



Advancing the Role of Rapid Learning in Mainstream Health Care

A Progress Report on an effort to improve quality, safety and efficiency—directed by Lynn Etheredge

INTRODUCTION

Since 2005, Lynn Etheredge and a group of health policy experts at George Washington University's Health Insurance Reform Project have developed and promoted the concept of a rapid-learning health system, which involves using electronic health records to create large, searchable national databases with personal health information removed. Researchers analyze these data to figure out how to improve the quality, safety, and cost effectiveness of medical technologies, medications, and procedures.

The Robert Wood Johnson Foundation (RWJF) has supported the rapid-learning project through three grants to the Health Insurance Reform Project from August 2005 to April 2012¹. A Program Results Report on the first two grants is available [online](#).

The Health Insurance Reform Project is a nonpartisan organization that develops and promotes innovative ideas to improve quality and reduce costs in health care. Lynn Etheredge is an independent consultant to the Health Insurance Reform Project and project director for the RWJF grants.

For a list of people interviewed for this report, see the [Appendix](#).

What Is the Project About?

Rapid learning is about improving the quality, safety, and efficiency of the health care system—and, thus, improving peoples' health, by tapping into and analyzing aggregated electronic patient data contained in large, searchable databases. The data are culled from electronic health record systems after identifying information has been removed.

Researchers, physicians, payers, and policy-makers can use the results of research on these databases to assess the overall value—or the cost versus the benefit—of myriad

¹ ID# 53797 for \$201,254 from August 2005 through January 2007; ID# 60413 for \$696,500 from March 2007 to March 2010; and ID# 67397 for \$747,234 from April 2010 to April 2012.

current and future medical technologies, medications, and procedures at individual organizations, across organizations, and nationally through Medicare and Medicaid.

“We want to build a rapid-learning health system where rapid progress becomes automatic—a system that learns quickly in the process of patient care and ongoing operations,” explains Etheredge.

“We normally think of research as separate. People in academia do research and everyone else delivers care. This is trying to integrate rapid learning into the whole health system—not only through registries of collective learning but also at individual institutions that are learning as well about their performance and best practices.”

WHAT PROBLEM IS THE PROJECT ADDRESSING?

“The concept of a rapid-learning system is addressing two tightly related problems. One is the need for an efficient approach to learning about how different treatments and technologies work in diverse patient populations,” says Carolyn Clancy, MD, director of the Agency for Healthcare Research and Quality (AHRQ). “For reasons of efficiency, people included in clinical trials need to be free from other medical problems. The challenge that clinicians and patients face every day is that the patients seen in medical practice often don’t look like the people in the trials,” she adds. Real-world patients often have multiple chronic diseases, such as high blood pressure and diabetes, and disabilities, such as limited eyesight or hearing.

The gap between clinical trial subjects and complex, real-world patients leads to the second problem. “Clinicians innovate or try new things and when it works, that’s great, but it usually stops there. It doesn’t get shared with the broader community. We don’t have a systematic way to learn from it,” says Clancy, whose organization has funded work to facilitate the development of large, searchable research databases.

Impact on Cost and Quality

The lack of a systematic approach to learning contributes to escalating costs as well as quality and safety problems in health care. One often-cited example is Vioxx—a nonsteroidal, anti-inflammatory medication to reduce pain, inflammation, and stiffness caused by osteoarthritis and rheumatoid arthritis—which was pulled from the market in 2004 after researchers found a link between the medication and a higher risk of heart attack and stroke. That connection could have been uncovered much earlier through the use of a large, searchable database filled with data from real-world patients who had used the drug, Etheredge believes.

These databases also could help rein in health care expenditures. “If you want to control costs, you want to promote prevention and use of the most cost-effective treatments and

strategies. Why don't we use cost-effective treatments and strategies? We don't have any way of producing evidence-based quality care that can diffuse rapidly through the health care system," says Nancy Barrand, MPA, senior advisor for program development at RWJF.

HOW HAS THE CONCEPT OF RAPID LEARNING SPREAD?

Etheredge "has developed, promoted, and spread the idea of rapid-learning systems and has been successful in framing the vision—which didn't exist when he started—and in moving it out into the field, and having it resonate with lots of different people; with lots of different institutions," says Barrand.

Turning an abstract idea into a rapid-learning health system involves a laborious process of information dissemination and discussion about this innovation. That is why Etheredge writes journal articles, white papers, reports, and creates and responds to numerous blogs, organizes meetings and workshops, is the lead-off presenter to set the stage for conferences, meets and collaborates with experts and federal health policy staff, demonstrates the concept to numerous groups, and shares his ideas via email to a large network of interested and influential people. All of the promotion and networking is why Barrand thinks rapid learning "is now part of our lexicon." See the [Bibliography](#).

