tunis, MD  
Center for Medical Technology Policy  
Baltimore, MD

Presentation Overview: "A CER Methods Overview and Going Beyond Randomized Controlled Trials"
1. Discuss the need for using strong CER methods while maintaining a level of balance and realism to allow the CER studies to be feasible to conduct and applicable to clinical practice.
2. Present a brief overview of CER study design methodologies (e.g., registries, systematic reviews, meta-analyses, as well as retrospective, prospective, and pragmatic trials).
3. Discuss surrogate imaging outcomes and pragmatic trial study design considerations.
4. Present other recent CER trends and general suggestions for the CER community.
Jerry Jarvik, MD, MPH  
*University of Washington*  
Seattle, WA

**Presentation Overview:** "A Radiologist and HSR Perspective on CER in Molecular Imaging."

1. Present a radiologist’s perspective on CER using health services research methods.
2. Provide examples of linking diagnostic outcomes and patient outcomes in CER studies.
3. Logistical challenges and opportunities associated with multi-center partnerships in CER studies.

Brian Bresnahan, PhD  
*University of Washington*  
Seattle, WA

**Presentation Overview:** "An Economist Perspective on CER in Molecular Imaging."

1. Present a health economist’s perspective on CER.
2. Discuss standard cost-effectiveness and modeling approaches in diagnostics.
3. Present preliminary findings from a FDG-PET/CT systematic review in oncology.

**Challenges:**

1. What particular methods should be applied to which specific types of technology questions?
2. What are the unique challenges for CER in molecular imaging?
3. How should research priorities be set for molecular imaging and in relation to other clinical fields?
4. How should the new Patient-Centered Outcomes Research Institute (PCORI) address these issues?
5. What role could modeling play in the evidence hierarchy, in decision-making, and in stakeholder deliberations?

**Opportunities:**

1. How best to take advantage of the PCORI initiative?
2. Can more be done with Coverage with Evidence Development in molecular imaging?
3. What can be done to take advantage of the growing interest in greater and more structured stakeholder involvement?

**References:**

July 22, 2010 – 10:00 – 10:45am
Case Study: Evidence in Action: The Recent NOPR Experience

Overview: This session will recount the actions that led to the creation of the registry and how that registry was leveraged to improve Medicare coverage for PET imaging. In addition, an explanation of lessons learned and how this experience can be used for future studies and trials.

Barry A. Siegel, MD
Mallinckrodt Institute of Radiology
St. Louis, MO

Challenges:
1. Finding the correct balance between data quantity and quality and access to the service (within a self-funded model with non-engaged participants).
2. Addressing multiple start-up steps and defining human subjects protection strategy.
3. Bringing community up to speed.
4. Obtaining clean, logically consistent data.

Opportunities:
1. Collect more detailed clinical data and information about actual outcomes (but will require funding of participating sites/referring MDs).
2. Collect better quality data, but will require more education of participants (to include certification of participants, on-line data entry with logic checks, and audit/cleaning of incoming data).
3. Use CED registry approach, but obtain chart extraction data in real time to validate outcomes.

Bruce E. Hillner, MD
Virginia Common Wealth University Internal Medicine
Richmond, VA

Challenges:
1. Defining appropriate comparison (control) groups for Registry based Imaging Studies
2. Potential comparators
   a. Historical controls to Non-PET care when PET not available
   b. Contemporary controls to Non-PET when PET was available
3. Indication Bias
   a. Differ in presentation
   b. Differ in probability of metastasis
   c. Differ in potential extent of metastasis
4. Provider Bias (MDs and hospitals) - patterns of care by referring MDs and hospitals using PET likely to differ from non-PET users

5. Spectrum Bias - for non-PET imaging, clinical indication not available

**Opportunities:**

1. Moving beyond the "if" to the “how" by addressing the relative value of:
   a. Sequencing
   b. Frequency
   c. Timing
   d. Combinations of “advanced imaging” (PET, MRI and CT)
Overview: Based upon the morning’s discussion, workshop participants will be divided into teams to examine specific evidence gaps and create key questions that can be answered by CER approaches. The result of the breakout session will be a set of draft CER questions, potential research methods to answer those questions, and possible funding sources.

