



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES



HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH

An Institute of Medicine workshop sponsored by the Patient-Centered Outcomes Research Institute



June 20, 2014
The National Academies
2101 Constitution Avenue, NW
Washington, DC 20418

Health System Leaders Working Towards High Value Care Through Integration of Care and Research



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<http://www.iom.edu/HealthSystemLeaders>.
- Healthcare executives' opinions on the value and challenges of integrating research into care systems: Preliminary results. GroupHealth Research Institute.

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- The Learning Health System Series, IOM Roundtable on Value & Science-Driven Health Care
- *Best Care at Lower Cost* report brief, IOM Roundtable on Value & Science-Driven Health Care
- Huang, S. S., et al. 2013. Targeted versus universal decolonization to prevent ICU infection. *New England Journal of Medicine* 368:2255–2265.
- Platt, R., S. S. Huang, and J. Perlin. 2013. A win for the learning health system. Commentary, Institute of Medicine, Washington, DC. <http://www.iom.edu/WinforLHS>.
- Fleurence, R. L., L. H. Curtis, R. M. Califf, et al. 2014. Launching PCORnet, a national patient-centered clinical research network. *Journal of the American Medical Informatics Association* <http://jamia.bmj.com/content/early/2014/05/12/amiajnl-2014-002747.full>
- McGlynn, E. A., T. A. Lieu, M. L. Durham, et al. 2014. Developing a data infrastructure for a learning health system: the PORTAL network. *Journal of the American Medical Informatics Association* 21:596–601.
- Kaushal, R., G. Hripcsak, D. D. Ascheim, et al. 2014. Changing the research landscape: the New York City Clinical Data Research Network. *Journal of the American Medical Informatics Association* 21:587–590.

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Workshop Framing Materials



HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF RESEARCH AND PRACTICE



*An Institute of Medicine Workshop
Sponsored by the Patient-Centered Outcomes Research Institute*



A LEARNING HEALTH SYSTEM ACTIVITY

JUNE 20, 2014
THE NATIONAL ACADEMIES OF SCIENCES BUILDING
2101 CONSTITUTION AVE NW
WASHINGTON, DC

Meeting goals

1. **Continuous learning infrastructure and business case.** What are the key infrastructure, value proposition, and business case implications in integrating research and practice as the foundation of a continuously learning health system?
2. **Aligning continuous improvement and knowledge generation.** What infrastructure commonalities exist in aligning executive agendas and **knowledge generation** priorities, and driving continuous improvement through learning.
3. **Institutional opportunities.** Consider common principles and strategies for participants to move priorities forward in their own institutions.
4. **PCORI contributions.** Reflect on strategic infrastructure and research opportunities for PCORI that can support delivery systems in evolving toward learning health systems.

8:00 am Coffee and light breakfast available

8:30 am	Welcome, introductions, and overview
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Welcome

Michael McGinnis, Institute of Medicine

Opening comments from the IOM

Victor Dzau, President-elect, Institute of Medicine

Opening comments from PCORI

Joe Selby, Executive Director, Patient-Centered Outcomes Research Institute

Opening comments from Planning Committee

Eric Larson, Planning Committee Chair, Group Health Research Institute

9:00 am	Continuous learning and improvement in health care
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This session will introduce the concepts of a learning health system and highlight an example of an effort that was successful in integrating research and practice and resulted in cost savings.

The learning health system (8 minutes)

Michael McGinnis, Institute of Medicine

The REDUCE MRSA Trial (12 minutes)

Jonathan Perlin, HCA Inc

Open Discussion (40 minutes)

10:00 am	Continuous learning as an executive agenda priority
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This session will include a panel and moderated roundtable discussion among workshop participants of the challenges and opportunities they see to continuous learning within their institutions.

Moderator- *Lew Sandy*, UnitedHealth Group

Panel (20 minutes)

Glenn Steele, Geisinger Health System

Ronald DePinho, University of Texas MD Anderson

Rodney Hochman, Providence Health and Services

Steven Corwin, New York-Presbyterian Hospital

Open Discussion (55 minutes)

11:15am	Introduction to PCORI's research network
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This session will provide a brief introduction to the PCORI-funded national patient-centered clinical research network, PCORNet.

PCORNet (12 minutes)

Joe Selby, Executive Director, Patient-Centered Outcomes Research Institute

Open Discussion (13 minutes)

11:40 am	Lunch
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12:25 pm	Clinical Data Research Networks
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This session will include brief presentations from PCORNet Clinical Data Research Networks (CDRNs) leadership on their progress and plans.

**Patient Outcomes Research to Advance Learning (PORTAL) Network
(10min)**

Elizabeth McGlynn and Ray Baxter, Kaiser Permanente

New York City Clinical Data Research Network (10min)

Rainu Kaushal, Weill Cornell Medical College

Open Discussion (20 minutes)

1:10 pm	Multi-use infrastructure for continuous learning
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This session will include a panel and moderated roundtable discussion among workshop participants of the challenges and opportunities to the establishment and maintenance of infrastructure for continuous learning including through PCORNet.

Moderator- *Sarah Greene*, Patient-Centered Outcomes Research Institute

Panel (25 minutes)

Patrick Conway, Centers for Medicare & Medicaid Services

Brent James, Intermountain Health Care

Scott Armstrong, Group Health Cooperative and MedPAC

John Warner, University of Texas Southwestern Medical Center

Open Discussion (50 minutes)

2:25 pm	Break
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2:40 pm	Open discussion of needs, opportunities, and strategies
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This session will include a discussion to identify strategic opportunities, priorities, and commitments from participants to move priorities forward in their own institutions.

3:50 pm	Wrap-up and next steps
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4:00 pm **Adjourn**

**HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH
INTEGRATION OF CARE AND RESEARCH**

Workshop Planning Committee

Chair

Eric B. Larson, MD, MPH, MACP
Vice President for Research
Group Health

Members

Raymond Baxter, PhD
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Research and Health Policy
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Artist and Patient Data Activist

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HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH

June 20, 2014

Workshop Participants

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Health System Leaders Working Toward High-Value Care Through Integration of Care and Research—Workshop in Brief

In April 2014, the Institute of Medicine's (IOM's) Roundtable on Value & Science-Driven Health Care and the Patient-Centered Outcomes Research Institute (PCORI) convened the first of two workshops aimed at engaging health system leaders in accelerating progress toward the seamless integration of clinical practice and research, one of the fundamental concepts of a continuously learning health system.

Ongoing real-time assessment of the effectiveness and efficiency of care is basic to a continuously learning and constantly improving health care system (see Figure 1). Advancements in the digital infrastructure and development of innovative methods for research and learning now make this aim achievable in health care. As described by Eric Larson of Group Health in his introductory comments, the workshop brought together health care system leaders, both administrative and clinical, and researchers, including grantees of PCORI's National Patient-Centered Clinical Research Network (PCORnet, see Box 1) to

- broaden and deepen health system leadership's awareness of the prospects for and from a continuously learning health system;
- foster the development of a shared commitment, vision, and strategy among health system leaders for building and maintaining the networked capacity;
- identify common approaches in meeting health systems responsibilities for science, technology, ethics, regulatory oversight, business, and governance;
- consider and learn from models and examples of productive integration of research with care delivery programs; and
- explore strategic opportunities for executive, clinical, and research leaders to forge working partnerships for progress.

BOX 1 PCORnet

PCORnet is a large, highly representative national network of health care information networks—11 Clinical Data Research Networks and 18 Patient-Powered Research Networks—that will conduct large-scale clinical outcomes research by establishing a resource of clinical data gathered in real time and in real-world settings such as hospitals and clinics. A hallmark of PCORnet is its requirement that patients, clinicians, and health care systems that provide the research data housed in each constituent network be involved in the governance and use of the data. PCORnet aims to advance the shift in clinical research from investigator-driven to patient-centered studies, and by the end of its first 18-month phase, PCORI expects that a fully functional research network will be in place and ready to support comparative effectiveness research. PCORnet hopes to be a unique opportunity to make a real difference in the lives of patients and their families by building clinical research into the health care process to provide the answers that patients need quickly, efficiently, and at lower costs than previously possible.

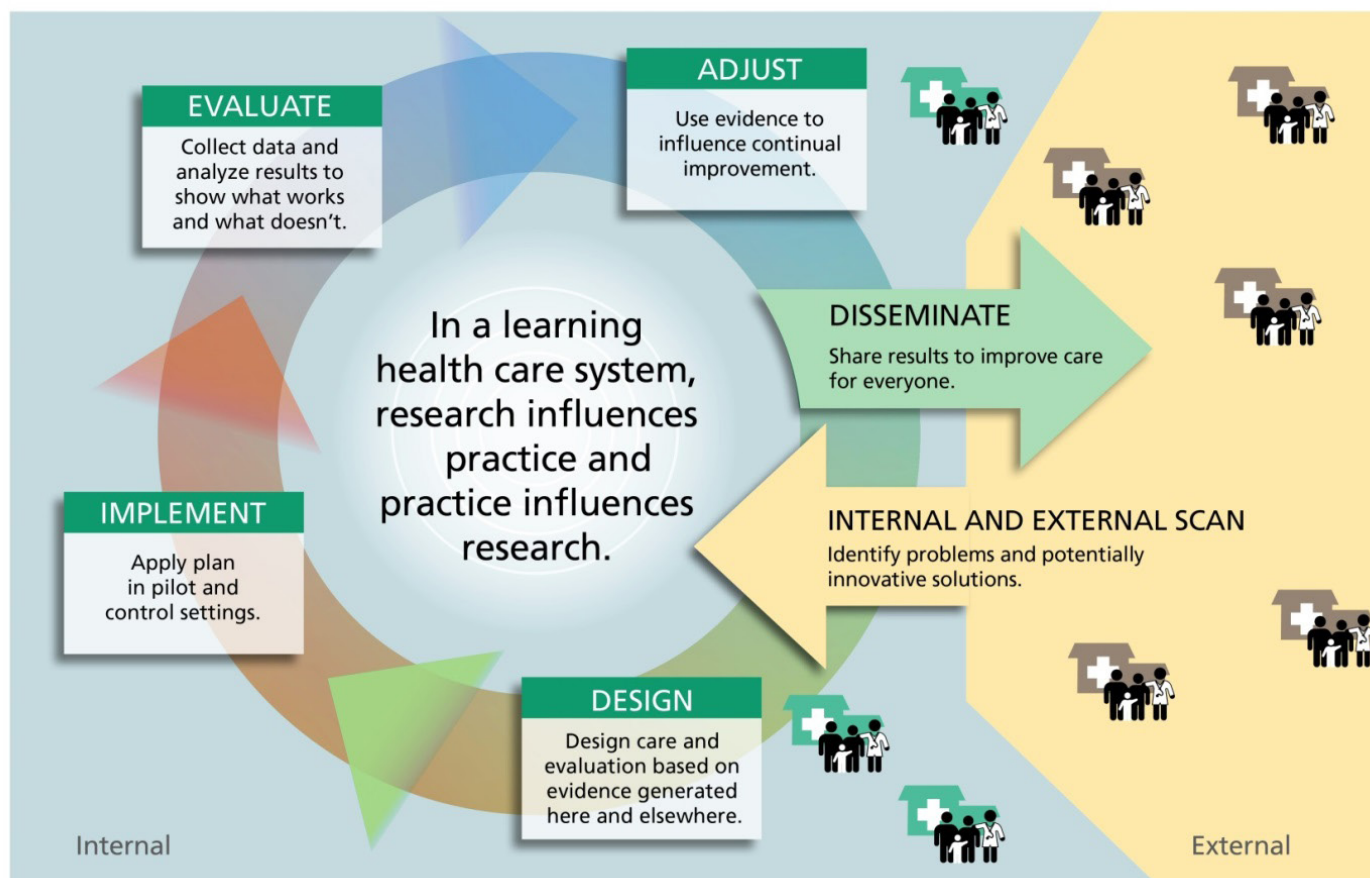


FIGURE 1 The “virtuous cycle” of a learning health care system.

SOURCE: Greene SM, Reid RJ, Larson EB. Implementing the learning health system: from concept to action. *Ann Intern Med.* 2012 Aug 7;157(3):207-10. doi: 10.7326/0003-4819-157-3-201208070-00012. PubMed PMID: 22868839.

This workshop in brief summarizes the major topics of the workshop’s presentations and discussions. In June 2014, a second workshop will convene health system chief executive officers (CEOs) on opportunities for leadership in building, growing, and making full use of the infrastructure necessary for greater integration of research and practice. A detailed summary of both workshops will be published after the June session.

Throughout the workshop, sessions focused on the value proposition, sustainability, ethics, governance, and stakeholder engagement, and individual workshop participants identified specific issues captured in the sections below. Statements, recommendations, and opinions expressed are those of individual presenters and participants and are not necessarily endorsed or verified by the Roundtable or the IOM, and they should not be construed as reflecting any group consensus.

The role of leaders

Throughout the course of the workshop, many speakers and commenters, including Russ Waitman of the University of Kansas Medical Center and Raymond Baxter from Kaiser Permanente, stressed the need for CEOs to take the lead in getting all stakeholders, including patients and families, involved as partners in a continuously learning health system. “CEOs need to be out front in enlisting patients and families as active allies, particularly with vulnerable populations. This can bring a community perspective and research perspective together with the health system perspective and have the potential to generate great solutions,” said Waitman.

The observation was made by several speakers that every organization has a limited bandwidth, not only in terms of the research it can support financially but also with respect to institutional energy. Therefore, it was suggested that it is critical to align research initiatives with institutional improvement priorities to maximize the impact of research. “It is important when judging whether to move forward with a research project to consider whether it takes up too much intellectual capital in the context of its place in the institution’s priorities,” said Brent James of Intermountain Healthcare.

Peter Knox of Bellin Health stated in his presentation that “creating a culture that creates value at speed is critical.” Health care systems face tremendous financial pressures today, placing a premium on research that can be deployed rapidly to increase system efficiency, improve patient outcomes and satisfaction, and reduce costs, he said. Demonstrating that PCORnet can enable fast, focused studies will be key to winning CEO support for creating a sustainable learning system, commented Mary Brainerd of HealthPartners, Inc.: “We need performance change and time horizons that are more rapid than those created by the standard research structure.”

Brainerd noted that from her standpoint as a CEO, “I want to bring patientness to everything that we do, everything we design, every way we think about what we are going to do in research and what we need to learn so that patient/family member partnership is hugely important.” “Without the patient’s perspective, a continuous learning health system will not be sustainable,” said Sally Okun of PatientsLikeMe, voicing a sentiment echoed by almost all of the workshop’s speakers.

Value proposition and sustainability

Several speakers, including Baxter and David Labby from Health Share of Oregon, noted that given the financial pressures facing health systems today, it is imperative that knowledge generation activities, whether through PCORnet or under other institutional auspices, have a viable value proposition if they are to be sustainable over the long term. As Baxter put it, “CEOs want speed and they want relevance, so unless we can organize our research and analytic capabilities in a way that builds on core functions and demonstrates impact on improving care and improving health, that will be a cost that the health system cannot afford to bear.”

Sarah Greene from PCORI noted that creating a meaningful value proposition requires specifying the factors that are important to the customers and impact the customers’ belief that they are getting value. As Thomas Graf from Geisinger Health system put it, “If we want to be successful and we want to maintain that value proposition long term, it has to be tied to the things that intrinsically create value for the folks that are delivering that care.”

Organizational alignment was raised by several speakers and discussants, both with respect to the functional alignment of infrastructure capacities needed for financial and management tracking, quality improvement, and knowledge generation, as well as how to align an organization around a value proposition and deliver on that value proposition using the energy that the organization has. “I would argue that unless we can align research around that value proposition and help organizations to deliver value, that we won’t integrate research in practice,” said Knox.

“Transformation of a research enterprise requires a transformation of governance,” said John Steiner of Kaiser Permanente Colorado. Effective, skillful governance is needed to promote sustainability of research, both in terms of being able to develop shared research assets to conduct studies and developing a community of researchers and stakeholders who reuse and develop those assets.

Quality can be a competitive advantage, and those generating data to support improvement may not want to share because it could erode their competitive advantage and negatively impact an organization’s value proposition. “Knowledge can be a public good or a private commodity where people are setting up infrastructure for financial incentives that provide a competitive advantage,” warned Trent Haywood of the Blue Cross Blue Shield Association.

Research will be sustainable when the findings it generates are integrated into clinical workflow, so that “best care” is the default choice that happens automatically unless modified for a specific patient, said James. One of the challenges for researchers and quality improvement staff in most health systems is that they are not skilled at making value propositions using the financial language that chief financial officers understand, noted Stephen Grossbart of Catholic Health Partners. “There is a need for finance and quality improvement groups to work collaboratively, and that can be a real challenge,” Grossbart said.

Implementation at scale

Insights and knowledge not captured or applied do little to advance the development of a continuously learning health care system. As Jean Slutsky of PCORI said, “Where the rubber meets the road is integrating learning into the delivery of care.”

“We need to advance the science of how to implement what we know,” said Robert Dittus of Vanderbilt University Medical Center. Jonathan Tobin of the Clinical Directors Network noted that “PCORnet provides the opportunity to collect the information needed to advance that science in a rigorous manner.” David Posch of Vanderbilt University Hospital and Clinics suggested that PCORI should study the science of execution and added that “the pressing issue today is how do we execute and implement at scale what we already know, because as CEO, I have to make cost cuts now.”

A challenge that must be addressed is how to balance the needs of researchers to publish their work and the needs of health care systems to deploy improvements as rapidly as possible, said Susan Huang of the University of California, Irvine, and others. Janice Nevin of Christiana Care Health System also cast light on the tension that exists between the questions that interest researchers and those that are priorities for health system leaders.

Patrick Conway of the Centers for Medicare & Medicaid Services wondered how to make the individual examples of success the rule rather than the exception. He suggested that one solution might be to integrate streams of revenue and incentives in a way that is standard in most industries and that can provide solid evidence to support a value proposition.

Improvement as an ethical imperative

“There is an ethical imperative to improve the system and to the extent that we impede improving the system [through unresponsive oversight], we are doing something that is probably unethical,” said Edward Havranek of Denver Health. He noted that health systems and their internal review boards (IRBs) need to recognize when it is appropriate to have an expedited process for demonstrating that quality-directed research poses little risk to individual patients. Agreeing with Havranek, Huang asked, “How do we get more uniformity in the way IRBs treat minimal risk studies aimed at quality improvement?”

In a learning health care system, ethics-relevant policies must be transparent about ongoing learning, engage patients to help decide which studies need consent and further protections, and be accountable, said Nancy Kass of Johns Hopkins.