For example, since 2005, Etheredge has worked with many representatives of large health systems, the Institute of Medicine (IOM), the Center for Health Care Strategies (CHCS), the federal government (Centers for Medicare & Medicaid Services, National Institutes of Health (NIH), and AHRQ), and medical specialty societies, among others.

Networking also plays a big role in Etheredge's strategy. "One of the things he does really well in the process of popularizing ideas is making connections to people. Emails I have gotten from him on rapid-learning issues have said, 'X and Y are doing this. Here is a way you might be able to tie into that,' " explains Robert Crane, MBA, MPA, retired senior vice president of research and policy development at Kaiser Permanente, which has been involved in rapid learning for many years.

Key activities to date to popularize the concept of a rapid-learning health system include articles in *Health Affairs*, collaboration on workshops with the IOM, informal guidance to the American Society of Clinical Oncology, collaboration on a conference and a report with the Center for Health Care Strategies, and unpublished pieces he distributes regularly to his network via email—instead of waiting for publication.

Health Affairs

Content in *Health Affairs* has included:

- A special 2007 supplement, *A Rapid-Learning Health System*,² composed of 13 articles, which describe the research potential of rapid learning and the obstacles that must be overcome to implement a rapid-learning health system.
- A 2009 article, “*Medicare’s Future: Cancer Care*,”³ in which Etheredge proposed developing a rapid-learning system for comparative effectiveness, a quality measurement system, and payment reforms to reward high-quality cancer care.
- A 2010 article, “*Creating a High-Performance System for Comparative Effectiveness Research*,”⁴ in which Etheredge suggests how the U.S. Department of Health and Human Services, working with collaborators, can build a high-performing comparative effectiveness research system using rapid learning. (Comparative effectiveness research is a process to compare different ways to diagnose, treat, prevent, or monitor disease.) He also suggests that the federal government build a national, open database with standardized data sets for quality assurance and effectiveness research.

Institute of Medicine (IOM)

Collaboration on projects with staff at the IOM has included:

- A series of workshops on the learning health care system. Etheredge worked with IOM officials on the first workshop, held in July 2006, and was on the planning committee for two subsequent workshops. Between 2006 and September 2011, the IOM held about 20 workshops and produced 11 publications on the learning health care system.

Some of the topics covered in the workshops were:

- The development of evidence-based best practices
 - The role of patients and the public in the rapid-learning system
 - The digital infrastructure that is required to create a rapid-learning system
- A workshop on rapid learning in cancer care (October 2009). Etheredge was a member of the planning committee. The IOM published a summary report in 2010, *A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer*

² “A Rapid-Learning Health System.” *Health Affairs*, 26(2): w107–w118 2007. Available [online](#).

³ Etheredge LM. “Medicare’s Future: Cancer Care.” *Health Affairs*, 28(1): 148–159, 2009. Available [online](#).

⁴ Etheredge LM. “Creating a High-Performance System for Comparative Effectiveness Research.” *Health Affairs*, 29(10): 1761–1767, 2010. Abstract available [online](#).

Care.⁵ Etheredge and other authors also published an article in the *Journal of Clinical Oncology* (2010).⁶

The IOM also formed a consensus committee, A Learning Health Care System in America, to develop recommendations on the government policies or private initiatives that are necessary to accelerate the development of a rapid-learning health system. RWJF is one of several organizations funding this work.⁷ The committee expects to release recommendations in the summer of 2012. Etheredge was briefly involved with this committee.

American Society of Clinical Oncology

After members attended the IOM workshop on rapid learning in cancer care, the American Society of Clinical Oncology decided to develop a rapid-learning network, which it calls the Real-Time Oncology Knowledge Network. Etheredge provides the society with ongoing, informal guidance.

This central knowledge base, with information from millions of physician and patient experiences, will be used to improve clinical decisions, educate patients, and provide data for quality and comparative effectiveness studies, as well as other research. The society is in the very early planning stages of the network, which builds on quality improvement work begun in the early 2000s. It hopes to launch a small pilot focusing on breast cancer in the summer of 2012.

The idea is to create a “continuous cycle of quality improvement, so we can get better and better as we practice,” says Allen Lichter, MD, chief executive officer at the American Society of Clinical Oncology.

