



## Forum Session Meeting Announcement

**Friday, June 8, 2007**

11:45am — Lunch

12:15–2:00pm — Session

# Advancing Evidence-Based Health Care: New Tools, New Data, New Opportunities

### A Discussion Featuring:

**David Eddy, MD, PhD**

*Founder and Medical Director  
Archimedes, Inc.*

**Carolyn Clancy, MD**

*Director  
Agency for Healthcare Research and Quality  
U.S. Department of Health and Human Services*

### Location

**Reserve Officers Association  
of the United States**

One Constitution Avenue, NE  
Congressional Hall of Honor  
Fifth Floor

*(Across from the Dirksen Senate  
Office Building)*

### Registration Required

Space is limited. Please respond  
as soon as possible.

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# Advancing Evidence-Based Health Care: New Tools, New Data, New Opportunities

## OVERVIEW

*As technology proliferates and treatment alternatives multiply, even the best-intentioned clinicians find it challenging to figure out best practices for treating the varied health conditions of their patients. For many diagnoses and patients, best practices have never been defined. Moreover, what is good for patients on average may not be indicated in individual cases. Evidence development has been a slow process. Some health care leaders envision a new national process, enabled by electronic health records and predictive computer modeling, that will allow for greatly accelerated learning. At this Forum session, a computer simulation model called Archimedes will be presented by its developer, Dr. David Eddy.*

## SESSION

At the heart of health policy discussions in 2007 is the seemingly eternal question: How can we most rapidly advance the evidence base for clinical care and improve the delivery of high-quality health care? Some are ready with favored solutions that focus on what we already know: more sophisticated health information technology, pay for performance, integrated delivery systems. Others suggest that we need to start with science and ask more nuanced questions. What works? For whom? Under what conditions?

Randomized clinical trials (RCTs) have long been the gold standard for testing a new drug or procedure, but they come with built-in drawbacks. RCTs require copious time and money to conduct. They often—for practical or ethical reasons—leave out many segments of the population, such as children, women of child-bearing age, seniors, minorities, persons with disabilities, or those with multiple co-morbid conditions. Further, any RCT is limited in the variables it can consider; at its conclusion it can only signal that, on average, the experience of an intervention group is better (or not) than that of a control group. Variation within the intervention group typically is not accounted for, despite how important it may be to know how outcomes may vary by gender, race or ethnicity, age, or other factors. Physicians and patients must deal with many “inferential gaps” between the RCT evidence base and real-world patients and clinical situations.

Health policy leaders have begun to envision an alternative way of advancing clinical knowledge. Lynn Etheredge and others advocate a

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rapid-learning approach, whereby large electronic databases of de-identified clinical information can offer the raw material for efficient analysis of questions relating to outcomes, effectiveness, safety, and cost.<sup>1</sup> A recent Institute of Medicine Roundtable on Evidence-Based Medicine, starting from the premise that evidence development is not keeping pace with the complexity of modern medicine, calls for a reevaluation of how health care is structured to develop and supply evidence and endorses a health care system that is able to learn.<sup>2</sup> (A summary of the Roundtable workshop and a *Health Affairs* supplement on rapid learning will be available at the Forum session.)

The federal government and the private sector are now considering the use of large databases for clinical analysis in a variety of contexts. Legislation to amend the Federal Food, Drug, and Cosmetic Act introduced by Sen. Edward Kennedy (D-MA) (S. 1082, which passed the Senate 93-1 on May 9, 2007) includes a provision to establish a monitoring system for post-market drug safety with the use of a database incorporating 100 million patient records by 2012. Researchers and policymakers await action by the Centers for Medicare & Medicaid Services to make available Medicare Part D data on drugs and drug use and to integrate it with medical data collected under Parts A and B for Medicare's 45 million enrollees.

The Agency for Healthcare Research and Quality (AHRQ), as part of the Effective Health Care Program authorized in section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other legislation, has established a national network of organizations to conduct research on large databases of clinical information. Building on this network, AHRQ proposes to ensure that information essential for decision-making can be linked to the deployment of new interventions and innovations. Even more money and oversight might be in the offing, under a new bill (H.R. 2184), introduced by Reps. Tom Allen (D-ME) and Jo Ann Emerson (R-MO). It would authorize \$3 billion over five years to conduct more comparative research on effectiveness.