Partnership and respect

A hallmark of successful, continuously learning health systems is the partnership that develops among clinicians, patients, and health system leaders, said Peter Margolis of Cincinnati Children's Hospital Medical Center. Strong partnerships, particularly those that include patients, based on ethical principles and respect, will be just as important for realizing the full potential of PCORnet to generate the data needed to inform a learning health system.

"We need structure that deliberately and purposefully includes patients and families in designing care in a meaningful way; otherwise we're not going to get it right," commented Nevin. "CEOs need to embrace the idea of partnership with patients and families as a core business strategy, and then they can start to provide an infrastructure that not only gives patients a seat at the table but a voice at the table," she said. "Engaging patients around the definition of value is an interesting way of framing patient engagement and a real opportunity," said Holly Peay of the National Human Genome Research Institute. Margolis noted that one of the keys to engaging physicians in learning is understanding what incentives, economic as well as social and intrinsic, are important to them. He added that these can vary and are often reflective of the institutional cultures in which they practice.

Shared data plus shared decision making equals shared accountability, said Okun. She added that "patients want to see their data coming to life in a way that is going to be useful to you. If you begin to embrace that notion, you will find that patients are ready, willing, and able to participate in a variety of research studies." Margolis noted that to achieve shared learning, more work is needed on how to inform patients about comparative effectiveness research and how being part of a network can benefit them.



Integration of research and practice is fundamental to progress toward a health system that continuously learns and improves care, outcomes, and value. Individual workshop presentations and discussions highlighted the importance of engaging health system leaders as essential partners and leaders in building the necessary and sustainable infrastructure, such as PCORNet, needed to achieve this integration. The challenges identified will inform future discussion, including the second part of this two-workshop series focusing on opportunities for CEO leadership. 

Roundtable on Value & Science-Driven Health Care

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*Ex Officio

PLANNING COMMITTEE ON HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH**

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This workshop in brief was reviewed by **John Steiner**, Kaiser Permanente, and **David Ballard**, Baylor Scott & White Health. **Chelsea Frakes**, Institute of Medicine, served as review coordinator to ensure that the workshop in brief meets institutional standards for quality and objectivity.

This workshop was sponsored by the Patient-Centered Outcomes Research Institute.

DISCLAIMER: This workshop in brief has been prepared by **Claudia Grossmann** and **Joe Alper** as a factual summary of what occurred at the meeting. The statements made are those of the authors or individual meeting participants and do not necessarily represent the views of all meeting participants, the planning committee, or the National Academies.

**IOM planning committees are solely responsible for organizing the workshop, identifying topics, and choosing speakers. The responsibility for the published workshop in brief rests with the institution.

For additional information regarding the workshop, visit www.iom.edu/activities/quality/vsrt/2014-apr-23.aspx

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EXECUTIVE SUMMARY

Healthcare executives' opinions on the value and challenges of integrating research into care systems: Preliminary results

Introduction

On April 23-24, 2014, the Institute of Medicine (IOM) convened a meeting sponsored by the Patient-Centered Outcomes Research Institute (PCORI) on "Health system leaders working towards high value care through integration of care and research." This report summarizes a follow-up survey about the value and challenges of integrating research into care systems, focusing on responses from healthcare executive attendees.

Methods

The PCORnet Health Systems Interaction & Sustainability Task Force staff at Group Health Research Institute administered the survey. We asked respondents open-ended questions about their perspectives on the value, if any, as well as the barriers and challenges of conducting what we termed "knowledge generation activities" in their organization (see box).

We received a 62.8% response rate and 47% of respondents (23) had a "C-suite" role such as chief medical officer or chief executive officer. We categorized their responses into themes. The most common ones are listed below along with example quotes.

Top ways knowledge generation adds value

1. It advances organizational mission and strategy
"The greater the value, the more our healthcare system is preferred by patients and payers."
2. It supports operations
"...by facilitating process improvement utilizing data, at least in part, that has been generated from within the organization."
3. It improves care
"It helps us to be successful in our primary mission which is to deliver health care that is safe, timely, effective, efficient, equitable and patient centered."

Definition used in survey

A continuous learning healthcare system is one where knowledge is derived from practice and used to drive the cycle of continuous improvement. *Knowledge generation* can include data analysis for process improvement as well as a range of research activities, for example:

- An observational study using data from different organizations to compare stroke rates among patients treated with either dabigatran or warfarin therapy for atrial fibrillation.
- A cluster randomized trial where hospitals are randomized to either routine care or chlorhexidine bathing and nasal decolonization in order to assess if this reduces hospital-associated infections.

Top concerns and challenges

1. It interferes with operations (note that operations appeared both as a value and challenge)
“The value of well done research, while potentially tremendous, seems to be significantly out of synch with the needs of a health care system that is facing growing pressure and an ever increasing pace of change.”
2. Research and healthcare systems are set up differently
“The infrastructure for learning and improvement is not adequate; there is a disconnect between those who see themselves as generating knowledge with those who are trying to meet new expectations for better system outcomes.”
3. Integrating research into healthcare systems involves a culture change
“Speed of transfer is somewhat reliant on the standardization of the generated knowledge, and the willingness of the care ecosystem to accept that standardization. While there are logistical challenges in this, the cultural challenges are greater.”

A new model and approach

In addition to the value and challenges discussed above, a theme that emanated from the responses was that knowledge generation supporting a learning healthcare system may be *different* in terms of objectives and methods from how either research or quality improvement is typically understood. As one participant wrote:

“Research of this kind should be undertaken as the result of a disciplined organizational process that sets priorities and links the value of the research back to the mission of the organization. In addition, knowledge generation around the ‘science of execution’ is a critical component of the knowledge need for organizations that desire to be high performing and competitive in the marketplace.”

These findings will be used alongside other work by the IOM’s Roundtable on Value & Science-Driven Health Care and by PCORI to inform the methods and value proposition for linking research and practice to advance high-quality, patient-centered care at a reasonable cost in the United States. In particular, PCORnet: The National Patient-Centered Clinical Research Network will use this information to develop resources and strategies to support the sustainable conduct of studies using “real-time” data in “real-world” settings.

Prepared 6/11/2014 by:

Karin Johnson, PhD, Research Associate, Group Health Research Institute

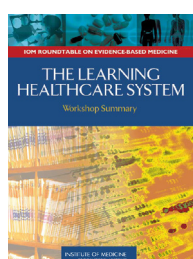
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Background Materials

The Learning Health System Series

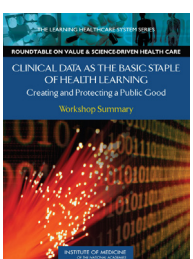
Continuous improvement and innovation in health and health care

To facilitate progress toward the development of a *learning health system*—in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience—the Roundtable on Value & Science-Driven Health Care has marshaled the insights of the nation's leading experts to explore in detail the prospects, and the necessity, for transformational change in the fundamental elements of health and health care. The assessments are reported in the 15 volumes of the IOM *Learning Health System Series*, published by the National Academies Press.



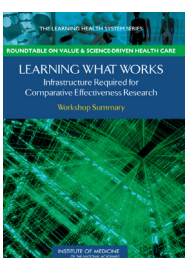
VISION

Vision. *The Learning Healthcare System*, the first in the series, explores the various dimensions—evidence development and standards, care culture, system design and operation, health data, clinical research, information technology, value—on which emerging insights and scientific advances can be applied for health care in which both evidence development and application flow seamlessly and continuously in the course of care.



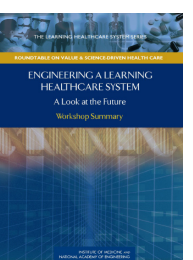
THE DATA UTILITY

The Data Utility. *Clinical Data as the Basic Staple of Health Learning: Creating and Protecting a Public Good* identifies the transformational prospects for large interoperable clinical and administrative datasets to allow real-time discovery on issues ranging from disease etiology to personalized diagnosis and treatment. Also explored are key priorities for data stewardship if clinical data are to be a carefully nurtured resource for continuous learning and better care.



EVIDENCE

Evidence. *Learning What Works: Infrastructure Required for Comparative Effectiveness Research* assesses the nature and magnitude of needed capacity for new knowledge and evidence about what care works best under different circumstances, including the necessary skills and workforce, data linkage and improvement, study coordination and results dissemination, and research methods innovation.



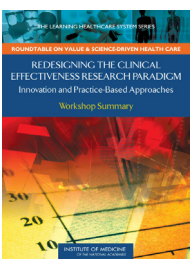
SYSTEMS ENGINEERING

Systems Engineering. *Engineering a Learning Health System: A Look at the Future* reviews transferable lessons from the systems and operations engineering sciences applicable for improving the organization, structure, and function of the delivery, monitoring and change processes in health care—in effect, engineering approaches to continuous feedback and improvement on quality, safety, knowledge, and value in health care.



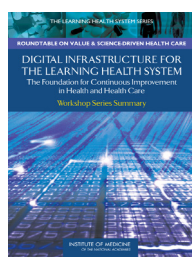
CARE COMPLEXITY

Care Complexity. *Evidence-Based Medicine and the Changing Nature of Health Care* explores the forces, such as genetic insights and increasing care complexity, driving the need for better medical evidence; the challenges with which patients and providers must contend; the need to transform the speed and reliability of new medical evidence; and the legislative and policy changes that could enable evolution of an evidence-based, learning system.



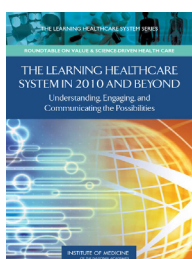
EFFECTIVENESS RESEARCH

Effectiveness Research. *Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Practice-Based Approaches* reviews the growing scope and scale of the need for clinical effectiveness research alternatives, the limits of current approaches, the potential for emerging research and data networks, innovative study designs, and new methods of analysis and modeling.



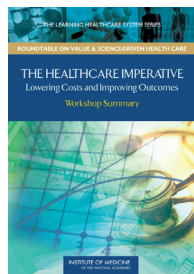
DIGITAL PLATFORM

Digital Platform. *Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care* explores current efforts and opportunities to accelerate progress in improving health and health care, and identifies priority follow-up action targets: technical innovation; data and research insights; patient and public engagement; and stewardship and governance.



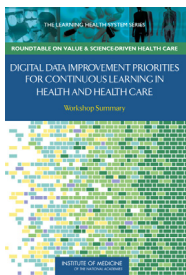
PATIENTS & THE PUBLIC

Patients & the Public. *Patients Charting the Course: Citizen Engagement and the Learning Health System* assesses the prospects for improving health and lowering costs by advancing patient involvement in the elements of a learning health system, and underscores the centrality of communication strategies that account for and engage individual perspectives, needs, preferences, understanding, and support necessary to mobilize change.



COST & OUTCOMES

Cost & Outcomes. *The Healthcare Imperative: Lowering Costs and Improving Outcomes* presents a 6-domain framework for understanding and estimating excess healthcare costs: unnecessary services, inefficiently delivered services, excessive administrative costs, prices that are too high, missed prevention opportunities, and medical fraud. Additionally, the volume summarizes estimates of the excessive costs, reviews approaches to their control, and considers ways to reduce health expenditures by 10% within 10 years, without compromising health status or valued innovation.



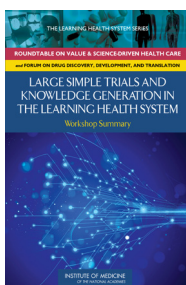
DATA QUALITY

Data Quality. *Digital Data Improvement Priorities for Continuous Learning in Health and Health Care* presents the current deficiencies in the reliability, availability, and usability of digital health data and considers strategies, priorities, and responsibilities to address such deficiencies, as the totality of available health data is a crucial resource that should be considered an invaluable public asset in the pursuit of better care, improved health, and lower health care costs.



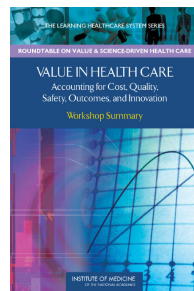
CORE METRICS

Core Metrics. *Core Measurement Needs for Better Care, Better Health, and Lower Costs: Counting What Counts* considers needs, approaches, and metrics most important for tracing progress on care that is better quality, lower cost, and yields better health outcomes, and accounts for factors influencing the implementation of core measure sets, including the data infrastructure, resources, and policies that are needed for the use of core metrics across independent organizations and providers.



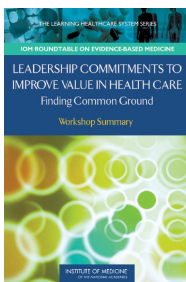
LARGE SIMPLE TRIALS

Large Simple Trials. *Large Simple Trials and Knowledge Generation in a Learning Health System* presents the pros and cons of the design characteristics of large simple trials (LSTs), explores the utility of LSTs on the basis of case studies of past successes, and considers the challenges and opportunities for accelerating the use of LSTs in the context of a US clinical trials enterprise.



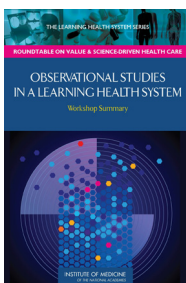
VALUE

Value. *Value in Health Care: Accounting for Cost, Quality, Safety, Outcomes, and Innovation* explores alternative perspectives and approaches for defining, estimating, and attaining value in health care, including case studies on value-enhancing strategies in development—e.g. value-based insurance design, accountable care organizations—and emphasizing the basic need for broad transparency as to cost, quality, and outcomes in care.



LEADERSHIP

Leadership. *Leadership Commitments to Improve Value in Healthcare: Finding Common Ground* presents discussions of opportunity statements from those in key health stakeholder sectors—patients, clinicians, health organizations, insurers, product manufacturers, employers, government, IT, and researchers—on priority actions they can and will undertake cooperatively to transform quality and value in health care.



OBSERVATIONAL STUDIES

Observational Studies. *Observational Studies in a Learning Health System* reviews leading approaches to observational studies and how to chart the course for the use of this growing utility in the most responsible fashion possible by considering how they can be made more rigorous and internally valid, how to deal with bias, the use of observational studies to generalize findings from randomized controlled trials, and how to evaluate treatment heterogeneity.

Consensus Report



BEST CARE

Best Care. *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* explores the central challenges to health care today and identifies three major imperatives for change: the rising complexity of modern health care, unsustainable cost increases, and outcomes below the system's potential, and points out that emerging tools like computing power, connectivity, team-based care, and systems engineering techniques—tools that were previously unavailable—make the envisioned transition possible, and are already being put to successful use in pioneering health care organizations.

Best Care at Lower Cost

The Path to Continuously Learning Health Care in America



Health care in America has experienced an explosion in knowledge, innovation, and capacity to manage previously fatal conditions. Yet, paradoxically, it falls short on such fundamentals as quality, outcomes, cost, and equity. Each action that could improve quality—developing knowledge, translating new information into medical evidence, applying the new evidence to patient care—is marred by significant shortcomings and inefficiencies that result in missed opportunities, waste, and harm to patients.

The full extent of these shortcomings is visible when considering how other industries routinely operate compared with many aspects of health care. Builders rely on blueprints to coordinate the work of carpenters, electricians, and plumbers. Banks offer customers financial records that are updated in real time. Automobile manufacturers produce thousands of vehicles that are standardized at their core, while tailored at the margins. While health care must accommodate many competing priorities and human factors unlike those in other industries, the health care system could learn from these industries how to better meet specific needs, expand choices, and shave costs. Americans would be better served by a more nimble health care system that is consistently reliable and that constantly, systematically, and seamlessly improves. In short, the country needs health care that learns by avoiding past mistakes and adopting newfound successes.

In response to widespread demand for an improved health care system, the Institute of Medicine (IOM) convened a committee to explore health care challenges and to recommend ways to create a continuously learning health care system. Its work was supported by the Robert Wood Johnson Foundation, the Blue Shield of California Foundation, and the Charina Endowment Fund, and it builds on landmark IOM reports published in the past two decades, including *To Err Is Human: Building a Safer Health System*, *Crossing the Qual-*

Americans would be better served by a more nimble health care system that is consistently reliable and that constantly, systematically, and seamlessly improves.

ity Chasm: A New Health System for the 21st century, and *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. The IOM offers its recommendations in *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*.

Building an Adaptive System

Because health care is complex and constantly changing, the committee set out to chart a transition to a system that learns, in real time and with new tools, how to better manage problems. Indeed, such opportunities now exist that were not available just a decade ago. Vast computational power is increasingly affordable, and connectivity allows information to be accessed in real time. Human and organizational capabilities offer expanded ways to improve the reliability and efficiency of health care. And health care organizations and providers recognize that effective care must be delivered by collaborative teams of clinicians, each member playing a vital role. Yet simply acknowledging such opportunities does not necessarily result in putting them to good use.

The responsibility for building a continuously learning health care system rests on many shoulders because the stakes are high. As the IOM committee reports, every missed opportunity for improving health care results in unnecessary suffering. By one estimate, almost 75,000 needless deaths could have been averted in 2005 if every state had delivered care on par with the best performing state. Current waste diverts resources; the committee estimates \$750 billion in unnecessary health spending in 2009 alone.

Data generated in health care delivery—whether clinical, delivery process, or financial—should be collected in digital formats, compiled, and protected as resources for managing care, capturing results, improving processes, strengthening public health, and generating knowledge.

The Department of Health and Human Services (HHS) can encourage not only this digital capacity, but also the development of distributed

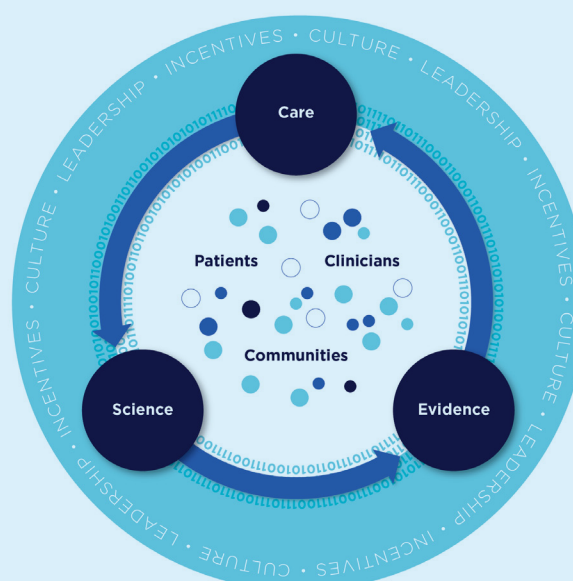
data research networks and expanded access to health data resources to improve care, lower costs, and enhance public health. Payers and medical product companies also should contribute more data to research groups to generate new insights. Patients should participate in developing robust data utility; use new tools, such as personal portals, to better manage their own care; and be involved in building new knowledge, such as through patient-reported outcomes.