Center for Health Care Strategies

Etheredge also worked with the staff at the Center for Health Care Strategies on an April 2008 conference and a report to present the case for creating a rapid-learning network for Medicaid. The report, *Building a Medicaid Rapid-Learning Network: A Key Investment for Medicaid's Future* (January 2009)⁸ outlines ways in which Medicaid could play a leading role in facilitating rapid learning nationally. The Center for Health Care

⁵ *A Foundation for Evidence-Driven Practice: A Rapid-Learning System for Cancer Care*. Washington: National Academies Press, 2010. Available [online](#).

⁶ Abernethy AP, Etheredge LM, Ganz PA, Wallace P, German RR, Neti C, Bach PB and Murphy SB. “Rapid-Learning System for Cancer Care.” *Journal of Clinical Oncology*, 28(27): 4268–4274, September 2010. Available [online](#).

⁷ ID# 68536, December 2010 to June 2012.

⁸ Bella M, Shearer C, Somers S, Etheredge L and Moore J. *Building A Medicaid Rapid-Learning Network: A Key Investment for Medicaid's Future*. Washington: George Washington University, 2009. Available [online](#).

Strategies is a nonprofit research organization in Hamilton, N.J., focused on improving health care quality for low-income children and adults, people with chronic illnesses and disabilities, frail elders, and racially and ethnically diverse populations experiencing disparities in care. It was founded with funding from RWJF.

Speeding Up the Spread of Ideas

To spread his ideas more rapidly than is possible through traditional media, Etheredge also has distributed opinion pieces to his professional network through email.

Topics he has covered include how to build a rapid-learning system for pediatric medical research; and a national set of core data elements and applications to be included in electronic medical-record systems to support clinical care, quality reporting and medical research.

RWJF's Support for Other Rapid-Learning Projects

Building on the growing interest in rapid learning, RWJF has made other grants to support pieces of a rapid-learning health system. Although Etheredge did not bring these projects to RWJF, “he has done more to promote them than any dissemination strategy we could have funded,” says RWJF’s Barrand:

- A five-year, \$15.6 million grant⁹ in 2007 to Archimedes, Inc., to build a reasonably priced health care simulator (ARCHimedes Health Care Simulator or ARCHeS) for use in answering questions about the effects of clinical and administrative interventions on health and logistics and economic outcomes in specific groups of people.
- A three-year, \$8.5 million grant¹⁰ in 2008 to the Kaiser Foundation Research Institute (part of Kaiser Permanente) to help fund the creation of a biobank to determine which behavioral, environmental, and genetic factors are linked to certain diseases. RWJF’s investment was followed by a \$24.8 million NIH grant in 2009.
- Three grants totaling \$5.2 million¹¹ and running from February 2009 to May 2012 for Project ECHO (Extension for Community Healthcare Outcomes) to train primary care providers in best practices for complex health conditions in order to expand access to specialized care for vulnerable populations and underserved areas, using state-of-the-

⁹ ID# 57707

¹⁰ ID# 64362

¹¹ ID# 63945, for \$5 million. The second and third grant, ID# 69313 and ID# 69723, are to position Project ECHO to get funding from the Centers for Medicare & Medicaid Services and to develop a business plan.

art telehealth technology and clinical-management tools that help to build capacity among community-based providers.¹²

HOW IS THE FIELD EMBRACING RAPID LEARNING?

Rapid-learning ideas and initiatives are becoming part of mainstream health care, something few people believed possible when Etheredge started this work. “The system is much more open than most people would have expected to new ideas and new paradigms,” Etheredge says.

Helping the Federal Government Apply Rapid Learning

Etheredge has worked with health care executives and researchers to show federal health policy staff how rapid learning applies to federal programs such as Medicare and Medicaid. The federal government has applied the concept of a rapid-learning health system in two federal laws:

- A \$10-billion Center for Medicare & Medicaid Innovation, which was included in the health reform law (the Patient Protection and Affordable Care Act) passed in March 2010. The innovation center is charged with rapidly researching, testing, and disseminating information on new models for health care delivery and financing. Projects begun in 2011 include:

Demonstration projects in hospitals to reduce hospital-acquired injuries and complications as part of the \$1 billion Partnership for Patients. The partnership is designed to prevent millions of injuries and complications in hospitalized patients and reduce re-admissions due to complications after leaving the hospital.

A project called, Million Hearts, which is designed to prevent one million heart attacks by 2017 by empowering Americans to make healthy choices (e.g., not smoking and reducing consumption of sodium and trans fats) and improving health care for people at risk of having a heart attack. The project includes \$85 million in grants to 10 states for Medicaid Incentives for Prevention of Chronic Diseases.