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<th>Group 1: Oncology - GI and GYN</th>
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Challenges:
1. How to demonstrate the clinical utility (in terms of benefit-risk) and cost-effectiveness of molecular imaging for GI and GYN cancer?

2. What it the role of comparative effectiveness methods, such as observational/administrative databases, patient registries, and pragmatic clinical trials—in assessing the clinical utility of imaging in GI and GYN cancers?

3. How to Identify which GI and GYN cancers for which clinical indications (i.e., diagnosis, staging, re-staging, and/or recurrence) are the best candidates for CER in terms of the health impact and cost-effectiveness of the additional research?

4. How will GI and GYN candidates be compared to the best candidates from the other cancer areas?

5. How should these research priorities be set? What will be the deliberative process? What stakeholder should be involved?

Opportunities:
1. Using decision-modeling to assess the clinical utility (benefit-risk) and cost-effectiveness.

2. Using value-of-information analysis to aid in priority setting for CER PET cancer studies.

References GI:


Nam EJ, Yun MJ, Oh YT, Kim JW, Kim JH, Kim S, Jung YW, Kim SW, Kim YT. Diagnosis and staging of primary ovarian cancer: correlation between PET/CT, Doppler US, and CT or MRI. *Gynecol Oncol.* 2010 Mar;116(3):389-94. Epub 2009 Nov 18.


References GYN:


Overview: Based upon the morning’s discussion, workshop participants will be divided into teams to examine specific evidence gaps and create key questions that can be answered by CER approaches. The result of the breakout session will be a set of draft CER questions, potential research methods to answer those questions, and possible funding sources.

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<th>Group 2: Oncology - Breast and Lymphoma</th>
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Challenges:

Opportunities:

Areas to Consider:
1. Is FDG PET/CT effective and/or cost-effective for early-stage breast cancer, compared to no systemic staging? (Hypothesis in “no”, given prior data for systemic staging of breast cancer for CT and bone scan)
2. Is FDG PET/CT effective and/or cost-effective for locally advance breast cancer versus standard staging? (CCT and bone scan) (Hypothesis is “yes”, given recent data on FDG PET/CT for this disease category.)
3. Is serial FDG PET/CT effective and/or cost-effective for monitoring Stage IV breast cancer, especially for bone-dominant disease? ((Hypothesis is “yes”, but based mostly on small, retrospective studies.)

References:


Overview: Based upon the morning’s discussion, workshop participants will be divided into teams to examine specific evidence gaps and create key questions that can be answered by CER approaches. The result of the breakout session will be a set of draft CER questions, potential research methods to answer those questions, and possible funding sources.

Challenges:

1. Large number of anatomic sites where tumor occurs in the H&N, combined with multiples levels of tumor grade, make it difficult to recruit for a tight RCT. This also means that data needs to be analyzed with attention to anatomic location.

2. Different sites have different vintage PET/CT systems. Difficult to harmonize results.

Opportunities:

1. PET/CT is now being used as part of staging and followup of lung and H&N cancer in large numbers of patients at many centers. This should provide a large number of subjects for a prospective (or retrospective) patient registry.

Gaps:

1. In patients with lung nodules measuring 8 to 30 mm in diameter, is it safe to "watch and wait" when there is no FDG uptake (or minimal uptake) on PET? Under what circumstances? Stated somewhat differently, what are the (negative) consequences of delayed surgery in a patient with a malignant nodule that is managed by watchful waiting after a negative PET scan?

2. Under what circumstances should a non-surgical biopsy be obtained prior to VATS wedge resection in a patient with a lung nodule that is hypermetabolic by PET?

3. In patients with stage IA NSCLC (T1N0M0) who are medically fit for surgery, should PET be obtained to identify occult metastatic disease in the mediastinum or outside the thorax?

4. In patients with clinical (CT) stage IIIA NSCLC, should PET be used for restaging to assess resectability following combined chemoradiation?
5. Under what circumstances (if any) should PET be used in patients with clinical (CT) stage IV NSCLC?

6. When is it appropriate to act on the results of the PET/CT study, without biopsy confirmation, in lung cancer? Example: Past history of lung cancer with resection. Now with a spiculated mass with high FDG uptake in the suture line of the prior resection. Do you need a biopsy to start radiotherapy?