Delivering Reliable Clinical Knowledge to Patients

Improving the data infrastructure and data utility would require revising and streamlining research regulations to improve care, promote capture of clinical data, and generate knowledge. Regulators can clarify and improve rules governing the collection and use of clinical data to safeguard patient privacy while promoting the seamless use of such data for better care coordination and management, improved care, and enhanced knowledge.

Decision support tools and knowledge management systems can be included routinely in health care delivery to ensure that decisions are informed by the best evidence.

FIGURE: A Continuously Learning Health Care System



Current waste diverts resources; the committee estimates \$750 billion in unnecessary health spending in 2009 alone.

Among possible actions, clinicians and health care organizations can adopt tools that deliver reliable clinical knowledge to patients. Research organizations, advocacy organizations, professional specialty societies, and care delivery organizations can facilitate the development, accessibility, and use of evidence-based and harmonized clinical practice guidelines. Also, education programs should evolve so that health professionals learn new methods for accessing, managing, and applying evidence, with an emphasis on engaging in lifelong learning; understanding human behavior and social science; and delivering safe care in an interdisciplinary environment. Agencies and organizations that fund research should support investigations into improving the usefulness and accessibility of patient outcome data and scientific evidence for clinicians and patients.

Health providers should place a higher premium on fully involving patients in their own health care to the extent that patients choose. Clinicians should employ high-quality, reliable tools and skills for sharing decision making with patients, tailored to clinical needs, patient goals, social circumstances, and the degree of control that patients prefer. Health care delivery organizations should monitor and assess patients' perspectives and use those insights to improve care; establish patient portals to facilitate data sharing among clinicians, patients, and families; and make high-quality tools available for shared decision making with patients.

In addition, the federal Agency for Healthcare Research and Quality, partnering with the Centers for Medicare & Medicaid Services (CMS), other payers, and stakeholders, should support

developing and testing a reliable set of measures of patient-centeredness for consistent use across the health care system. CMS and other payers should promote and measure patient-centered care through payment models, contracting policies, and public reporting programs. And digital technology developers and health product innovators should develop tools to assist individuals in managing their health and health care.

Improving the Policy Environment

The culture of health care is central to promoting learning at every level. The prevailing approach to paying for health care, based predominantly on individual services and products, encourages wasteful and ineffective care. Instead, payments should reward desired care outcomes and movement toward providing the best care at lower cost. Payers should adopt outcome- and value-oriented payment models, contracting policies, and benefit design to reward and support high-quality, team-based care focused on patients' needs.

Health care delivery organizations, clinicians, and payers should increase the availability of information about the quality, price, and outcomes of care, and professional specialty societies should encourage transparency in the information provided by their members. Likewise, payers should promote transparency to help their members make better decisions. And consumer and patient organizations should disseminate this information to spur conversations and promote informed decision making.

The adoption of a learning health care sys-



Committee on the Learning Health Care System in America

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The Charina Endowment Fund

tem will require broad participation by patients, families, clinicians, care leaders, and those who support their work. Health care delivery organizations should develop organizational cultures that encourage continuous improvement by incorporating best practices, transparency, open communication, staff empowerment, coordination, teamwork, and mutual respect, and that align incentives accordingly. Also, specialty societies, education programs, specialty boards, licensing boards, and accreditation organizations should incorporate basic concepts and specialized applications of continuous learning and improvement into health professionals' education, licensing, certification, and accreditation requirements.

Conclusion

The entrenched challenges of the U.S. health care system demand a transformed approach. Left unchanged, health care will continue to underperform; cause unnecessary harm; and strain national, state, and family budgets. The actions required to reverse this trend will be notable, substantial, sometimes disruptive—and absolutely necessary.

The imperatives are clear, but the changes are possible—and they offer the prospect for best care at lower cost for all Americans. 

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The Institute of Medicine serves as adviser to the nation to improve health.

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Best Care at Lower Cost

The Path to Continuously Learning Health Care in America

The *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* report offers findings, conclusions, and recommendations for implementation by key stakeholders to achieve a health care system that is consistently reliable and that constantly, systematically, and seamlessly improves.

TABLE: Characteristics of a Continuously Learning Health Care System

Science and Informatics
<ul style="list-style-type: none"> • Real-time access to knowledge—A learning health care system continuously and reliably captures, curates, and delivers the best available evidence to guide, support, tailor, and improve clinical decision making and care safety and quality. • Digital capture of the care experience—A learning health care system captures the care experience on digital platforms for real-time generation and application of knowledge for care improvement.
Patient-Clinician Relationships
<ul style="list-style-type: none"> • Engaged, empowered patients—A learning health care system is anchored on patient needs and perspectives and promotes the inclusion of patients, families, and other caregivers as vital members of the continuously learning care team.
Incentives
<ul style="list-style-type: none"> • Incentives aligned for value—In a learning health care system, incentives are actively aligned to encourage continuous improvement, identify and reduce waste, and reward high-value care. • Full transparency—A learning health care system systematically monitors the safety, quality, processes, prices, costs, and outcomes of care, and makes information available for care improvement and informed choices and decision making by clinicians, patients, and their families.
Culture
<ul style="list-style-type: none"> • Leadership-instilled culture of learning—A learning health care system is stewarded by leadership committed to a culture of teamwork, collaboration, and adaptability in support of continuous learning as a core aim. • Supportive system competencies—In a learning health care system, complex care operations and processes are constantly refined through ongoing team training and skill building, systems analysis and information development, and creation of the feedback loops for continuous learning and system improvement.

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Targeted versus Universal Decolonization to Prevent ICU Infection

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ABSTRACT

BACKGROUND

Both targeted decolonization and universal decolonization of patients in intensive care units (ICUs) are candidate strategies to prevent health care–associated infections, particularly those caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

METHODS

We conducted a pragmatic, cluster-randomized trial. Hospitals were randomly assigned to one of three strategies, with all adult ICUs in a given hospital assigned to the same strategy. Group 1 implemented MRSA screening and isolation; group 2, targeted decolonization (i.e., screening, isolation, and decolonization of MRSA carriers); and group 3, universal decolonization (i.e., no screening, and decolonization of all patients). Proportional-hazards models were used to assess differences in infection reductions across the study groups, with clustering according to hospital.

RESULTS

A total of 43 hospitals (including 74 ICUs and 74,256 patients during the intervention period) underwent randomization. In the intervention period versus the baseline period, modeled hazard ratios for MRSA clinical isolates were 0.92 for screening and isolation (crude rate, 3.2 vs. 3.4 isolates per 1000 days), 0.75 for targeted decolonization (3.2 vs. 4.3 isolates per 1000 days), and 0.63 for universal decolonization (2.1 vs. 3.4 isolates per 1000 days) ($P=0.01$ for test of all groups being equal). In the intervention versus baseline periods, hazard ratios for bloodstream infection with any pathogen in the three groups were 0.99 (crude rate, 4.1 vs. 4.2 infections per 1000 days), 0.78 (3.7 vs. 4.8 infections per 1000 days), and 0.56 (3.6 vs. 6.1 infections per 1000 days), respectively ($P<0.001$ for test of all groups being equal). Universal decolonization resulted in a significantly greater reduction in the rate of all bloodstream infections than either targeted decolonization or screening and isolation. One bloodstream infection was prevented per 99 patients who underwent decolonization. The reductions in rates of MRSA bloodstream infection were similar to those of all bloodstream infections, but the difference was not significant. Adverse events, which occurred in 7 patients, were mild and related to chlorhexidine.

CONCLUSIONS

In routine ICU practice, universal decolonization was more effective than targeted decolonization or screening and isolation in reducing rates of MRSA clinical isolates and bloodstream infection from any pathogen. (Funded by the Agency for Healthcare Research and the Centers for Disease Control and Prevention; REDUCE MRSA ClinicalTrials.gov number, NCT00980980.)

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*Investigators for the Centers for Disease Control and Prevention (CDC) Prevention Epicenters Program and the Agency for Healthcare Research and Quality (AHRQ) Developing Evidence to Inform Decisions about Effectiveness (DECIDE) Network and Healthcare-Associated Infections Program are listed in the Supplementary Appendix, available at NEJM.org.

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HEALTH CARE–ASSOCIATED INFECTION is a leading cause of preventable illness and death and often results from colonizing bacteria that overcome body defenses.^{1–5} Among the pathogens causing health care–associated infection, methicillin-resistant *Staphylococcus aureus* (MRSA) has been given priority as a target of reduction efforts because of its virulence and disease spectrum, multidrug-resistant profile, and increasing prevalence in health care settings, particularly among patients in the intensive care unit (ICU). Hospitals commonly screen patients in the ICU for nasal carriage of MRSA and use contact precautions with carriers.^{2–6} Nine states mandate such screening.⁷

Decolonization has been used to reduce transmission and prevent disease in *S. aureus* carriers, primarily carriers of methicillin-resistant strains but also carriers of methicillin-sensitive ones.^{8,9} *S. aureus*, including both methicillin-resistant and methicillin-susceptible strains, accounts for more health care–associated infections than any other pathogen.⁴ It is the most common cause of ventilator-associated pneumonia and surgical-site infection and the second most common cause of central-catheter–associated bloodstream infection.⁴ Decolonization commonly involves a multi-day regimen of intranasal mupirocin and chlorhexidine bathing.

There is debate about whether decolonization should be used and, if so, whether to target high-risk pathogens or patient populations that are susceptible to infection from many pathogens.¹⁰ In particular, the broad antimicrobial activity of chlorhexidine makes it attractive for preventing health care–associated infection from many pathogens.^{11–14} Several studies have shown that daily chlorhexidine bathing of all patients in the ICU can reduce MRSA acquisition, the concentration of bacteria on the body surface, and bloodstream infection from all pathogens.^{11–14} A comparative-effectiveness trial is needed to determine what type of decolonization strategy works best to reduce MRSA and other pathogens in ICUs.¹⁵ In addition, it is important to know whether decolonization can be effective in routine ICU care. We conducted a cluster-randomized, pragmatic, comparative-effectiveness trial in adult ICUs to compare targeted and universal decolonization with one another and with MRSA screening and contact precautions alone.

METHODS

STUDY DESIGN

We designed the Randomized Evaluation of Decolonization versus Universal Clearance to Eliminate MRSA (REDUCE MRSA) trial, a three-group, cluster-randomized trial, to compare strategies for preventing MRSA clinical isolates and infections in adult ICUs in Hospital Corporation of America (HCA) hospitals. The trial design has been described previously,¹⁵ and the protocols are available with the full text of this article at NEJM.org. The training materials are provided in the Supplementary Appendix, available at NEJM.org. All the authors vouch for the accuracy of the reported data and the fidelity of the study to the protocol. There was a 12-month baseline period from January 1 through December 31, 2009; a phase-in period from January 1 through April 7, 2010; and an 18-month intervention period from April 8, 2010, through September 30, 2011.

The three strategy groups were defined as follows. In group 1 (screening and isolation), bilateral screening of the nares for MRSA was performed on ICU admission, and contact precautions were implemented for patients with a history of MRSA colonization or infection and for those who had any positive MRSA test. This was the previous standard of care in all hospitals. The MRSA screening program for patients in the ICU, who are a group at high risk for infection, began in 2007 at HCA hospitals.¹⁶ More than 90% of the patients admitted to the ICU underwent screening, and contact precautions were implemented for carriers of MRSA and other multidrug-resistant pathogens.

In group 2 (targeted decolonization), MRSA screening and contact precautions were similar to those in group 1. Patients known to have MRSA colonization or infection underwent a 5-day decolonization regimen consisting of twice-daily intranasal mupirocin and daily bathing with chlorhexidine-impregnated cloths.

In group 3 (universal decolonization), there was no screening for MRSA on admission to the ICU. Contact precautions were similar to those in group 1. All patients received twice-daily intranasal mupirocin for 5 days, plus daily bathing with chlorhexidine-impregnated cloths for the entire ICU stay.

All adult ICUs in a participating hospital were

assigned to the same study group. Contact-precaution policies, which were based on long-standing guidance from the Centers for Disease Control and Prevention (CDC), were identical and unchanged for all hospitals. Precautions were initiated on the basis of current or historical MRSA cultures or other standard indications.⁶ Results of cultures obtained on admission became available the next day.

STUDY OUTCOMES

The primary outcome was ICU-attributable, MRSA-positive clinical cultures. Screening tests were excluded from all analyses because hospitals implementing universal decolonization discontinued such cultures. Secondary outcomes included ICU-attributable bloodstream infection caused by MRSA and ICU-attributable bloodstream infection caused by any pathogen. Clinical cultures were obtained at the clinician's discretion.

RECRUITMENT AND ELIGIBILITY CRITERIA

Recruitment occurred among the 160 HCA hospitals. Most were community hospitals with single-occupancy ICU rooms. Eligibility criteria included commitment by the hospital administration to have the hospital undergo randomization for the trial, less than 30% of patients in participating adult ICUs receiving either chlorhexidine bathing or intranasal mupirocin at baseline, stable use of infection-prevention initiatives and products during the baseline period, and agreement to refrain from adopting new initiatives that would conflict with the trial. Throughout the study, corporate-wide campaigns were used to ensure compliance with national practice guidelines.¹⁶⁻¹⁸

Each hospital obtained approval from an institutional review board, with more than 90% of the hospitals delegating review to the Harvard Pilgrim Health Care institutional review board. Patient notices about group-specific protocols were posted in each ICU room. The requirement for written informed consent was waived.¹⁹

RANDOMIZATION

Randomization was stratified to optimize balance in patient volume and baseline prevalence of MRSA carriage on the basis of clinical cultures and screening tests from July 2008 through June 2009. Hospitals were ranked according to ICU volume and were grouped into sets of six. Within

each set, we ordered the hospitals according to the prevalence of MRSA carriage in the ICU. Each group of three consecutive hospitals was randomly assigned, one to each strategy group, with the use of block randomization. Hospitals in states with legislative mandates for MRSA screening in the ICU were similarly and separately randomly assigned to group 1 or 2.

IMPLEMENTATION

On-site activities were implemented by hospital personnel responsible for quality-improvement initiatives, including ICU directors, infection preventionists, and nurse educators. Standard communication channels were used, including group-specific, computer-based training modules and daily electronic documentation by nursing staff for all groups. On-site training in bathing with chlorhexidine-impregnated cloths was provided to hospitals assigned to a decolonization regimen (i.e., group 2 or 3). Nursing directors performed at least three quarterly observations of bathing, including questioning staff about protocol details.

Investigators hosted group-specific coaching teleconferences at least monthly to discuss implementation, compliance, and any new, potentially conflicting initiatives. Compliance assessment involved verification on 1 day per week for each ICU. HCA leadership evaluated trial processes during routine hospital visits. Additional site visits were made at the request of the hospital or if compliance was found to be low.

Intranasal mupirocin ointment 2% (Bactroban, GlaxoSmithKline) and 2% chlorhexidine-impregnated cloths (Sage Products) were used for decolonization. All mupirocin and chlorhexidine-impregnated cloths were purchased at their usual cost by the participating hospitals. In groups 2 and 3, bathing products and products used for wound prophylaxis that were incompatible with chlorhexidine were replaced with compatible products. Adverse events were managed by treating physicians.

DATA COLLECTION AND OUTCOME ASSIGNMENT

Census (i.e., the unit location of each patient for every hospitalization day), microbiologic, pharmacy, supply-chain, nursing-query, and administrative data were obtained from corporate data warehouses, which undergo line-item validation until 99% accuracy is achieved. CDC criteria were

used for microbiologic outcomes (first outcome per patient). Pathogens were attributed to an ICU if the collection date occurred during the period from the third day after ICU admission through the second day after ICU discharge. For bloodstream infections to be attributed to skin-commensal organisms, the same organism had to be isolated from two or more blood cultures obtained within 2 calendar days of one another.²⁰

STATISTICAL ANALYSIS

We powered the trial on the basis of the rarest outcome, MRSA bloodstream infection. The study was designed to have 80% power to detect a 40% relative reduction in the rate of MRSA bloodstream infection in group 2, and a 60% relative reduction in the rate in group 3, as compared with group 1. The primary analyses were conducted according to the intention-to-treat principle (as-assigned analyses) and were unadjusted. Proportional-hazards models with shared frailties accounted for clustering within hospitals (see the Supplementary Appendix).^{21,22} The intervention effect was assessed on the basis of the interaction between group and study period, reflecting the difference in hazard between the baseline and intervention periods among the groups. Data from the phase-in period were excluded from all analyses. When the null hypothesis of equal changes across the groups was rejected, we examined pairwise comparisons.

Sensitivity analyses included multivariable covariate-adjusted models, as-treated models, models that excluded hospitals in states mandating MRSA screening in the ICU, models that accounted for assigned randomization strata, and models that excluded the small numbers of medical-only and surgical-only ICUs. Adjusted models accounted for age, sex, race, insurance type, coexisting conditions (defined with the use of codes from the *International Classification of Diseases, 9th Revision*), and surgery during the hospital stay. Analyses were performed with the use of SAS software, version 9.3 (SAS Institute).

RESULTS

STUDY PARTICIPANTS

A total of 45 hospitals in 16 states underwent randomization (Fig. 1). A total of 43 (comprising 74 ICUs) implemented the assigned intervention; 2 hospitals that underwent randomization were excluded from all analyses because preexisting ex-

clusion criteria were discovered before the intervention started. One hospital in group 2 (assigned to targeted decolonization) withdrew after the intervention started and was included in the as-assigned analyses but not in the as-treated analyses.