- Funding totaling \$1.1 billion for what is known as comparative effectiveness research in the stimulus bill—the American Recovery and Reinvestment Act of 2009. The idea is to give physicians, patients, and decision-makers concrete information about which interventions work best for specific categories of patients under specific circumstances.

“Until we got this \$1.1 billion, nearly all comparative effectiveness research involved reading the published literature. This creates a system in which the federal government is going to figure out proactively the priorities of what the public needs

¹² Etheredge has helped disseminate Project ECHO to the U.S. Department of Veterans Affairs (VA) and other places, according to RWJF’s Barrand.

to know ... and have up to \$1.1 billion for new research that will specifically address those questions,” Etheredge says.

Under the stimulus law, the NIH received \$400 million and the AHRQ received \$300 for comparative effectiveness research. Examples of uses of this funding include:

NIH:

- New types of research that focus on health and science problems where significant progress can be made within two years
- Support of infrastructure and personnel for ongoing research

AHRQ:

- Many projects to build the electronic infrastructure and scientific methodologies necessary to conduct comparative effectiveness research

The HMO Research Network

Other organizations and groups, including the HMO Research Network, are also using rapid learning in health care. Etheredge often cites the HMO Research Network, comprised of 19 health care delivery organizations (including Kaiser Permanente and Geisinger Health System) as an example.

Since the early 2000s, the HMO Research Network has been developing a virtual data warehouse that can be used for comparative effectiveness studies and other research. Members are in the midst of developing common data standards for eight types of data, including prescription medications, procedures, and laboratory tests, for use in this research (as of September 2011). The NIH has helped support this work with a \$1 million grant.

“That process is really difficult,” says Walter “Buzz” Stewart, PhD, MPH, chairman of the board of the HMO Research Network. He also is the associate chief of the research office and director of the Center for Health Research at Geisinger. Stewart notes, though, that all network members are providing data that other sites can use. For example, “If I wanted to find out how many primary care patients who were 50 and older had an LDL over 130, I could submit the same SAS program to all those sites and get a count. That allows me to learn things quickly about potential partnering sites if I am planning a study.” (SAS is software for analyzing data.)

Researchers at the member organizations can access the data, which is stored at each individual organization, by making a request to that organization’s human gatekeeper.

A Focus on Two Medical Specialties

Along with work to broadly develop a rapid-learning health care system, Etheredge is also drilling down to focus on two medical specialties: cancer and pediatrics. Physicians in cancer and pediatrics have a history of sharing data and collaborating on research, making them logical starting points for specialty-specific rapid-learning research networks. Etheredge has spent a considerable amount of time on education and networking activities directed at these specialties.

Cancer

“Cancer is a big problem. It is very prevalent, very expensive, has a high societal burden, and is complicated. There is a lot of information about cancer that is not very well organized,” says Sharon Murphy, MD, a pediatric oncologist and scholar-in residence at the Institute of Medicine (IOM). “There also is a very big concern about the perfect storm: an aging population and the escalating costs of cancer care,” she adds. Murphy collaborated with Etheredge on a workshop on how to apply rapid-learning concepts to cancer.

The field of oncology also has a head start in the development of a rapid-learning network, through the National Cancer Institute’s network of cancer centers and multicenter cooperative group clinical trials. “There is a ton of information from the national cancer program,” Murphy says.

Pediatrics

“Most pediatric practices are so small. Even an academic center won’t have enough patients in sickle cell anemia or cerebral palsy and many other conditions to allow it to do all the research projects that need to be done,” says Etheredge.

But pediatricians also collaborate. One example is the Children’s Oncology Group, a clinical trials group supported by the National Cancer Institute and comprised of 7,500 experts in childhood cancer at more than 200 leading children’s hospitals, universities, and cancer centers. The Children’s Oncology Group collects, aggregates, and analyzes data from pediatric cancer clinical trials.

WHAT CHALLENGES IS THE PROJECT FACING?

“The biggest initial challenge is intellectual or psychological. This is a new way of thinking about how to make progress and how to develop the capabilities to exploit new technologies—electronic health records and computerized databases,” says Etheredge. That is why Etheredge has promoted the concept of rapid learning in many different venues—from one-on-one meetings to large conferences—since the project began in 2005.

AHRQ’s Clancy agrees, “Some of it is developing the culture within organizations. Part of what we do is provide the best care to patients that we can one at a time, but we also need to look back systematically, so that we see how we are doing. That is key to quality improvement.”