7. In H&N patients, if the 3 month study is negative, is it necessary to get any more surveillance scans? Is there a sub-population that does not require follow-up scans?

8. What is the added value of contrast CT in the followup of H&N patients?

9. Is there a group of patients with H&N cancer that a PET/CT scan of the N0 neck can confirm the absence of disease and avoid neck dissection?

10. In equivocal PET read at 3 months post chemoradiotherapy, is it best to biopsy or wait another 3 months and scan? Is there a sub-population where one strategy would clearly be best?

References:


Overview: Based upon the morning’s discussion, workshop participants will be divided into teams to examine specific evidence gaps and create key questions that can be answered by CER approaches. The result of the breakout session will be a set of draft CER questions, potential research methods to answer those questions, and possible funding sources.

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<th>CONFIRMED</th>
<th>Group: Cardiology</th>
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<tr>
<td>Albert J. Sinusas, MD</td>
<td>Imager</td>
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<tr>
<td>Rory Hachamovitch, MD, MSc</td>
<td>Cardiologist &amp; Outcomes Researcher</td>
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<tr>
<td>Brian Bresnahan, PhD</td>
<td>HSR/Econ</td>
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<td>Hansel J. Otero, MD</td>
<td>Radiology</td>
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<tr>
<td>Robert McDonough, MD</td>
<td>Payer/HTA</td>
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<td>Chris Barker, PhD</td>
<td>Biostats</td>
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Challenges:
1. Important outcomes in cardiology are infrequent and develop over a long period of time. There are controversies over the use of surrogate and composite outcomes in cardiology.

2. The differences in effectiveness of various established interventions for an indication may be small, requiring large studies to discern small but clinically important differences.

3. The lack of consensus about the type and quality of evidence necessary to reach reliable conclusions would apply to cardiology.

4. Cost of the technology (Rb generator)

5. Demonstrating added value over well known (Tc stress test) and emerging (CCTA) technologies.

6. Collecting enough data, recruiting enough patients.

7. Linking test results to patients outcomes in the absence of new therapies.

8. A number of challenges stand in the way of realizing these promises. The majority of cardiac imaging today is done with SPECT on an outpatient basis. Most cardiac practices have invested in and actively employ SPECT. Convincing them to turn to hospital-based PET may be a difficult task. Moreover, it is not yet clear whether targeted PET or SPECT imaging will be better for evaluation of patients with cardiovascular disease. Quantification of SPECT images will likely also require more expensive hybrid imaging systems. The limited availability of 123I is another challenge, and we need more 99mTc-labeled targeted agents. Finally, current nuclear imaging systems have not been optimized for cardiac applications, with inadequate correction for cardiac and respiratory motion and a lack of quantitative software for targeted agents.(With permission from author - Sinusas, A. The Journal of Nuclear Medicine. Vol. 49.No. 6. June 2008)
Opportunities:
1. Industry collaboration.
2. Value of information/patients’ awareness/possibility of a one-stop-shop test for cardiac.
4. It is imperative that we pursue the many possibilities that molecular imaging offers for cardiovascular medicine. For example, as outlined in (Sinusis, JNM 2008) molecular imaging can improve selection of patients after MI for AICD implantation, enhancing outcomes and having a potentially significant impact on reducing health care costs. Molecular imaging of MMP activation or other critical molecular processes after MI may also predict LV remodeling and subsequent development of congestive heart failure, as well as risk for sudden cardiac death. The application of these and other techniques promises to facilitate truly personalized medicine. (With permission from author - Sinusas, A. The Journal of Nuclear Medicine. Vol. 49.No. 6. June 2008)

Recommendations

From the cardiovascular perspective, I would recommend several actions that SNM and the molecular imaging community could take to increase utilization and adoption of these highly promising molecular imaging techniques:

Educational efforts should be created for outreach to both basic scientists and clinicians in the cardiovascular community, including outreach to members of the American Heart Association, the American College of Cardiology, and the American Society of Nuclear Cardiology. It is important to remember that cardiologists, unlike oncologists, are still relatively unaware of the potential value of molecular imaging.

NIH should be encouraged to support funding in cardiovascular molecular imaging. The National Cancer Institute has invested large amounts of money and resources in molecular imaging, but the National Heart, Lung, and Blood Institute has been slow to follow suit, despite the significant health implications.