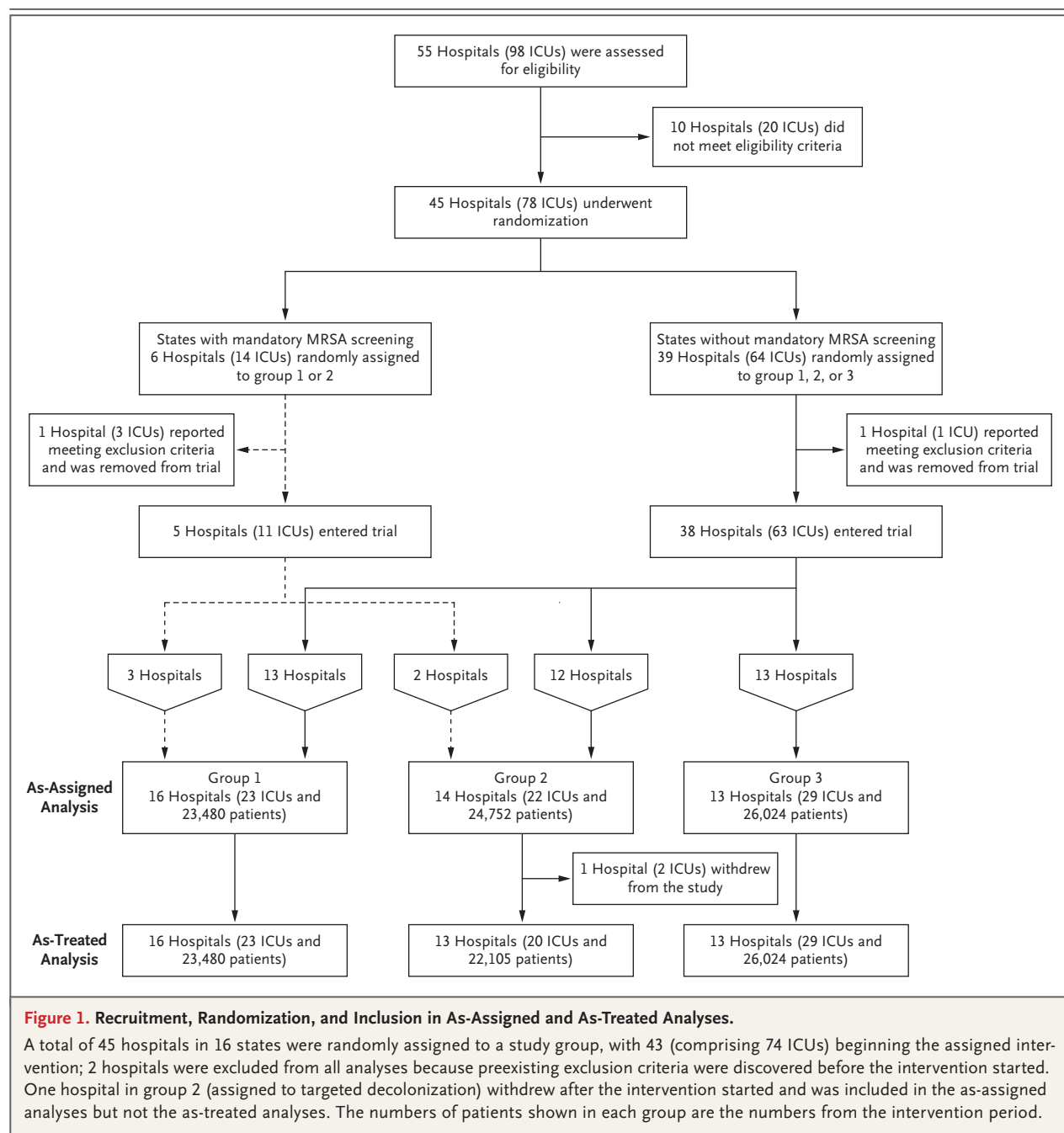
Patient characteristics were similar across groups and between the baseline and intervention periods (Table 1). There was excellent separation of interventions across groups. In group 1, less than 1.0% of patients (range for hospitals in group, 0 to 2.1%) received mupirocin or chlorhexidine. In group 2, a total of 90.8% of MRSA carriers (range for hospitals in group, 56.5 to 100%) received mupirocin and 88.8% (range for hospitals in group, 54.2 to 98.4%) received chlorhexidine. In group 3, a total of 86.1% of patients (range for hospitals in group, 41.0 to 99.1%) received mupirocin and 80.8% (range for hospitals in group, 53.1 to 98.6%) received chlorhexidine.

Reasons for noncompliance included discharge before scheduled bathing or mupirocin administration, discharge before MRSA-positive results were obtained, moribund state of the patient, length of ICU stay of less than 1 day, and patient's decision to decline the intervention. MRSA screening occurred in 97.5% of patients (hospital range, 90.6 to 100%) in group 1, in 98.6% (hospital range, 95.6 to 100%) in group 2, and in 0.7% (hospital range, 0 to 4.7%) in group 3. Of the 69 proposed practice changes that occurred at various hospitals during the trial, 36 conflicted with the trial protocol and were not implemented.

OUTCOMES

For the primary outcome of ICU-attributable, MRSA-positive clinical cultures in the as-assigned analysis, the relative hazards differed significantly among the groups in a comparison of the intervention period with the baseline period ($P=0.01$) (Fig. 2). Pairwise analyses showed that universal decolonization resulted in a significantly greater reduction in the hazard of MRSA-positive clinical cultures than did screening and isolation (hazard ratio in group 3, 0.63; 95% confidence interval [CI], 0.52 to 0.75; hazard ratio in group 1, 0.92; 95% CI, 0.77 to 1.10; $P=0.003$ for test of all groups being equal).

The effects of the strategies on ICU-attributable MRSA bloodstream infection were not significantly different across the study groups ($P=0.11$ for test of all groups being equal), although the hazard reduction with universal de-



colonization was greater than the reductions with the other strategies (hazard ratio, 0.72 [95% CI, 0.48 to 1.08] vs. 1.23 [95% CI, 0.82 to 1.85] for screening and isolation and 1.23 [95% CI, 0.80 to 1.90] for targeted decolonization). For ICU-attributable bloodstream infection from any pathogen, differences among the groups were significant ($P < 0.001$ for test of all groups being equal). In pairwise comparisons, universal decolonization resulted in a significantly greater reduction in the

hazard of infection (hazard ratio, 0.56; 95% CI, 0.49 to 0.65) than either screening and isolation (hazard ratio, 0.99; 95% CI, 0.84 to 1.16; $P < 0.001$) or targeted decolonization (hazard ratio, 0.78; 95% CI, 0.66 to 0.91; $P = 0.03$). We found no significant difference in mortality across the groups, although the trial was inadequately powered to observe even relatively large effects on death.

The effect of targeted decolonization was intermediate between the effects of usual care

Table 1. Characteristics of the Intensive Care Unit (ICU) Population, According to Study Period and Group.*

Variable	12-Mo Baseline Period (N=48,390)			18-Mo Intervention Period (N=74,256)		
	Group 1	Group 2	Group 3	Group 1	Group 2	Group 3
Admission with ICU stay (no.)	15,816	15,218	17,356	23,480	24,752	26,024
Attributable ICU patient-days (no.)	63,135	57,418	69,668	88,222	92,978	101,603
ICU type (no.)†						
Medical	3	5	5	3	5	5
Surgical	1	2	6	1	2	6
Mixed medical and surgical	19	14	18	19	15	17
Hospital stay (days)						
Median	7	7	8	7	7	7
Interquartile range	5–12	5–12	5–12	5–12	5–12	5–12
ICU stay (days)						
Median	3	3	3	3	3	3
Interquartile range	2–5	2–5	2–5	1–5	2–5	2–5
Age (yr)						
Median	65	66	65	65	66	65
Interquartile range	52–77	53–77	51–77	52–77	53–77	52–77
Female sex (%)‡	47.2	47.2	47.9	47.6	47.2	47.5
Nonwhite race (%)§	25.9	22.1	30.8	25.9	23.5	31.7
Coexisting condition (%)						
Diabetes	31.3	33.0	30.7	31.8	32.7	31.5
Renal failure	20.0	20.4	19.0	20.3	22.2	19.7
Cancer	10.4	10.8	14.1	9.9	10.8	13.0
Liver failure	3.4	4.4	3.9	4.0	4.1	4.2
History of MRSA infection (%)¶	10.2	11.5	10.6	9.7	11.1	3.9
Surgery during hospitalization (%)	40.5	38.6	47.5	38.7	37.7	46.2

* Group 1 implemented methicillin-resistant *Staphylococcus aureus* (MRSA) screening and isolation; group 2, targeted decolonization (i.e., screening, isolation, and decolonization of MRSA carriers with chlorhexidine and mupirocin); and group 3, universal decolonization (i.e., no screening and all patients underwent decolonization). At baseline, there were no significant between-group differences. For additional details, see the Supplementary Appendix.

† Differences in the number of ICUs in the groups between the baseline and intervention periods reflect the fact that one ICU in group 2 opened during the trial and one in group 3 closed.

‡ Data were missing for eight patients.

§ Race was determined from electronic administrative data at each hospital.

¶ A history of MRSA infection was identified with the use of all available screening and clinical cultures, with the history defined as MRSA carriage documented by the Hospital Corporation of America during the period from 1 year before admission to day 2 of the ICU stay. Data from group 3 during the intervention period are not comparable to data from the other groups because universal decolonization, without screening, was performed for all patients in this group. As the intervention progressed, patients who were readmitted to the ICU were less likely to be identified as MRSA-positive.

(i.e., screening and isolation) and universal decolonization for ICU-attributable MRSA cultures and bloodstream infection from any pathogen. Targeted decolonization resulted in significantly lower rates of bloodstream infection from any pathogen than did screening and isolation; other outcomes did not differ significantly between these two groups. Findings in all sensitivity analyses were similar to those in the as-assigned analysis (Table 2).

Outcome events and their associated rates are shown in Table 3 and in the Supplementary Appendix. There were no significant between-group differences at baseline ($P \geq 0.30$ for all outcomes). The baseline rate of MRSA-positive clinical cultures was higher in group 2 (4.3 per 1000 attributable days) than in the other strategy groups (3.4 per 1000 attributable days in each), but the difference was not significant. At baseline, the rate of bloodstream infections from any patho-

gen was higher in group 3 (6.1 infections per 1000 attributable days) than in groups 2 and 3 (4.2 and 4.8 infections per 1000 attributable days, respectively), but the difference was not significant ($P=0.87$).

By chance, group 3 contained three of the four hospitals that performed bone marrow and solid-organ transplantations. These three hospitals accounted for much of the excess risk in this group, including 72% of the baseline coagulase-negative staphylococcal bloodstream infections (baseline risk of 0.01 events per patient in these three hospitals). The baseline risk per patient in all other hospitals in group 3 (0.004 events) was similar to the baseline risks in all hospitals in groups 1 and 2 (0.003 events in each group). During the intervention period, the risk declined in the three hospitals (0.002) and in all other hospitals implementing universal decolonization (0.0004), as compared with the baseline risks and as compared with the intervention risk for groups 1 and 2 (0.002 in each group). Analyses with adjustment for coexisting conditions such as cancer supported the findings of the as-assigned analyses (Table 2).

ADVERSE EVENTS

There were seven adverse events (two in group 2 and five in group 3) (see the Supplementary Appendix). All involved mild pruritus or rash after chlorhexidine bathing and resolved on discontinuation of the use of chlorhexidine-impregnated cloths.

DISCUSSION

Universal decolonization of patients in the ICU was the most effective strategy, significantly reducing MRSA-positive clinical cultures by 37% and bloodstream infections from any pathogen by 44%. This effect was observed under usual practice conditions in a wide array of hospitals, including community hospitals, that had already implemented national, evidence-based recommendations for preventing health care–associated MRSA infection. A total of 181 patients would need to undergo decolonization to prevent one MRSA-positive clinical culture, and 99 patients would need to undergo decolonization to prevent one bloodstream infection from any pathogen.

Several factors may account for our observation that universal decolonization had a greater preventive effect than the two other strategies.

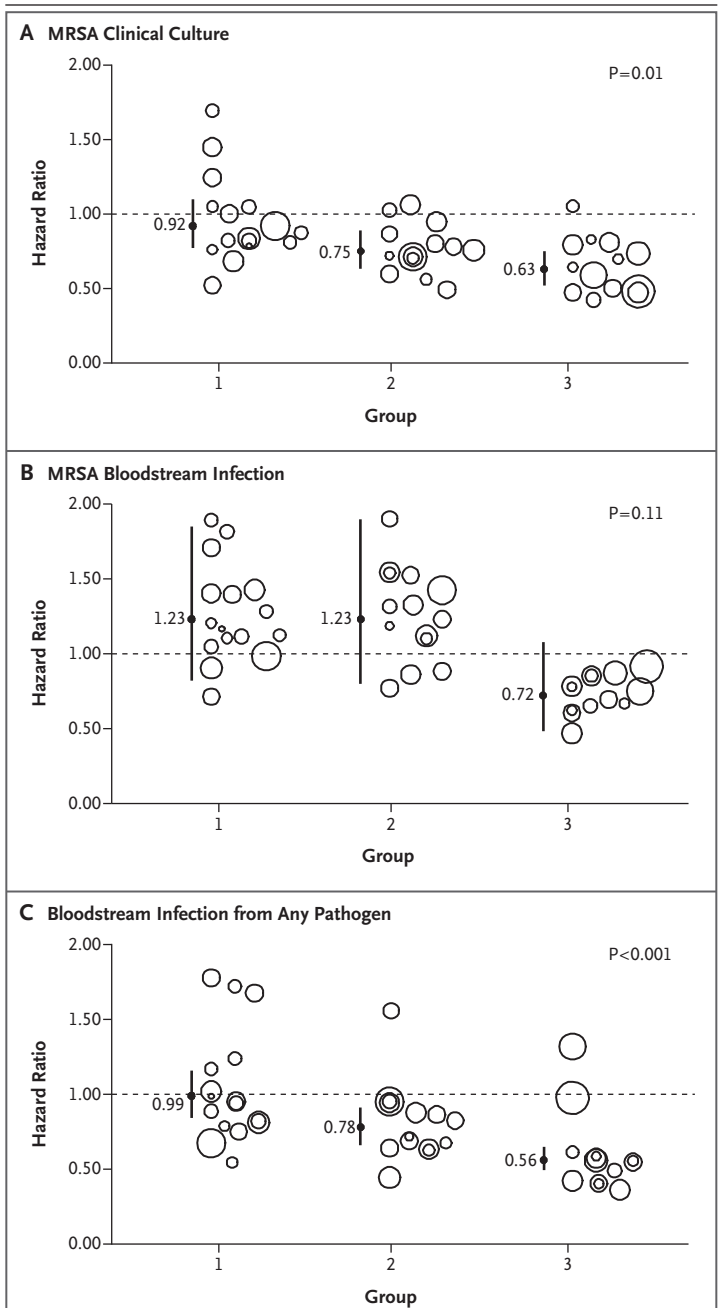


Figure 2. Effect of Trial Interventions on Outcomes.

Shown are group-specific hazard ratios and 95% confidence intervals (indicated by vertical lines) for outcomes attributable to the intensive care unit. Results are based on unadjusted proportional-hazards models that accounted for clustering within hospitals. Analyses were based on the as-assigned status of hospitals. Panel A shows hazard ratios for clinical cultures that were positive for methicillin-resistant *Staphylococcus aureus* (MRSA) infection, Panel B hazard ratios for MRSA bloodstream infection, and Panel C hazard ratios for bloodstream infection from any pathogen. Bubble plots of hazard ratios (predicted random effects or exponentiated frailties) from individual hospitals relative to their group effects are shown. The size of the bubble indicates the relative number of patients contributing data to the trial.

Table 2. Hazard Ratios for Primary and Secondary Trial Outcomes.

Variable	Hazard Ratio (95% CI)			Overall P Value
	Group 1	Group 2	Group 3	
MRSA				
Clinical culture				
As-assigned analysis				
Unadjusted*	0.92 (0.77–1.10)	0.75 (0.63–0.89)	0.63 (0.52–0.75)	0.01
Adjusted	0.92 (0.77–1.10)	0.74 (0.62–0.88)	0.64 (0.53–0.77)	0.02
As-treated analysis, unadjusted	0.93 (0.78–1.11)	0.78 (0.65–0.94)	0.63 (0.52–0.75)	0.01
Randomization to all three groups, unadjusted analysis†	0.93 (0.76–1.13)	0.74 (0.62–0.89)	0.63 (0.52–0.75)	0.02
Randomization strata accounted for, unadjusted analysis	0.93 (0.78–1.11)	0.75 (0.63–0.89)	0.63 (0.52–0.75)	0.01
Mixed medical and surgical ICUs only, unadjusted analysis	0.93 (0.76–1.12)	0.71 (0.59–0.86)	0.57 (0.46–0.71)	0.004
Bloodstream infection				
As-assigned analysis				
Unadjusted	1.23 (0.82–1.85)	1.23 (0.80–1.90)	0.72 (0.48–1.08)	0.11
Adjusted	1.20 (0.80–1.81)	1.19 (0.77–1.84)	0.74 (0.49–1.12)	0.18
As-treated analysis, unadjusted	1.24 (0.82–1.86)	1.34 (0.84–2.15)	0.72 (0.48–1.08)	0.08
Randomization to all three groups, unadjusted analysis†	1.15 (0.74–1.79)	1.18 (0.74–1.89)	0.72 (0.48–1.08)	0.19
Randomization strata accounted for, unadjusted analysis	1.24 (0.83–1.86)	1.22 (0.79–1.88)	0.73 (0.48–1.09)	0.12
Mixed medical and surgical ICUs only, unadjusted analysis	1.15 (0.75–1.77)	1.20 (0.75–1.93)	0.72 (0.44–1.20)	0.28
Bloodstream infection from any pathogen				
As-assigned analysis				
Unadjusted‡	0.99 (0.84–1.16)	0.78 (0.66–0.91)	0.56 (0.49–0.65)	<0.001
Adjusted	0.98 (0.84–1.15)	0.77 (0.65–0.90)	0.55 (0.48–0.64)	<0.001
As-treated analysis, unadjusted	0.99 (0.84–1.16)	0.78 (0.66–0.92)	0.56 (0.49–0.65)	<0.001
Randomization to all three groups, unadjusted analysis†	0.93 (0.78–1.10)	0.77 (0.65–0.91)	0.56 (0.49–0.65)	<0.001
Randomization strata accounted for, unadjusted analysis	0.99 (0.84–1.16)	0.78 (0.66–0.91)	0.56 (0.49–0.65)	<0.001
Mixed medical and surgical ICUs only, unadjusted analysis	0.96 (0.81–1.13)	0.80 (0.67–0.96)	0.59 (0.50–0.69)	<0.001

* P values in the pairwise analysis were as follows: P=0.09 for the comparison of group 2 with group 1, P=0.003 for the comparison of group 3 with group 1, and P=0.16 for the comparison of group 3 with group 2.

† This analysis excluded the five hospitals in states with laws requiring MRSA screening in the ICU.

‡ P values in the pairwise analysis were as follows: P=0.04 for the comparison of group 2 with group 1, P<0.001 for the comparison of group 3 with group 1, and P=0.003 for the comparison of group 3 with group 2.