In the private sector, America's Health Insurance Plans and the Blue Cross Blue Shield Association also have announced proposals for a public-private entity to explore the effectiveness of new and existing medical procedures, drugs, devices and biologics.

As these initiatives and more are considered or approach implementation, it is important for policymakers to understand possibilities for using these clinical databases that have the potential to advance biomedical knowledge and medical practice. One tool is Archimedes, a large-scale simulation model of human physiology, treatment effects, and health care developed by David Eddy, MD, PhD, and Len Schlessinger, PhD. The Archimedes model provides the engine for a new Robert Wood Johnson Foundation-funded project known as ARChES (ARChimedes Health care Simulator), which will make the Archimedes technology more widely available to health care decision makers and others.

In a recent *Health Affairs* Web Exclusive article, “Linking Electronic Medical Records to Large-Scale Simulation Models: Can We Put Rapid Learning on Turbo?” Dr. Eddy explains that Archimedes is at heart a set of equations that represent physiological pathways relating (so far) to diabetes, congestive heart failure, coronary artery disease, stroke, hypertension, obesity, metabolic syndrome, and asthma.<sup>3</sup> Other equations represent the development of symptoms, patients’ and physicians’ behaviors, clinical events, treatments, resource utilization, measures of quality of life, and so on.

The National Health Policy Forum is pleased to present Dr. Eddy in a session highlighting the ways that the virtual world (and virtual patients) of Archimedes, acting as a truly disruptive technology, may change health care as we know it. (Potential attendees should know that actual equations will not be part of the presentation.) Carolyn Clancy, MD, will offer her commentary on the rapid-learning vision. Lynn Etheredge, author and consultant with the Health Insurance Reform Project of The George Washington University will also be on hand to help guide the discussion.

## SPEAKERS

**David Eddy, MD, PhD**, is the founder and medical director of Archimedes, Inc., whose development was supported by Kaiser-Permanente. He has previously served as chief scientist for the Blue Cross Blue Shield Technology Evaluation and Coverage Program, as director of the World Health Organization’s Collaborating Center for Research in Cancer Policy, and as the J. Alexander McMahon Professor of Health Policy and Management at Duke University.

**Carolyn Clancy, MD**, is director of the Agency for Healthcare Research and Quality (AHRQ). Prior to her appointment, she served as acting director of AHRQ’s Center for Outcomes and Effectiveness Research. Dr. Clancy is a general internist and health services researcher who also holds an academic appointment at The George Washington University School of Medicine.

## KEY QUESTIONS

- What is Archimedes and what is the potential for it and ARChES to “disrupt” or transform our current, relatively slow rate of learning?
- Why was the Archimedes model developed? How will it link up with new, large electronic medical record databases? What are the anticipated benefits?
- How has Archimedes been used to influence the delivery of care? How far away are we from using rapid learning to inform health care delivery for the major medical diseases and conditions?
- What obstacles or impediments might hinder the development and application of Archimedes and ARChES?

Key Questions / continued ►

- How might physicians in daily practice benefit from these initiatives? What gains might patients see?
- How will efforts such as ARChES lead to truly personalized care, with treatment customized to the individual?
- What are the best data sources for rapid learning with Archimedes?
- Where can investments in electronic medical records and new data have the greatest payoff?
- How could ARChES and Archimedes be used as part of a national initiative for comparative effectiveness research?

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## ENDNOTES

1. "Rapid Learning" supplement, *Health Affairs*, Web Exclusives, 26, no. 2 (2007): pp. w106–w194.
2. LeighAnne Olsen, Dara Aisner, and J. Michael McGinnis, Eds., *The Learning Healthcare System: Workshop Summary*, Roundtable on Evidence-Based Medicine, prepublication copy, April 2, 2007, p. S-2.
3. David M. Eddy, "Linking Electronic Medical Records to Large-Scale Simulation Models: Can We Put Rapid Learning on Turbo?" *Health Affairs*, Web Exclusives, 26, no. 2 (2007): w125–w126.



*The National Health Policy Forum is a nonpartisan research and public policy organization at The George Washington University. All of its publications since 1998 are available online at [www.nhpf.org](http://www.nhpf.org).*