The development of hybrid imaging systems for small and large animal translational research in cardiovascular medicine should be encouraged. Translational research in cardiology is somewhat more challenging than in oncology. Often larger animal models and, therefore, larger research scanners are required.

Current clinical imaging systems should be optimized to facilitate cardiovascular molecular imaging.

And, as many individuals at the Molecular Imaging Summit have emphasized, standardization of imaging protocols and quantification schemes is needed to facilitate evidence-based, multicenter clinical studies.

References:


Hoffmann U, Bamberg F. Is computed tomography coronary angiography the most accurate and effective noninvasive imaging tool to evaluate patients with acute chest pain in the emergency department?: CT coronary angiography is the most accurate and effective noninvasive imaging tool for evaluating patients presenting with chest pain to the emergency department. Circ Cardiovasc Imaging. 2009 May;2(3):251-63; discussion 263.


Shapiro MD, Pena AJ, Nichols JH, Worrell S, Bamberg F, Dannemann N, Abbara S, Cury RC, Brady TJ, Hoffmann U. Efficacy of pre-scan beta-blockade and impact of heart rate on image quality in patients...


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Group 5: Neurology

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<tr>
<td>CONFIRMED</td>
<td>Daniel Silverman, MD, PhD</td>
<td>Imager</td>
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<td>Jerry Jarvik, MD, MPH</td>
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<td>Eliot Siegel, MD</td>
<td>IT/Coordinating</td>
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<td>CONFIRMED</td>
<td>Soo Borson, MD</td>
<td>Psychiatrist</td>
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Challenges:

1. Emphasis has largely been on development of imaging techniques, ligands, etc - the basic rather than population science of dementia imaging.

2. As a result, the usual study design is a two- or three-group comparison (AD vs control, AD vs FTD vs control, etc/iterations) when the clinical diagnoses are clearly established. This is just the first step in developing a test.

3. Methods focus on eventual biomedical applications, mainly selecting therapeutic targets (e.g. amyloid in AD) and arguing that imaging will provide a key measure of treatment outcome. There are other ways to think about the utility of imaging from the standpoint of health care systems, delivery, and insurers. If time from symptom onset to disease diagnosis can be shortened by routine use of imaging, this may result in fewer protracted searches for answers (many specialist visits with vague results, family frustration and excess fear, prolonged inappropriate treatment with antidepressants for 'depression' that is pseudodepression (loss of motivation, reduced activity) due to cognitive disorder.

4. Progress in dementia nuclear imaging since FDG PET has occurred mainly for amyloid imaging. ADNI data (and many experienced specialists) challenge the primacy of amyloid as a pathogen in AD, so using amyloid imaging as an outcome measure may be less relevant than some presume.

5. Should PIB be viewed as a clinical tool (e.g. use of FDG-PET to improve diagnostic accuracy) or a research tool (e.g. use of PIB-PET to identify beta amyloid burden in the aged brain) ?

6. Following 1 above should PIB be used in the cross sectional setting (one time medical work up on hypometabolism for suspected dementia) or in the longitudinal setting (changes in amyloid levels over time) ?

7. Vaccine development (immunotherapy) is driving the use of PIB PET.
8. What is PIB PET safety profile especially in repeated use?

9. Linking surrogate outcome of imaging to patient related outcome
   a. Health related quality of life
      i. Psychological function
      ii. Physical function
   b. Memory
   c. Impact on patient’s family
      i. Prognostic information
      ii. Value in planning care
   d. Other?

10. Linking imaging to change in patient management
    a. Potential impact on costs
       i. Additional direct cost of PET
       ii. Specialist referrals
       iii. Subsequent diagnostic testing
       iv. Disability
       v. Subsequent interventions
    b. Potential impact on allocation of medical resources (availability of PET vs. other diagnostic modalities)

Opportunities:
1. Could CER principles be applied to investment in novel imaging methods that might prove closer to the pathogenetic cascade than amyloid, and could new methods apply to other forms of dementia in addition to AD?

2. Is there added clinical value in nuclear imaging as part of a clinical diagnostic workup? I.e. would more liberal use of imaging offset other health care or quality costs in heterogeneous groups of cognitively impaired persons? Would it improve 'consumer' satisfaction with dementia care services and expedite comprehensive care patients and families?