First, chlorhexidine reduces skin colonization by many pathogens, thus protecting patients in the ICU from their own microbiota during a period of heightened vulnerability to infection.^{11–14} Second, universal decolonization reduces the environmental microbial burden, reducing opportunities for patient-to-patient transmission.^{14,23} Third, universal decolonization began on the first ICU

day, thus avoiding the delay in decolonization pending the results of screening tests.

Another potential benefit of universal decolonization is the elimination of MRSA surveillance tests and the associated reduction in contact precautions, which can interfere with care.²⁴ These findings have implications for legislative mandates requiring MRSA screening in the ICU.²⁵

Table 3. Frequency and Rates of Outcomes during the Baseline and Intervention Periods, According to Study Group.*

Outcome	Group 1		Group 2		Group 3	
	Baseline	Intervention	Baseline	Intervention	Baseline	Intervention
	<i>no. of events (crude rate per 1000 patient-days)</i>					
MRSA clinical cultures	216 (3.4)	279 (3.2)	245 (4.3)	301 (3.2)	240 (3.4)	217 (2.1)
Bloodstream infection						
MRSA	37 (0.6)	63 (0.7)	31 (0.5)	61 (0.6)	46 (0.6)	48 (0.5)
Any pathogen†	265 (4.2)	360 (4.1)	273 (4.8)	341 (3.7)	412 (6.1)	356 (3.6)
Gram-positive organism	165 (2.6)	228 (2.6)	159 (2.8)	203 (2.2)	253 (3.7)	187 (1.9)
Skin commensal organism	50 (0.8)	55 (0.6)	49 (0.9)	46 (0.5)	120 (1.8)	38 (0.4)
Noncommensal organism	115 (1.8)	173 (2.0)	110 (1.9)	157 (1.7)	133 (2.0)	149 (1.5)
Gram-negative organism	62 (1.0)	83 (0.9)	58 (1.0)	75 (0.8)	100 (1.5)	107 (1.1)
Candida species	38 (0.6)	49 (0.6)	56 (1.0)	63 (0.7)	59 (0.9)	62 (0.6)

* Provided rates are crude rates, defined as the number of events per 1000 ICU-attributable patient-days at risk for the event. Patient-days after each event were excluded from the analysis; thus, denominators are different for each cell and are not included.

† The distribution of all bloodstream events is based on the first eligible event from any pathogen per patient. For example, a patient with a first ICU-associated bloodstream infection (due to a gram-positive organism) followed by a second ICU-associated bloodstream infection (due to a gram-negative organism) would be counted only in the listing for gram-positive organisms.

Nevertheless, there may be occasions when screening is warranted, such as periodic monitoring of resistance. Formal cost-effectiveness analysis is needed to understand whether the observed cessation of screening, reduced contact precautions, and reduced infections offset the product costs and the potential emergence of resistance. It remains to be seen whether universal decolonization can obviate the need for all contact precautions for carriers of MRSA or other multi-drug-resistant organisms.

The benefits attributable to universal decolonization are notable for several reasons. First, the large reductions in infections that we observed were achieved over and above the substantial reductions in bloodstream infections due to MRSA and other pathogens that have occurred at HCA hospitals and other hospitals nationally within the past decade.^{3,26,27} Our study included a direct comparison with high-compliance active surveillance and accompanying contact precautions, which have been associated with decreased rates of MRSA transmission and MRSA bloodstream infection.^{9,16,25,27,28} Hospitals that have not fully implemented a strategy of screening and isolation may derive additional benefit from this intervention. Second, universal decolonization was implemented as part of routine practice with the use of the usual infrastructure of the hospital for practice change, without the need for on-site study personnel. These results are thus likely to be generally

achievable as part of regular practice. Third, the intervention was effective in community hospitals, which make up the majority of U.S. hospitals.

The reduction in bloodstream infections from any pathogen occurred in the context of the relatively higher baseline rates of infection for all pathogen types (gram-positive, gram-negative, and fungal) in group 3, as compared with the other groups. One explanation for these high rates is that this group included three of the four hospitals providing bone marrow and solid-organ transplantations. Such differences across groups are largely accounted for by comparing the outcome rate in each hospital with that hospital's baseline rate, providing reassurance that the benefit is attributable to decolonization rather than to baseline variation in case mix or clinical practices across groups. In addition, group 3 did not have higher baseline rates of MRSA-positive clinical cultures than the other groups did, so regression to the mean would not explain the beneficial effect on that outcome.

It is unknown whether a threshold level of compliance with universal decolonization is required to achieve the observed benefit or whether a compliance rate higher than the rate in our study (85%) would yield further improvement. Although hospital staff members were aware of the assigned strategy, which could have resulted in unmeasured behavior that affected trial outcomes,²⁹ it is unclear what unmeasured behavior could effect a 44% improvement.

This trial provides no information on the attributable benefit of mupirocin, either alone or in combination with chlorhexidine. On the basis of microbiologic activity, any reduction in non-*S. aureus* bloodstream infections should be attributed to chlorhexidine. However, for *S. aureus*, the most common cause of health care–associated infection,⁴ clearance of the nasal reservoir in combination with body decolonization may be superior to either method alone.³⁰

Widespread use of chlorhexidine and mupirocin could possibly engender resistance.^{9,31,32} Mupirocin resistance has been reported in some studies of MRSA decolonization,^{9,30} but not all such studies.^{8,32–35} MRSA resistance to chlorhexidine lacks a standard definition, but recent reports suggest that resistant strains are rare in the United States.^{36,37} A gene encoding a multidrug efflux pump that is active against chlorhexidine has been reported in MRSA,³⁸ but its clinical significance is not understood. Reduced susceptibility to chlorhexidine has also been reported in gram-negative bacteria.³⁹ It will therefore be important for surveillance programs to monitor mupirocin and chlorhexidine resistance.^{3,8}

This trial was designed as a pragmatic, comparative-effectiveness trial implemented primarily through usual hospital processes.^{15,19} We chose this design to obtain results that could be generalized to the broadest set of hospitals, to use processes potentially adoptable by many hospitals, and to conduct a study of sufficient size — all ICUs in dozens of hospitals — with the available resources. Randomization of entire hospitals allowed us to recruit a broad array of hospitals, including community hospitals with

no prior experience in clinical research. Finally, the efficient design meant that the total cost of the trial, including the decolonizing product and contributed personnel effort, was less than \$3 million, or approximately \$40 per patient.

Opportunities to integrate comparative-effectiveness research into routine clinical settings with the use of methods such as those used in the current study will increase as more hospitals adopt electronic health data systems and as multi-center care-improvement collaboratives develop. This trial also highlights the importance of performing rigorous evaluation of quality-improvement initiatives and controlling the introduction of new processes and products. Harnessing such initiatives to identify best practices is an important tenet of the advocacy by the Institute of Medicine for a learning health system.⁴⁰

In conclusion, we found that universal decolonization prevented infection, obviated the need for surveillance testing, and reduced contact isolation. If this practice is widely implemented, vigilance for emerging resistance will be required.

The views expressed in this article are those of the authors and do not necessarily represent the views of the Agency for Healthcare Research and Quality (AHRQ), the Department of Health and Human Services, or the Centers for Disease Control and Prevention (CDC).

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A Win for the Learning Health System

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A central tenet of the learning health system philosophy is that evidence development should be part of care delivery. Furthermore, it should be possible to address difficult problems in the learning health system; health care–associated infections are such problems. They are among the most serious complications of health care, and are increasingly demonstrated to be avoidable.

Preventing infections caused by a virulent, antimicrobial-resistant pathogen, methicillin-resistant *Staphylococcus aureus* (MRSA), has been an especially high priority because of its morbidity and mortality, as well as its increasing prevalence, particularly among intensive care unit (ICU) patients. MRSA complicates more than 250,000 hospitalizations and contributes to almost one-quarter of the 80,000 deaths in the United States each year from hospital-acquired infections.^{1,2} Three strategies to prevent these infections in ICUs are described in the literature—screening and isolating patients who carry the organism; screening and isolation, plus decolonization; and decolonization of all patients without any screening. There has been limited evidence to guide selection of one approach over another. Nonetheless, nine states mandate the first approach.

This is a problem the learning health system should be able to address, and we and our colleagues recently reported a head-to-head comparison of the three strategies.³ The study of 43 hospitals and more than

The views expressed in this commentary are those of the authors and not necessarily of the authors' organizations or of the Institute of Medicine. The commentary is intended to help inform and stimulate discussion. It has not been subjected to the review procedures of the Institute of Medicine and is not a report of the Institute of Medicine or of the National Research Council.

74,000 patients provided strong evidence that decolonizing all patients prevented 44 percent of blood stream infections.

The study design was straightforward—a pragmatic, cluster-randomized trial that randomized hospitals to one of the three prevention strategies. Although the design was straightforward, the study was extraordinary for several reasons beyond its large size. Important features included the fact that the study was embedded in the hospitals' routine care delivery system. It was implemented by the hospitals' own quality and infection prevention teams, ICU directors, and staff; there was active participation throughout by nursing departments, hospital pharmacies, supply chain managers, microbiology laboratories, and others; and an integrated information technology system both supported day-to-day implementation and served as the source for all of the outcome data. Most hospitals delegated institutional review board oversight to the lead institution. Finally, embedding the trial into the routine care delivery system meant that the total extra cost was less than \$3 million, a tiny fraction of the cost of a conventional clinical trial.

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Commentary Series of the IOM Roundtable on Value &
Science-Driven Health Care.

All of these features were possible because the study was embedded in a single system, Hospital Corporation of America.

This study has four immediate lessons for the learning health system. First, embedding pragmatic clinical trials into routine practice settings provides information that can directly inform care delivery; it is important to design trials that fit clinical practice. Second, large networks of committed institutions that use interconnected, interoperable information systems can provide essential organizational, logistical, and data resources to learn from and compare the systematic introduction of medical practices in ways that have been effectively impossible until now. We should especially encourage evidence development programs in these venues. Third, randomization is sometimes necessary, and cluster randomization is especially well suited to pragmatic trials. It will be important to develop a clear understanding of when randomization is appropriate, and to ensure appropriate ethical oversight and protection of patients. Finally, high-quality delivery science is not free, even though it is inexpensive by the standards of both conventional clinical trials and the total cost of care. For the learning health system to become an effective national research and development system, it requires the financial and organizational support of the delivery systems it improves.

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In this commentary, simultaneously released with a corresponding [New England Journal of Medicine article](#), Drs. Platt, Huang, and Perlin describe the implications for evidence generation in a learning health system demonstrated by the results from a recent randomized trial of MRSA prevention strategies within several allied hospitals. Their study grew out of a partnership facilitated by participation in the IOM Roundtable on Value & Science-Driven Health Care, for which Dr. Platt serves as co-chair of the IOM Clinical Effectiveness Research Innovation Collaborative and Dr. Perlin serves as co-chair of the IOM Digital Learning Collaborative. The commentary discussion touches on several concepts central to continuously improving care, including the potential gains from:

- Embedding pragmatic clinical trials into delivery systems' routine care practices;
- Harmonized evidence generation coordinated among institutions that share information systems;
- Systematic variation in care, sometimes including cluster randomization;
- Delivery systems' logistical and financial support of research and development.

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Launching PCORnet, a national patient-centered clinical research network

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ABSTRACT

The Patient-Centered Outcomes Research Institute (PCORI) has launched PCORnet, a major initiative to support an effective, sustainable national research infrastructure that will advance the use of electronic health data in comparative effectiveness research (CER) and other types of research. In December 2013, PCORI's board of governors funded 11 clinical data research networks (CDRNs) and 18 patient-powered research networks (PPRNs) for a period of 18 months. CDRNs are based on the electronic health records and other electronic sources of very large populations receiving healthcare within integrated or networked delivery systems. PPRNs are built primarily by communities of motivated patients, forming partnerships with researchers. These patients intend to participate in clinical research, by generating questions, sharing data, volunteering for interventional trials, and interpreting and disseminating results. Rapidly building a new national resource to facilitate a large-scale, patient-centered CER is associated with a number of technical, regulatory, and organizational challenges, which are described here.

LAUNCHING PCORNET, A NATIONAL CLINICAL RESEARCH NETWORK

The potential of comparative effectiveness research (CER) for dealing with practical clinical questions, enhancing the quality and effectiveness of care, and personalizing evidence-based care, is clear.¹ Yet CER strains the current clinical research paradigm because of its emphasis on assessing effectiveness in typical care delivery settings, its requirement for very large study populations to study effectiveness heterogeneity, and, often, its need for treatments to be allocated by randomization.

In July 2012, the Patient-Centered Outcomes Research Institute (PCORI) convened a national multi-stakeholder workshop to advance the use of electronic health data in CER.² Building on research networks that include among others, the HMO Research Network, the Agency for Healthcare Research and Quality (AHRQ) American Recovery and Reinvestment Act (ARRA) investments in data networks, the US Centers for Disease Prevention and Control (CDC) Vaccine Safety Data Link, the Food and Drug Administration's (FDA) Mini-Sentinel, the National Institutes of Health (NIH) Health Care Systems Research Collaboratory, two components of a national research infrastructure emerged.^{3–8} These comprise clinical data research networks (CDRNs) based on the electronic health records and other electronic sources of very large populations receiving healthcare within integrated

or networked delivery systems⁹ and patient-powered research networks (PPRNs) built by communities of motivated patients, forming partnerships with researchers.¹⁰ CDRN and PPRN brief communications included in this special focus issue provide further information about these networks.

In December 2013, PCORI's board of governors funded 11 CDRNs and 18 PPRNs for a period of 18 months starting in March 2014 that together form PCORnet (<http://www.pcori.org>). Each CDRN is committed to building a large patient cohort with comprehensive, longitudinal electronic clinical data; developing policies for data standardization, shared governance, efficient use of clinical information for multicenter studies, stringent attention to data security and patient privacy, and robust, scalable centralized research support tools; and building the capacity to participate successfully in multi-network randomized trials and observational studies. Each CDRN is a collaboration of health systems that include among others academic health centers, community hospitals, health plans, inpatient and outpatient hospitals and providers, federally qualified health centers, veterans' administration clinics, pediatric hospitals and providers, integrated delivery systems, private electronic health record companies, and a regional health information exchange (table 1).

Each PPRN consists of patients, caregivers, or families, who are linked by the experience of a shared condition (table 2). An important commitment of these patient-based networks is to collect and curate data from at least 80% of their membership. The PPRNs are also expected to expand the number of patients in their network; to collect standardized patient data; and, when necessary, for the purposes of research, engage patients to participate in interventional research and in building, using, and governing their networks. The organizational set-up of PPRNs is diverse, as exemplified by the number of different partnership models that link patient foundations and associations with academic research centers. The CDRNs and PPRNs are geographically diverse, with patients in 50 states (figure 1).

A coordinating center co-led by the Harvard Pilgrim Health Care Institute and Duke University (contract awarded in September 2013) provides technical and logistical expertise and assistance to awardees. It has established 11 task forces (figure 2), whose members are nominated from the CDRNs and PPRNs and whose role is to develop policies, operations, and products to support the development of PCORnet. A steering committee, subject to the oversight of PCORI, guides members of



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Brief communication

Table 1 Clinical data research networks

Clinical Data Research Network (CDRN) name	Lead organization
Accelerating Data Value Across a National Community Health Center Network (ADVANCE)	Oregon Community Health Information Network
Chicago Area Patient Centered Outcomes Research Network (CAPriCORN)	The Chicago Community Trust
Great Plains Collaborative	University of Kansas Medical Center
Kaiser Permanente and Strategic Partners Patient Outcomes Research to Advance Learning (PORTAL)	Kaiser Foundation Research Institute
Louisiana CDRN	Louisiana Public Health Institute
Mid-South CDRN	Vanderbilt University
A National Pediatric Learning Health System (PEDSNet)	The Children's Hospital of Philadelphia
New York City clinical data research networks (NYC-CDRN)	Weill Medical College of Cornell University
Patient-oriented SCALable National Network for Effectiveness Research (pSCANNER)	University of California, San Diego
A P2aTH Towards a Learning Health System in the Mid-Atlantic Region (P2aTH)	University of Pittsburgh
Scalable Collaborative Infrastructure for a Learning Healthcare System (SCILHS)	Harvard University

PCORnet and advises PCORI leadership (figure 2). Final approval of all policies, activities, and recommendations resides with the PCORI leadership.

PCORNET DISTRIBUTED DATA RESEARCH NETWORK

PCORnet is being developed as a distributed research network (DRN) that facilitates multi-site, observational and interventional research across the CDRNs, PPRNs, and other interested contributors, while minimizing the transfer of individual-level clinical data outside of the system where care is received. PCORnet's unique vision is to create a network that supports the CDRN and PPRN internal network development while creating a mechanism to facilitate research across these networks. Advantages of conducting research across multiple networks of

PCORnet comprise greater sample size and power, the ability to study effects of practice pattern and treatment variation, the inclusion of diverse populations, and the possibility of supporting analyses that assess heterogeneity of treatment effect.