Other challenges include:

- **Ownership of data.** Many large health systems are engaged in rapid learning already. They have robust electronic health record systems and large databases. But to learn rapidly on a national scale, the individual databases or at least the information contained in them would need to be linked together. This raises the issue of ownership of the data.

“That involves fundamentally moving the market dynamics into a very different position in which clinical data are treated as a public trust; as a common good in which all parties involved—manufacturers, insurers, health systems—give up their right to economic gains by selling their data or intellectual gain by publishing their data before anyone else,” says J. Michael McGinnis, MD, MPP, senior scholar and executive director of the Roundtable on Value and Science-Driven Health Care at the IOM.¹³

The federal government, particularly the NIH, has a role in facilitating the concept of public data. “Government funds a big chunk of the health care research. It could help by both requiring data sharing (for government-funded research) and bringing the best research into a central database, so you can literally log on to the world’s best evidence,” Etheredge says.

- **Data consistency.** To extract data from multiple sources, the definitions of data elements need to be the same. For example, there are many different ways to express gender, a basic data element.
- **Automated data collection.** And the process of feeding data from multiple sources into a national database should be automatic. Otherwise, the process of keeping large, national research databases current would be time-consuming and expensive.
- **Privacy.** The federal Health Insurance Portability and Accountability Act (HIPAA) regulates the use/disclosure of personal health information by health care providers, health plans, and health care clearinghouses (which process nonstandard health information received from others into a standard electronic format or data content, or vice versa.) The use of patient data in research was a secondary consideration in the law, in the opinion of Etheredge.

As a result, it is not entirely clear how to apply HIPAA to large, searchable databases that many researchers could have access to for many research projects. “Many experts

¹³ McGinnis is a former RWJF vice president, who was in charge of the Health Group.

think HIPAA will eventually need to be updated for the emerging world of electronic health records and rapid-learning research,” says Etheredge.

WHAT HAVE WE LEARNED?

It is possible to rise above partisan politics. “Much of Washington has been caught up for decades in health policy as a partisan, contentious, and highly politicized endeavor with endless budget debates—ideologies about markets versus regulations. People said to me, ‘This will never work,’ ” says Etheredge. But it did.

WHERE DO WE GO FROM HERE?

While rapid-learning ideas and initiatives are becoming part of mainstream health care, “There is still much progress to be made, and the pieces are not yet functioning together as a coherent, high-performance learning system,” says Etheredge.

Etheredge continues to informally advise the staff at the Center for Medicare & Medicaid Innovation on how to apply a rapid-learning approach to the Partnership for Patients and Million Hearts.

And he continues to meet with representatives of medical specialty societies and other organizations to encourage the development of rapid-learning systems in cancer and pediatrics. He also will begin to devote some of his time to networking and communication activities targeted at a third specialty—cardiology.

Ultimately, however, the health care sector must move beyond such a piecemeal approach to creating a rapid-learning health system. An institutional leader needs “... to stand up and say, ‘This is a vision of the future that we could all embrace and make happen’—instead of stumbling toward it and possibly missing certain parts of it,” Barrant says.

Prepared by: **Linda Wilson**

Reviewed by: Lori De Milto and Molly McKaughan

Program Officer: Nancy Barrant

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APPENDIX

People Interviewed for this Report

Nancy Barrand, MPA

Senior Advisor for Program Development
Robert Wood Johnson Foundation
Princeton, N.J.

Lynn Etheredge, PhD

Consultant
National Health Policy Forum
George Washington University
Washington, D.C.

Allen Lichter MD

Chief Executive Officer
American Society of Clinical Oncology
Alexandria, Va.

Carolyn Clancy, MD

Director
Agency for Healthcare Research and Quality
U.S. Department of Health and Human
Services
Rockville, Md.

Robert Crane, MBA, MPA

Retired Senior Vice President of Policy
Development
Senior Advisor

Kaiser Permanente
Encinitas, Calif.

J. Michael McGinnis, MD, MPP

Senior Scholar
Institute of Medicine
National Academies of Sciences
Washington, D.C.

Sharon B. Murphy, MD

Scholar-in-Residence
National Cancer Policy Forum
Institute of Medicine
National Academy of Sciences
Washington, D.C.

Janet L. Shikles, MA, MSW

Independent Health Care Consultant and
Policy Analyst
Denver, Colo.

Walter “Buzz” Stewart, PhD, MPH

Associate Chief Research Officer
Geisinger Center for Health Research
Danville, Pa.

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