3. Does nuclear medicine diagnosis (classification) of results (using current imaging methods) predict prognosis any better than clinical diagnosis?

4. Can PET be used as an effective screening tool to identify patients with very early MCI that will eventually go on to become demented? How accurate and cost effective is PIB in this setting?

5. Alternatively, can PIB be used with other biomarkers (e.g. CSF levels of isoprostanes, tau, Abeta42, etc) in a high risk population (APOE 4 carrier, positive family history, low education, age 70+) to improve identification of those at high risk for dementia?

6. Alternatively, do a safety study. Recruit 150 early AD and MCI patients randomized to receive baseline PIB PET, MRI, or neither (three arm study). Endpoint is 12 month change in the ADAS-COG score.
7. Identify situations where there is a close relationship between imaging outcome and change in management

8. Can PET substitute for other diagnostic testing (anatomic MR, SPECT, fMRI, MRS) rather than be an add-on? If so, what is comparative effectiveness at:
   a. Decreasing w/u costs
   b. Improving HRQOL
   c. Decreasing disability
   d. Improving QOL of family

References:


Overview: The speaker will present a broad perspective on the process of developing high-quality CER evidence in medicine and in imaging, as well as discuss the impact of CER evidence on multiple stakeholders. He will highlight the need to design and conduct studies, evaluate findings, learn from CER experiences, and then modify/adapt CER approaches in order to continue to improve methods during the long-run process of gathering comparative health information.

J. Sanford (Sandy) Schwartz, MD
University of Pennsylvania - School of Medicine and The Wharton School

Dr. Schwartz will present a broad perspective on the process of developing high-quality CER evidence in medicine and in imaging, as well as its impact on multiple stakeholders. He will highlight the need to design/conduct studies, evaluate findings, learn from CER experiences, and then modify/adapt CER approaches in order to continue to improve methods during the process of gathering comparative health information.

In addition, Dr. Schwartz will discuss the complexities of conducting high-quality CER studies, in general and for imaging in particular. His talk will focus on the challenges in specifying, framing, design, conduct, interpretation and application of clinical evaluative research and its findings, providing suggestions for improving the assessment process. He will review and discuss:

- Review the role of diagnostic information in medical decision making
- Identify information needs of imaging CER
- Discuss the strengths and weaknesses of current assessment approaches and methods
- Discuss potential new conceptual and methodological approaches for assessing the value of imaging
- Discuss assessing the value of information produced by CER by the range of stakeholders and decision makers for whom the research is targeted
On behalf of the Society of Nuclear Medicine (SNM), thank you for attending the *Comparative Effectiveness in Molecular Imaging* workshop held July 21-22, 2010 at the Doubletree Hotel and Executive Meeting Center in Bethesda, MD. This two-day meeting will be hosted by the SNM with grant support from the Agency for Healthcare Research and Quality (AHRQ).

SNM believes that CER is an essential component to the future of medical imaging and improved patient care. Three years ago, SNM’s PET Center of Excellence created a Research Working Group (co-chaired by Michael M. Graham, PhD, MD and Brian W. Bresnahan, PhD) charged with understanding the evolving research environment for imaging modalities. CER has since been one of the Working Group’s main areas of focus, and this workshop, with Dr. Graham serving as the conference chair, is part of our efforts to develop patient-centered, methodologically sound CER in molecular imaging.

While many studies in molecular imaging have demonstrated clinical benefit, there is a need for additional comparative effectiveness evidence. The purpose of this workshop is to bring experts in molecular imaging together with leaders in health services research in order to identify key areas for comparative research in molecular imaging. The output of the workshop will include a targeted list of research priorities and a CER agenda in molecular imaging based on input from multiple stakeholders. The objectives of the workshop are to help coordinate and to provide direction to the molecular imaging community in designing and conducting CER studies moving forward.

We encourage you actively participate in the workshop by asking questions and providing feedback regarding existing gaps and priorities as well as identify next steps and important future research initiatives.

Sincerely,

Michael M. Graham, PhD, MD  
SNM Immediate Past President  
Workshop Co-Chair

Brian Bresnahan, PhD  
Workshop Co-Chair