The distributed network will enable research studies to be conducted, while allowing each participating organization to maintain physical and operational control over their data. This structure lowers institutional barriers to participation and ensures availability of local experts who can interpret the data.^{11 12} The Data Standards, Security and Network Infrastructure (DSSNI) task force will identify minimal data standards and technical specifications for data standardization across CDRNs and PPRNs and develop an approach to cross-network querying that meets the security, patient privacy,

Table 2 Patient powered research networks

Patient-Powered Research Network (PPRN) name	Condition
Adrenoleukodystrophy (ALD) Connect	ALD
American BRCA Outcomes and Utilization of Testing PPRN (ABOUT Network)	Hereditary breast and ovarian cancer
ARthritis patient Partnership With comparative Effectiveness Researchers (AR-PoWER PPRN)	Arthritis (rheumatoid arthritis, spondyloarthritis), musculoskeletal disorders (osteoporosis), and inflammatory conditions (psoriasis)
Chronic Obstructive Pulmonary Disease (COPD) Patient Powered Research Network	COPD
Collaborative Patient-Centered Rare Epilepsy Network (REN)	Aicardi syndrome, Lennox–Gastaut syndrome, Phelan–McDermid syndrome, hypothalamic hamartoma, Dravet syndrome, and tuberous sclerosis
Community-Engaged Network for All (CENA)	Alström syndrome, dyskeratosis congenita, Gaucher disease, hepatitis, inflammatory breast cancer, Joubert syndrome, Klinefelter syndrome and associated conditions, metachromatic leukodystrophy, Pseudoxanthoma elasticum (PXE), psoriasis
Crohn's and Colitis Foundation of America (CCFA) Partners PPRN	Inflammatory bowel disease (Crohn's disease and ulcerative colitis)
Duchenne Connect Patient-Report Registry Infrastructure Project	Duchenne and Becker muscular dystrophy
Health eheart alliance: a PPRN focused on cardiovascular health	Cardiovascular health
ImproveCareNow: a learning health system for children with Crohn's disease and ulcerative colitis	Pediatric Crohn's disease and ulcerative colitis
Mood PPRN	Major depressive disorder and bipolar disorder
A multiple sclerosis PPRN	Multiple sclerosis
NephCure Kidney Network for patients with nephrotic syndrome	Primary nephrotic syndrome (focal segmental glomerulosclerosis, minimal change disease, and membranous nephropathy)
The Patients, Advocates and Rheumatology Teams Network for Research and Service (PARTNERS) Consortium	Juvenile rheumatic disease
Phelan–McDermid Syndrome Data Network	Phelan–McDermid syndrome
Primary Immunodeficiency Patient Research Connection (PI-Connect)	Primary immunodeficiency diseases
Sleep Apnea-Patient Centered Outcomes Network (SA-PCON)	Sleep apnea
The Vasculitis Patient Powered Research Network	Vasculitis

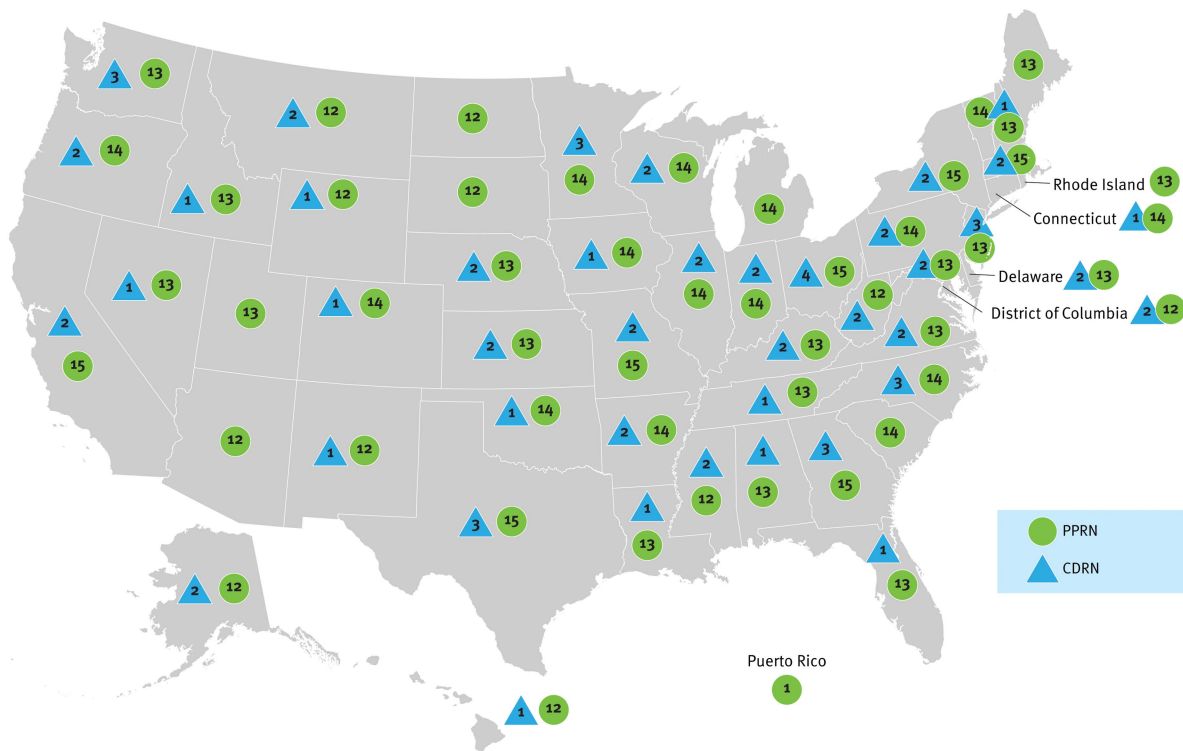


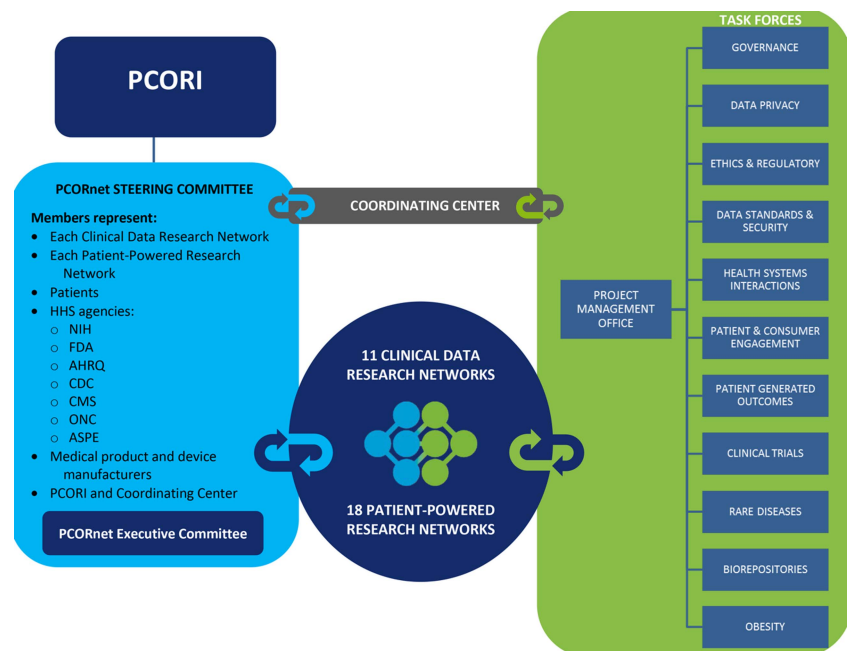
Figure 1 Map of clinical data research networks (CDRN) and patient-powered research networks (PPRN) across the USA.

institutional confidentiality, and governance needs of the network participants.¹³

The distributed querying approach allows simple and complex analyses to be executed behind institutional firewalls, thereby eliminating or minimizing the release of protected health information. Instead, only the minimum information needed to answer a specific question is transferred to the person making a request. Increasingly, even complex multi-site analyses can be accomplished without transfer of private health information by use of privacy preserving regression techniques.^{14 15}

As part of their PCORnet participation, each CDRN will develop an analyzable research dataset (to be specified by the DSSNI task force) that supports complex distributed analyses. After 18 months, this dataset should contain data on one million patients and the CDRN will be able to regularly complete queries against the dataset using the secure PCORnet DRN tools. An example of the type of observational studies that might be supported by the DRN is a comparison of the outcomes of ischemic and hemorrhagic stroke in adults with atrial fibrillation who are new users of dabigatran or warfarin.¹⁶ The

Figure 2 Organizational structure of PCORnet. AHRQ, Agency for Healthcare Research and Quality; ASPE, Assistant Secretary for Planning and Evaluation; CDC, US Centers for Disease Prevention and Control; CMS, Centers for Medicare and Medicaid Services; FDA, Food and Drug Administration; NIH, National Institutes of Health; ONC, Office of the National Coordinator for Health Information Technology; PCORI, Patient-Centered Outcomes Research Institute.



Brief communication

PCORnet DRN tools will be developed by input from the relevant task forces, including DSSNI, Governance, and Data Privacy during the first 18-month phase of funding (starting March 2014). The DSSNI task force will develop a PCORnet common data model (CDM) to support the development of analyzable research datasets that will permit efficient distributed analyses. The PPRNs aim in 18 months to have the ability to build a standardized clinical database with relevant clinical and patient-reported outcomes data from at least 80% of their membership. Overall, implementation of the PCORnet DRN networking and querying capabilities will prioritize rapid development, testing, use, and feedback learning cycles. This process will enable experimentation in networking approaches, demonstrate approaches to secure network operations, and identify potential barriers as early as possible.

PCORNET AND PATIENT-CENTEREDNESS

Over the 18-month funding phase, each CDRN and PPRN will develop effective patient-engagement strategies at the level of their networks. These strategies will involve ensuring that patients have a central role in collecting data for the generation of new knowledge for patients with their condition, as well as in participating in the governance of the network, prioritizing research questions, and disseminating results.¹⁰ At the CDRN level, patient engagement strategies require developing approaches to inform patients who are members of the systems of the existence and function of the research network, to involve patients in generating research questions, and in including patients in the governance associated with the development and uses of the network.⁹

CHALLENGES

Rapidly building a new national resource to facilitate large-scale, patient-centered CER will face a number of technical, regulatory, and organizational challenges.

Technical challenges, first, include successfully completing the capture of relevant longitudinal clinical data, a requirement for all CER studies. Since most electronic health record systems typically do not have information on care provided outside their health system, both CDRNs and PPRNs will need to explore approaches to dealing with this problem.¹⁷ Second, in order to achieve multi-institutional querying, PCORnet will have to deal with data harmonization.¹⁸ This will require understanding the context in which the data were collected, the various clinical and other terminologies in use, and changes in local systems and national standards (such as those associated with the Centers for Medicare and Medicaid's 'meaningful use' regulation) that affect the data. This should be done without requiring a change in the way the routine medical care data are collected, and will require data harmonization.^{19 20} PCORnet has chosen to develop a CDM, derived from the Mini-Sentinel CDM to enable efficient cross-networking querying.²¹ Third, the collection, harmonization, and use of a wide range of potential patient-reported data (eg, personal and family medical histories, use of remote monitoring devices, etc) for research is a nascent field,²² yet promises to empower patients to provide data that more fully describe their experience of, and preferences for, the treatment and management of their condition. In the absence of a standardized ontology or lexicon for a large number of these data elements, the ability to routinely include this information in analyzable research datasets will be explored in this first phase of PCORnet's development but will probably occur fully in later phases.

In addition to technical challenges, PCORnet will need to examine ethical and regulatory oversight. Many patients, advocates, and researchers describe the research oversight system as cumbersome, inefficient, and expensive.^{23–25} PCORnet will need to deal with problems associated with the design of appropriate clinical studies, informing prospective participants, and obtaining permissions in a manner that protects human rights while supporting the acknowledged need for more research to provide patients and clinical decision-makers with more reliable evidence.²⁶ Areas of interest that PCORnet will explore through its task forces include central institutional review boards or internet-facilitated shared review systems, and, centralized support for enrolling subjects and obtaining their consent. Because of the scale and complexity of the types of research envisaged, PCORnet will be challenged to develop streamlined approaches to the structure and function of the network and its projects while maintaining sound ethics and regulatory compliance.

PCORnet will be faced with the organizational challenges associated with the rapid development of a national resource with a heterogeneous group of CDRNs and PPRNs of varying size, populations served, health systems included and many other characteristics. Although this diversity among awardees was both predictable and desirable, one area in which the diversity of networks was quickly apparent was the divergent approaches used for data management. Nevertheless, each CDRN and PPRN will be challenged with balancing the demands of their local networks, research cultures, and areas of particular expertise with the requirements of participating in a national research resource. This will require them to agree rapidly on a common approach to data interoperability and to the conduct of joint analyses.

PCORnet's success and long-term sustainability will also depend on communicating with health system leaders and providing them with evidence of the benefits of conducting high-quality, efficient research as part of the routine delivery of care. Securing the commitment of delivery systems' leaders, health system administrators, and clinicians will require considerable strategy and effort by all PCORnet stakeholders. Finally, and importantly, PCORnet is committed to supporting patient engagement across the networks and will need to deal with the challenges of successfully supporting a variety of governance structures that fully ensure that patients are involved in setting policies for PCORnet and for their own networks, determining strategic direction, and prioritizing research questions.²⁷

PCORNET WILL BE OPEN TO EXTERNAL DATA PARTNERS, RESEARCHERS, AND FUNDERS

The PCORnet DRN will be open to external data and research affiliates willing to participate in research studies alongside the PCORI-funded CDRNs and PPRNs. Of particular note, PCORnet's distributed networking platform is shared by the FDA Mini-Sentinel program, the NIH Health Care Systems Research Collaboratory and other networks such as the HMO Research Network.^{3 6 7} Any organization that is part of these networks can make itself visible to the others and choose to receive queries from any of them. PCORI's vision is for the PCORnet DRN to be available for use by researchers not directly affiliated with PCORnet CDRNs and PPRNs through collaborative arrangements. The proposed governance models and mechanisms for these types of collaboration will be developed during the initial 18-month funding phase, which started in March 2014.

CONCLUSION

The first phase of building PCORnet will span 18 months. At the end of this time, we hope that a functional research network that can support both observational and interventional research will have emerged. We also expect a new model for efficiency and affordability in clinical research, made possible both by investments in, and use of, this evolving data infrastructure, and the involvement of host healthcare systems, clinicians, and patients together with researchers. Although PCORnet will need to continue to grow and improve its data resources and capabilities, a measure of success will be the willingness of external research funders, both public and private, to fund research studies using PCORnet.

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Developing a data infrastructure for a learning health system: the PORTAL network

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ABSTRACT

The Kaiser Permanente & Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) network engages four healthcare delivery systems (Kaiser Permanente, Group Health Cooperative, HealthPartners, and Denver Health) and their affiliated research centers to create a new national network infrastructure that builds on existing relationships among these institutions. PORTAL is enhancing its current capabilities by expanding the scope of the common data model, paying particular attention to incorporating patient-reported data more systematically, implementing new multi-site data governance procedures, and integrating the PCORnet PopMedNet platform across our research centers. PORTAL is partnering with clinical research and patient experts to create cohorts of patients with a common diagnosis (colorectal cancer), a rare diagnosis (adolescents and adults with severe congenital heart disease), and adults who are overweight or obese, including those with pre-diabetes or diabetes, to conduct large-scale observational comparative effectiveness research and pragmatic clinical trials across diverse clinical care settings.

BACKGROUND

Kaiser Permanente & Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) is a network that brings together four leading healthcare delivery systems: Kaiser Permanente, Group Health Cooperative, HealthPartners, and Denver Health. These systems include 11 affiliated research centers and serve 11 million members across nine states and the District of Columbia (table 1; figure 1), or approximately one of every 30 people in the USA. The four PORTAL health systems own or operate 44 hospitals, 674 clinics or medical offices, and 625 in-house pharmacies. The PORTAL partners represent a great diversity of care models and practices. The Kaiser Permanente regions, for example, contract out only a small proportion of ambulatory care, inpatient care, imaging, and highly specialized tertiary services. Group Health Cooperative, on the other hand, contracts externally for a relatively large proportion of its physicians and facilities services.

THE PORTAL DATA ENVIRONMENT

PORTAL network sites represent large and diverse integrated health systems that include inpatient and outpatient facilities; primary care and specialty provider networks; and ancillary services, pharmacies, and ambulatory procedure centers. Detailed clinical

and administrative data are integrated into a comprehensive longitudinal electronic health record (EHR). Each participating PORTAL organization maintains a separate electronic record that captures in-system encounters and incorporates billing and clinical care data from services delivered by providers outside the organization. Extensive historical records and relatively long average enrollment periods allow PORTAL sites to participate in comparative effectiveness research (CER) studies that involve long periods of time for exposure or outcomes.

The PORTAL common data model

Collaboration to conduct research among these different health plans and organizations presents challenges. PORTAL healthcare systems use different EHR vendors and different clinical, administrative, and patient-access applications to support clinical care. Institutional differences in configurations, workflows, and codes create additional barriers to sharing data *directly* using existing systems. Even among partners who use EHRs from the same vendor, differences in products, capabilities, versions, and local configurations create dissimilarities in data variable names, formats, and meanings.

To address these issues, PORTAL will use a common data model (CDM) that provides definitions for how each shared data element must be structured and which codes must be assigned to data values.¹ CDMs have been used successfully in large-scale national data sharing networks.^{2–4} One data model used in multiple national networks is the HMO Research Network Virtual Data Warehouse (HMORN VDW).^{5–6} Over a 20-year period, the HMORN has developed detailed definitions, documentation, and implementation guides for the structure of each data table and the allowed codes used in each field.^{6–7} The HMORN has developed an extensive set of data validation routines to assess data quality in VDW data extractions.⁸

The Kaiser Permanente Center for Effectiveness and Safety Research (CESR) CDM is an *expansion* of the current HMORN VDW and is the data model that will be implemented across PORTAL sites. Figure 2 illustrates the data domains defined in the current and future versions of the CESR CDM. A critical priority of the Patient Centered Outcomes Research Institute (PCORI) is to include a wide range of patient-reported outcomes (PROs) in addition to traditional clinical and administrative data. The CESR CDM contains four additional

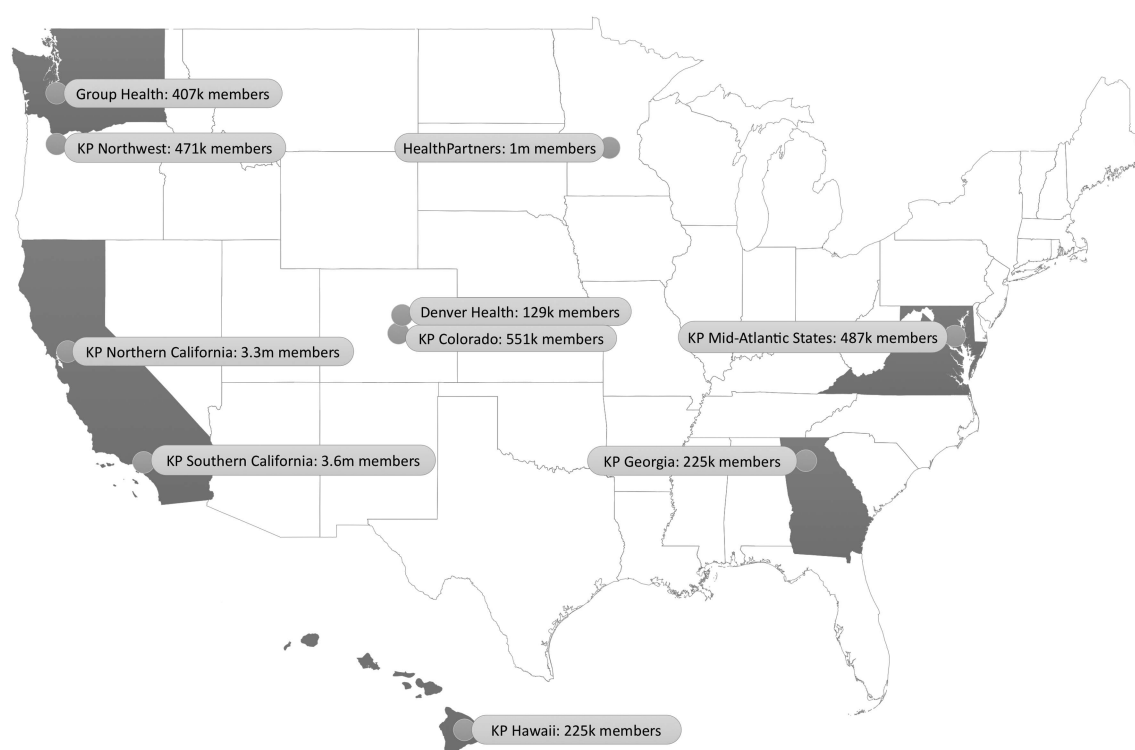
Table 1 The PORTAL health systems

Kaiser Permanente (KP)	KP was founded in 1945 to provide high-quality, affordable healthcare services and to improve the health of its members and the communities it serves. The KP Medical Care Program is an integrated delivery system comprising more than 9 million members in seven regions in eight states and the District of Columbia. Care for members and patients is focused on their total health and guided by their personal physicians, specialists, and teams of caregivers.
Group Health Cooperative (GHC)	GHC, located in Washington State, began in 1947 as a community coalition dedicated to making quality healthcare available and affordable. Along with HealthPartners, GHC is one of the few healthcare organizations in the country governed by consumers. Its 11-member Board of Trustees—all health plan members elected by other members—work closely with management and medical staff to ensure that the organization's policies and direction put the needs of patients first. GHC seeks to promote patient-centered care and innovation by continually focusing on the needs of its 407 000 members.
Health Partners (HP)	HP was founded in 1957 in Minnesota as a cooperative. Today, HP is the largest consumer-governed, non-profit healthcare organization in the nation. In 2013, HP partnered with Park Nicollet, a non-profit, integrated healthcare system in Minnesota, to improve health, patient experiences, and affordable care, and engage members and the community. The two organizations are now officially joined under the name HealthPartners and a single, consumer-governed board of directors. This new integrated healthcare and financing organization serves more than 1.4 million medical and more than 1 million dental patients in Minnesota and western Wisconsin.
Denver Health (DH)	DH was established in 1860 and is a comprehensive, integrated organization providing level-one care, regardless of ability to pay. Twenty-five percent of all Denver residents, or approximately 130 000 individuals, receive their healthcare at DH. DH cares for one in three children in Denver. As Colorado's primary safety net institution, DH has provided billions of dollars in uncompensated care. DH is an integrated, efficient, high-quality healthcare system serving as a model for other safety net institutions across the nation.

Patient Reported Outcomes tables for storing patient-reported data such as exercise as a vital sign (EVS), the Patient Health Questionnaire (PHQ-9),⁹ and the Brief Pain Inventory Survey (BPI).¹⁰ These new tables ensure that PORTAL will be able to store and analyze PROs in alignment with a central PCORI objective.

Information exchange, both among PORTAL sites and between the PORTAL network and other PCORnet networks, requires both syntactic (structure) and semantic (meaning) harmonization.^{11 12} For sharing data between multiple networks, mappings between CDMs can be constructed to provide syntactic harmonization. Semantic harmonization, however, can be difficult if two networks use different terms, coding systems, and data definitions.^{13–16} While not a complete solution to full

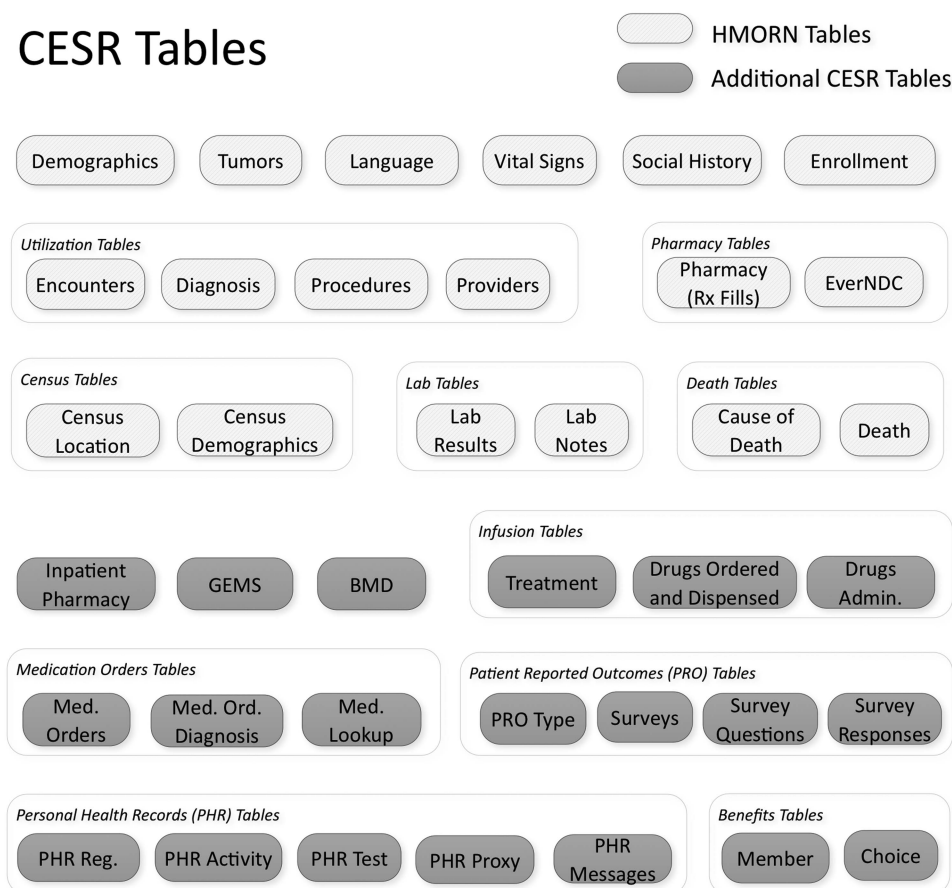
semantic harmonization, the CESR data model uses widely adopted national and international coding systems as data elements and values (table 2, figure 3). In August 2012, the Centers for Medicare and Medicaid Services and the Office of the National Coordinator for Health Information Technology released the Final Rule for Meaningful Use Stage 2, which specifies multiple terminologies that must be incorporated into certified EHR products by October 2014.^{17–19} The CESR CDM contains all of the terminologies specified in these regulations except for SNOMED Clinical Terms (SNOMED CT). As the delivery systems at PORTAL sites transition to these new coding systems, the CESR CDM will extract data elements encoded in these new terminologies. Because the current CESR CDM has the ability to record data in multiple coding standards

**Figure 1** Geographic distribution of PORTAL clinical practices. KP, Kaiser Permanente; k, thousands(s); m, million(s).

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Figure 2 The Kaiser Permanente Center for Effectiveness and Safety Research (CESR) common data model.

CESR Tables

**Table 2** National/international terminology standards used in the Kaiser Permanente Center for Effectiveness and Safety Research (CESR) common data model

Table/clinical domain	National/international coding standards in CESR data model
Demographics	Race: NIH*
Encounters	CMS DRG
Diagnosis	ICD-7-CM, ICD-8-CM, ICD-9-CM, ICD-10-CM
Procedures	ICD-9, ICD-10, ICD-11, CPT-3, CPT-4, HCPCS-3, HCPCS-4†
Tumor	ICD-O-3‡, SEER SS1997, SEER SS2000\$, Facility Oncology Registry Data Standards¶
Pharmacy dispensings	NDC, Medi-Span GPI**, AHFR Pharmacologic-Therapeutic Classification System††
Medication orders	ICD-9, ICD-10 diagnoses associated with medication orders
Census	FIPS/NIST geocoding standards‡‡
Death	ICD-9, ICD-10
Laboratory	LOINC

URLs to less common coding standards are provided as follows:

*http://www.whitehouse.gov/omb/fedreg_1997standards

†<http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/TransactionCodeSetsStandards/index.html>

‡<http://www.who.int/classifications/icd/adaptations/oncology/en/>

§<http://seer.cancer.gov/tools/ssm/>

¶<http://www.facs.org/cancer/coc/programstandards2012.html>

**<http://www.medspan.com/uniform-system-of-classification-cross-reference-file/>

††<http://www.ahfsdruginformation.com/license-pt-classification.aspx>

‡‡<http://www.nist.gov/itl/fipsinfo.cfm>

(eg, diagnosis in both ICD and SNOMED CT), adding SNOMED CT as valid values for coded data elements will not require changes to the data model structure. This functionality permits the co-existence of legacy data in legacy coding systems and data captured using newer coding systems, which is critical for conducting long-term longitudinal observational CER studies.

Distributed data sharing platform

Distributed data queries and data exchange across PORTAL partners will be managed using PopMedNet (<http://www.popmednet.org>) technology (figure 3).²⁰ PopMedNet provides the security, authentication, and auditing capabilities required to ensure only approved data requests are submitted and returned. PopMedNet is a data-model agnostic distributed data-sharing platform that supports a wide range of data governance models. PCORI has selected PopMedNet to support PCORnet's network-of-networks data sharing infrastructure.

Ensuring data consistency and quality across network partners

The PORTAL network will build upon the experiences of other established networks to develop new partnerships. Over the past 20 years, for example, the HMORN has developed extensive policies, procedures, and technologies for evaluating and investigating data validation, quality, and consistency. Brown and

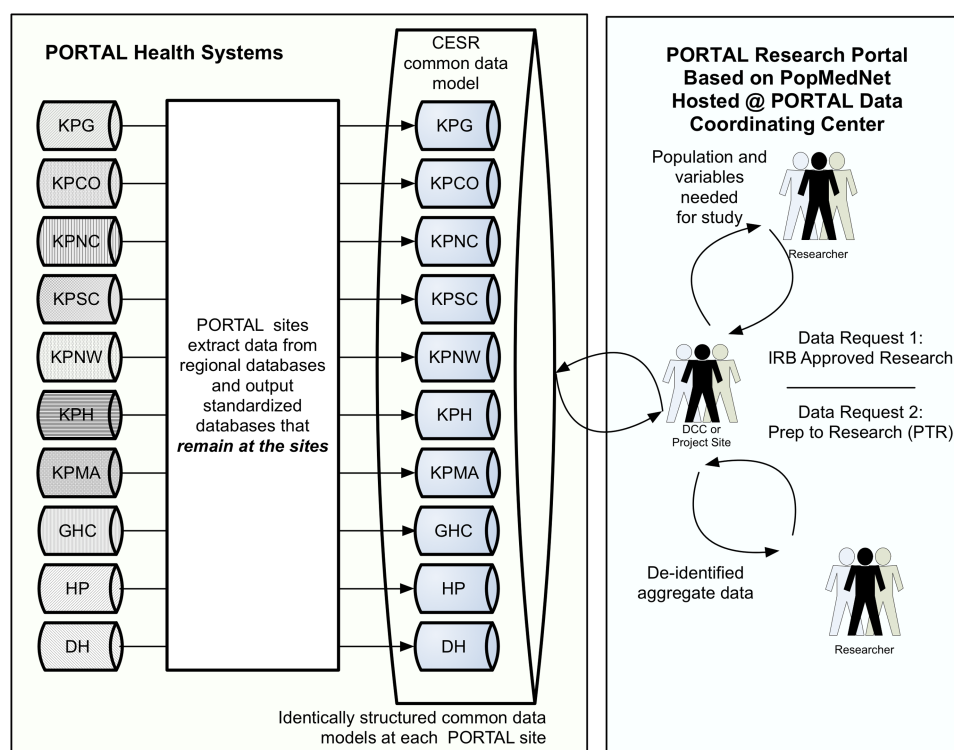


Figure 3 Data integration via the Kaiser Permanente Center for Effectiveness and Safety Research (CESR) common data model and PopMedNet distributed query platform. DH, Denver Health; GHC, Group Health Cooperative; HP, Health Partners; KP {G, CO, NC, SC, NW, H, MA}, Kaiser Permanente {Georgia, Colorado, Northern California, Southern California, Northwest, Hawaii, Mid-Atlantic}.

colleagues illustrate some of the ‘lessons learned’ from the vast field experience within the HMORN and Mini-Sentinel networks.²¹ Additionally, Kahn has published a detailed data quality assessment (DQA) model²² and, in collaboration with the Electronic Data Methods Forum, has developed a set of recommendations for standardized DQA reporting measures.²³ Similarly, Bauck and colleagues developed a conceptual model for a consistent DQA framework that is being implemented across the HMORN/CESR sites.⁸ PORTAL will draw upon these sources when developing common DQA policies and procedures and common data quality output structures so that investigators seeking to combine data from multiple networks can evaluate data quality measures from each participating site to assess their ‘fitness for use’ for their research question prior to incorporating data from that site.

PORTAL COHORTS

To ensure broad applicability, PCORI required each research network to develop cohorts representing a common clinical condition and a rare clinical condition. All networks were also required to develop an obesity cohort. The PORTAL network will construct three cohorts: (1) patients with a diagnosis of colorectal cancer (CRC), representing a common disease; (2) adolescents and adults with severe congenital heart disease (CHD), representing a rare disease; and (3) adults who are overweight or obese, including those who have pre-diabetes or diabetes. The characteristics of these cohorts are described briefly.

Colorectal cancer

We chose CRC because it is the third most common cancer in the USA, is the second leading cause of cancer death, and affects both men and women. Approximately 1.2 million people in the

USA currently live with CRC, which offers opportunities for studying issues of survivorship, including cancer treatment and transitions in care between primary and specialty physicians (eg, primary care, surgery, gastroenterology, and oncology). This allows researchers to examine differences in screening, treatment choices, and survivorship experiences by gender,²⁴ race/ethnicity, comorbid conditions, and patient preferences. There are more than 11 000 individuals with CRC across the network.

Severe congenital heart disease

Adolescents and adults with severe CHD were selected because this group faces three generalizable challenges to healthcare systems: (1) transitions in care from adolescence to adulthood; (2) monitoring of patients at increased risk for chronic conditions and associated morbidity and mortality (specifically, chronic heart failure); and (3) interfaces between primary, specialty (general cardiology), and subspecialty (CHD-specific) care. The Centers for Disease Control and Prevention recently convened a panel of experts that identified two gaps in understanding the public health implications of this condition: long-term outcomes for persons with CHD and the appropriateness of care delivery, particularly through the transition from adolescence to adulthood.²⁵ The PORTAL network contains approximately 330 patients with severe CHD.

Obesity

More than one-third of adults in the USA are obese.²⁶ The prevalence of obesity is similar for men and women, more common among persons age 60 and older, and varies by race/ethnicity, with non-Hispanic black individuals having the highest age-adjusted rates of obesity (49.5%). Obesity’s relationship to diabetes is well established, with more than 10% of the US adult population currently diagnosed with diabetes and with

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a prevalence greater than 25% for adults over the age of 65 years. Another 79 million adults have pre-diabetes, a condition of abnormally high blood glucose levels and a precursor to diabetes. Compared with white individuals, Mexican Americans and black individuals have a 87% and 77% higher risk of developing diabetes, respectively.²⁶ Each of the clinical data research networks will develop a cohort of persons who are overweight or obese that will demonstrate PORTAL's ability to work across the network of networks that comprise PCORnet. The PORTAL network has over 3 000 000 individuals who meet the criteria for obesity.

INCORPORATING PATIENT-REPORTED DATA IN ROUTINE CLINICAL PRACTICE

PORTAL members recognized the importance of capturing patient-reported data directly into the EHR many years ago. Three measures are routinely collected at all Kaiser Permanente and Group Health Cooperative sites: EVS, the BPI, and the PHQ-9, making these variables available to investigators seeking to link patient outcome measures to disease states, therapeutic interventions, and clinical outcomes.

PORTAL members have identified six critical success factors/barriers for incorporating patient-reported data into routine care delivery. First, clinicians are more likely to adopt and use measures that enhance the clinician's ability to deliver high-quality care. Clinicians often see disease-specific measures, such as the PHQ-9, as more relevant than general measures of overall functional status. Second, data collection must be hard-wired into daily workflows to ensure complete data capture. EVS measures, for example, are integrated into the routine information gathering performed by the medical assistant or nurse during the visit intake process. Third, resources must be available to ensure that the necessary functionality is implemented and is consistent with regulatory and compliance requirements. Fourth, the placement of information in the clinical record must be convenient and interpretable. All too often, PROs appear as a separate tab in the record or as a PDF that must be selected separately to view. Fifth, in some instances, patients have been reluctant to have these data incorporated into their medical record. For example, only 65% of members who take a Total Health Assessment Survey through Kaiser Permanent's web portal agree to share this information with their physician. Sixth, patients' willingness to provide this information depends on their belief that the data will be used in practice. These six principles, gleaned from many years of experience with a wide range of measures, will guide PORTAL's development of a sustainable data collection strategy within routine clinical practice.

CONCLUSION

With nearly 11 million people and more than 15 years of collaborative history among most of its partner sites, the PORTAL network offers a robust and experienced platform for comparative effectiveness and patient-centered outcomes research. This network holds promise for enhancing, storing, and analyzing patient-reported data and adopting new approaches for patient, clinician, and stakeholder engagement in all aspects of research, from the development of high-impact questions to the design of interventions and data collection approaches. These results will ultimately improve healthcare practices. As a partner in PCORnet, PORTAL can be a significant contributor to, and benefactor from, the rapidly evolving new model for interoperable large-scale national collaborative patient-centered research networks.

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Developing a data infrastructure for a learning health system: the PORTAL network

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Changing the research landscape: the New York City Clinical Data Research Network

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ABSTRACT

The New York City Clinical Data Research Network (NYC-CDRN), funded by the Patient-Centered Outcomes Research Institute (PCORI), brings together 22 organizations including seven independent health systems to enable patient-centered clinical research, support a national network, and facilitate learning healthcare systems. The NYC-CDRN includes a robust, collaborative governance and organizational infrastructure, which takes advantage of its participants' experience, expertise, and history of collaboration. The technical design will employ an information model to document and manage the collection and transformation of clinical data, local institutional staging areas to transform and validate data, a centralized data processing facility to aggregate and share data, and use of common standards and tools. We strive to ensure that our project is patient-centered; nurtures collaboration among all stakeholders; develops scalable solutions facilitating growth and connections; chooses simple, elegant solutions wherever possible; and explores ways to streamline the administrative and regulatory approval process across sites.

INTRODUCTION

New York City is home to one of the largest, most diverse urban populations in the USA, including more than 8 million people with a wide range of socioeconomic and health characteristics.¹ Its healthcare system is marked by a concentration of academic medical centers with expertise in clinical care, research, and education. Despite this wealth of resources, healthcare delivery remains fragmented, as patients often receive care from multiple institutions, complicating efforts to conduct research, manage population health, and develop learning healthcare systems.

Funded by the Patient-Centered Outcomes Research Institute (PCORI), the New York City Clinical Data Research Network (NYC-CDRN) was formed to create an accessible, sustainable, scalable clinical data network that will enable patient-centered research, support a national research network, and facilitate the development of learning healthcare systems. This project features a unique collaboration across 22 organizations, including seven independent health systems, which will create unprecedented opportunities for city- and nation-wide population

health management, patient-centered clinical trials, observational studies, and precision medicine. Specific goals include aggregating data on a minimum of 1 million patients, engaging patients and front-line clinicians in all phases of the project, embedding research activity into the delivery of healthcare, aligning regulatory oversight across multiple health systems, and disseminating study results across healthcare systems.

This paper describes the project's goals, governance and organizational structure, and technical approach.

ORGANIZATIONAL AND SCIENTIFIC APPROACH

The NYC-CDRN includes a robust and collaborative governance and organizational infrastructure, which takes advantage of its participants' experience, expertise, and history of collaboration.

Participating institutions

The NYC-CDRN's participating institutions (table 1) have several notable features that provide an important foundation for the consortium. The NYC-CDRN includes six Clinical and Translational Science Award (CTSA) centers,² which already collaborate on research, data sharing, and patient engagement. Second, the participating health systems—including five medical schools, four affiliated health systems, and one practice-based research network of federally qualified health centers—have robust electronic health records (EHRs) and clinical data warehouses with many years of data. Third, the New York Genome Center (NYGC), an independent non-profit entity, with which all health systems are affiliated, has important expertise in genomic data and acts as a neutral party and 'honest broker'³ for aggregating and hosting data from competing institutions for research purposes. In addition, two regional health information organizations, Healthix¹ and the Bronx RHIO's Bronx Regional Informatics Center (BRIC), provide important expertise in patient matching and record de-duplication. Cornell NYC Tech, a new graduate school emphasizing technology and entrepreneurship, provides access to new methods for collecting patient-generated data. The Biomedical Research Alliance of New York (BRANY) serves as the centralized institutional review board (IRB) process to ensure appropriate regulatory oversight and protocol reviews. Finally, several patients and patient advocacy groups provide important expertise in patient engagement.

Brief communication

Table 1 NYC-CDRN participating institutions

Partner	Organization	EHR/HIE platform	Patients in EHR/HIE*
Health system	Clinical Directors Network (CDN)	eClinicalWorks, GE Centricity	250k
	Columbia University College of Physicians and Surgeons (CUCPS)†	Allscripts Enterprise	767k
	Montefiore Medical Center and Albert Einstein College of Medicine (MMC)†	GE Centricity‡	1000k
	Mount Sinai Health System and Icahn School of Medicine (MSHS)†	Epic	4700k
	New York-Presbyterian Hospital (NYPH)	Allscripts Sunrise	1400k
	New York University Langone Medical Center and New York University School of Medicine (NYULMC)†	Epic	1800k
	Weill Cornell Medical College (WCMC)†	Epic	560k
Research infrastructure	Biomedical Research Alliance of New York	N/A	N/A
	Cornell NYC Tech Campus		
	New York Genome Center		
	Rockefeller University†		
HIE	Bronx RHIO (Bronx Regional Informatics Center)	Optum	1650k
	Healthix	InterSystems HealthShare	7000k
Patient organization	American Diabetes Association	N/A	N/A
	Center for Medical Consumers		
	Consumer Reports		
	Cystic Fibrosis Foundation		
	New York Academy of Medicine		
	NYS Department of Health		

*Patients overlap and are for the period 1 August 2008–31 July 2013.

†Denotes CTSA site.

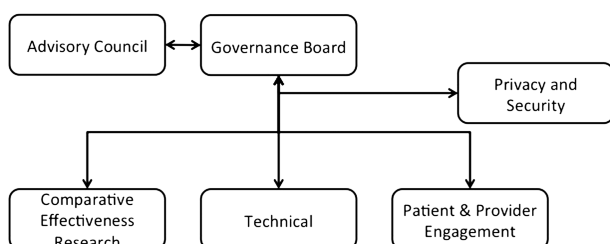
‡Montefiore is replacing existing EHR platforms with Epic.

CTSA, Clinical and Translational Science Award; EHR, electronic health record; HIE, health information exchange; N/A, not applicable; NYC-CDRN, New York City Clinical Data Research Network.

Organizational structure

The NYC-CDRN has created a multi-stakeholder organizational structure (figure 1) that includes leadership and participation from researchers, clinicians, and patients.^{4–6} We have organized our work according to seven overarching goals. One committee leads each section and liaises with the other committees to collaborate on cross-cutting issues. For example, the Technical Committee cannot develop its data model without input from researchers, clinicians, and patients in the Comparative Effectiveness Research (CER) and Patient and Engagement Committees.

1. *Create a strong governance and business infrastructure:* The NYC-CDRN has a robust, collaborative governance and organizational model that operates the network in the interests of all participants. The Governance Board oversees the entire project, sets policies in consultation with stakeholders and advisors, and ensures that all committees and stakeholders are on track to meet their deliverables. It addresses open issues within and among the committees, ensures common understanding of key network concepts and

**Figure 1** Organizational structure of NYC-CDRN (New York City Clinical Data Research Network).

functions, and facilitates interactions with the healthcare systems among other functions.

2. *Ensure strong accountability and coordination among project committees and stakeholders:* The NYC-CDRN project is a complex endeavor with many moving, intersecting, and inter-dependent parts. The Operations Group has established a project management infrastructure to guide that activity. It drives, monitors, and reports progress; ensures quality and accountability across all stakeholders; and tracks adherence to milestones and timelines.
3. *Develop an overarching vision and sustainability:* The NYC-CDRN reviews its strategy and vision with an Advisory Council of external healthcare leaders and subject matter experts. The Council ensures that the project benefits from new ideas, stays aligned with local and national developments, and focuses on financial sustainability.
4. *Establish a legal foundation that protects patient privacy and security:* All participating health systems have data sharing policies, IRB processes, and privacy and security policies in place. However, it would be a slow process for researchers interested in multi-site studies to obtain necessary approvals and negotiate separate policies and requirements individually from all IRBs. Thus, the project's Privacy and Security Group works with participants to agree to a common, consistent set of network processes, policies, and data sharing agreements. The participants have agreed to use a central IRB, housed at BRANY.
5. *Engage patients and clinicians:* This project relies on strong leadership and input from patients and clinicians in all its phases. Patients and clinicians participate in governance, inform and develop research questions, and ensure that the network's policies protect patient privacy and security. The Patient and Clinician Engagement Committee ensures that

Table 2 New York City population characteristics

Characteristic	%
Age (years)*	
≤19	24
20–44	39
45–64	24
65+	12
Median	36
Race*	
White	44
Black	26
Hispanic/Latino*	28
Female*	53
% Household income <\$25k†	28
% Publicly insured†	37
% Self-reported diabetes‡	11
% Self-reported high cholesterol‡	31
% Self-reported current cholesterol med‡	37
% Self-reported high blood pressure‡	29
% Self-reported asthma‡	12
% Overweight and/or obese‡	58
% Receiving mental health medication	4
% Current smoker	15

*2010 Census.

†2009 American Community Survey.

‡2011 NYC Community Health Survey.

all the other committees are identifying key policies and processes needing patient and clinician input. It also focuses on the collection of patient-reported outcomes.

6. *Embed research into practice:* Participating institutions all have expertise and experience in embedding aspects of research into practice while minimizing disruption of healthcare delivery—identifying patients for research, implementing research protocols, monitoring activities, and disseminating research outcomes to improve practice. The CER Committee develops use cases for the network and ensures that the network facilitates different types of research designs, including retrospective studies, observational studies, and randomized clinical trials at the level of the individual and cohort. Community workgroups are being established to identify the best ways to engage patients in those communities and to inform research.
7. *Build the technical infrastructure of the research data network:* In their initial 18 months, all CDRN projects must aggregate comprehensive, longitudinal data for at least 1 million patients for research purposes. Given the number of institutions involved, it is a significant challenge to compile that data in a standard way, match and link patient identities across institutions, de-identify the records, and

make available quality data. The project's Technical Committee oversees the design of the network architecture, the data model, and the design for the NYC-CDRN Informatics Center. These activities are described in more detail below.

Patient population and selected cohorts

PCORI CDRN awardees must focus on three conditions: a common condition, a rare condition, and obesity. NYC-CDRN has selected diabetes as its common condition and cystic fibrosis as its rare condition. According to the official city data, nearly 60% of New Yorkers are either overweight (34%) or obese (24%), and 11% have diabetes (table 2). Cystic fibrosis is a genetic disease that affects the digestive and respiratory systems, and NYC-CDRN has identified over 5000 patients among its institutions.

TECHNICAL APPROACH

The NYC-CDRN's technical approach will employ an information model to document and manage the collection and transformation of clinical data, local institutional staging areas to transform and validate data, a centralized data processing facility to aggregate and share data, and use of common standards and tools.

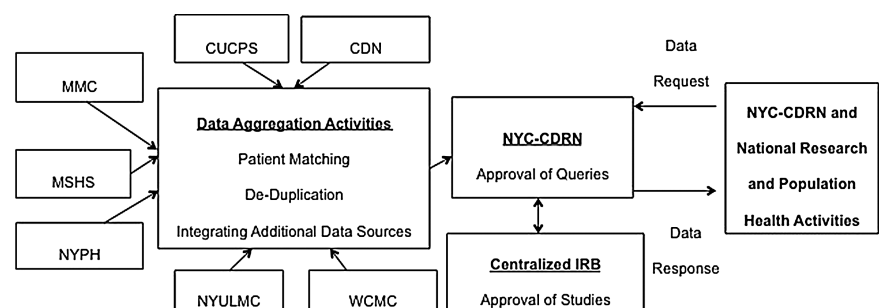
The NYC-CDRN Informatics Center, hosted at NYGC, will aggregate data from all the health systems centrally and make it available for research queries (figure 2). NYC-CDRN is being designed so that it is not constrained to a single technology or platform. It will utilize agile design and development with testing and iterative refinements as well as extensive quality controls.

Informational model

The NYC-CDRN will use a centrally defined information model and standardized set of terminologies to form the basis of data integration across institutions and for interoperability with PCORnet. Health systems will extract data from their EHRs or clinical data warehouse platforms according to a common set of vocabularies and then leverage existing models such as Observational Medical Outcomes Partnership (OMOP) to validate mappings between standard vocabularies to integrate demographics, ethnicity and race, diagnoses, procedures, medications, laboratory results, and other clinical elements.⁷ By separating representation of concepts from data storage implementation, the information model will enable use of different technologies for distinct purposes.

Local staging areas

Health systems will host a local staging area for their data feeds. They will follow procedures defined by NYC-CDRN for

Figure 2 NYC-CDRN (New York City Clinical Data Research Network) data flows.

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standards-based mapping of health information, quality assurance, data cleaning, and validation prior to sending a limited dataset to the Informatics Center. Systems iteratively will contribute data to the Informatics Center. For example, the first deliverable is for institutions to contribute patient demographics⁸ in a defined format followed by patient encounter data and then clinical observation data such as diagnoses, procedures, medications, and laboratory results as defined in the central information model.

Centralized data processing facility

The Informatics Center will aggregate each system's data into a patient-matched, de-duplicated central database and perform date shifting to preserve anonymity. This de-identified dataset will be available for query by investigators.⁹

It is critically important for a project like NYC-CDRN to match patients while preserving anonymity across multiple EHRs as a way of creating an integrated and complete view of longitudinal clinical data.^{10 11} The Informatics Center will leverage two health information exchanges' existing electronic master patient indices, patient matching algorithms, and patient de-duplication techniques provided by vendors (table 1) to align data contributed by systems to NYC-CDRN.

The central database will link to other sources including public and commercial claims data; patient-reported and patient-generated data, including data actively collected through surveys and passively collected through mobile devices; genomic data allowing for novel links to biologic and molecular disease markers; and other publicly available data.¹²

DISCUSSION

The NYC-CDRN is an ambitious project that has the potential to significantly change the research landscape in New York City and help shape national research efforts through the national PCORnet. To ensure our best chance of success, we abide by several guiding principles.

First, we strive to make the network truly patient-centered. We conduct all our activities in a fashion that is guided by, and accessible and understandable to, patients, caregivers, and their care teams. Patients have a wealth of knowledge about their conditions and healthcare experience that can inform and inspire new research opportunities.

Second, NYC-CDRN depends on the active and successful collaboration of many different institutions and individuals. By nurturing that collaboration effectively, we will have access not only to a great wealth of existing expertise and resources within our participating institutions but also to new ideas and initiatives created by the interaction of those parties, such as innovative research protocols, patient engagement methods, and technical models.

Third, the network needs to scale easily. As NYC-CDRN builds a network of health systems, we must continue to add new partners and link to the national PCORnet network. NYC-CDRN will draw strength from its scale.

Fourth, we strive to not over-complicate an already complex job. We endeavor to choose simple, elegant solutions wherever possible. For example, we are employing an iterative process to develop our data model—starting with small sections of the template, building, testing, and improving before expanding the dataset and moving on to new sections.

Finally, we strive to streamline the administrative and regulatory process to ensure that researchers can embark on critical research studies in a timely fashion, while ensuring the highest standards of patient safety and privacy.

CONCLUSION

With funding from PCORI, the NYC-CDRN is creating an accessible, sustainable, scalable clinical data network that will enable patient-centered research embedded within the functioning healthcare system, support a national research network, and facilitate the development of learning healthcare systems. The NYC-CDRN is well positioned to transform the research landscape in New York City and create new opportunities for wide-scale collaborations to design, conduct, and disseminate innovative clinical trials, CER, and population health management.

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Changing the research landscape: the New York City Clinical Data Research Network

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Organizational Background

The Roundtable

The Institute of Medicine's **Roundtable on Value & Science-Driven Health Care** provides a trusted venue for national leaders in health and health care to work cooperatively toward their common commitment to effective, innovative care that consistently adds value to patients and society. Members share the concern that, despite the world's best care, in certain circumstances, health in America falls far short on important measures of outcomes, value and equity. Care that is important is often not delivered, and care that is delivered is often not important. Roundtable Members are leaders from core stakeholder communities (clinicians, patients, health care institutions, employers, manufacturers, insurers, health information technology, researchers, and policy makers) brought together by their common commitment to steward the advances in science, value and culture necessary for a health system that continuously learns and improves in fostering healthier people.

What are the Roundtable's vision and goals?

- A **continuously learning health system** in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation—with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the care experience.
- Promote collective action and progress so that “By the year 2020, ninety percent of clinical decision will . . . reflect the best available evidence.” (*Roundtable Charter, 2006*)

How does the Roundtable work?

- Through stakeholder workshops and meetings: to accelerate understanding and progress toward the vision of a continuously improving and learning health system.
- Through joint projects through the work of six affinity group Innovation Collaboratives focused on:
 - **Best clinical practices** (health professional societies and organizations)
 - **Clinical effectiveness research** (innovative research scientists and institutions)
 - **Communication of medical evidence** (marketing experts and decision scientists)
 - **Digital technology for health** (health IT and care delivery experts)
 - **Incentives for value in health care** (health care purchasers and payers)
 - **Systems engineering for health improvement** (medical, engineering, and IT leaders)

How is the Roundtable making a difference?

- Describing the possible through the 13 publications in the Learning Health System series providing the foundation for the landmark IOM report *Best Care at Lower Cost*.
- Stewarding action projects of the Roundtable's Innovation Collaborative stakeholders, working cooperatively to advance science and value in health and health care. Examples include:

Value & performance transformation	Public & patient involvement	Science & evidence improvement
<ul style="list-style-type: none">• Documentation of cost and waste• Improving the science of transparency• Essential principles of team-based care• CEO checklist for high-value care• Point-of-care evidence access• Systems engineering for high-value care	<ul style="list-style-type: none">• Core metrics for better health at lower cost• Cost and evidence as patient priorities• Essential principles for evidence communication• Building patient and family leadership for system improvement	<ul style="list-style-type: none">• Making the case for outcomes research• Patient role in knowledge generation• Cooperative clinical research (PEDSNet)• Common Rule update• Digital infrastructure for a learning system• Strengthening the science of data-driven medicine

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The Brookings Institution

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ROUNDTABLE SPONSORS: AstraZeneca, Agency for Healthcare Research and Quality, American Hospitals Association, Blue Shield of California, Blue Shield of California Foundation, California HealthCare Foundation, Centers for Medicare and Medicaid, Epic Systems, Inc., Food and Drug Administration, GlaxoSmithKline, Gordon and Betty Moore Foundation, HCA, Inc., Health Resources and Services Administration, Kaiser Permanente, Merck & Company, National Institutes of Health, Office of the National Coordinator for Health IT, Partners HealthCare, Premier, Inc., Patient-Centered Outcomes Research Institute, Robert Wood Johnson Foundation, Sanofi US, UnitedHealth Foundation, WellPoint, Inc.

Roundtable Charter

The Institute of Medicine's Roundtable on Value & Science-Driven Health Care has been convened to help transform the way evidence on clinical effectiveness is generated and used to improve health and health care. Participants have set a goal that, by the year 2020, ninety percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence. Roundtable members will work with their colleagues to identify the issues not being adequately addressed, the nature of the barriers and possible solutions, and the priorities for action, and will marshal the resources of the sectors represented on the Roundtable to work for sustained public-private cooperation for change.

Vision: Our vision is for the development of a **continuously learning health system** in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation—with best practices seamlessly embedded in the care process, patients and families active participants in all elements, and new knowledge captured as an integral by-product of the care experience.

Goal: By the year 2020, ninety percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence. We feel that this presents a tangible focus for progress toward our vision, that Americans ought to expect at least this level of performance, that it should be feasible with existing resources and emerging tools, and that measures can be developed to track and stimulate progress.

Context: As unprecedented developments in the diagnosis, treatment, and long-term management of disease bring Americans closer than ever to the promise of personalized health care, we are faced with similarly unprecedented challenges to identify and deliver the care most appropriate for individual needs and conditions. Care that is important is often not delivered. Care that is delivered is often not important. In part, this is due to our failure to apply the evidence we have about the medical care that is most effective—a failure related to shortfalls in provider knowledge and accountability, inadequate care coordination and support, lack of insurance, poorly aligned payment incentives, and misplaced patient expectations. Increasingly, it is also a result of our limited capacity for timely generation of evidence on the relative effectiveness, efficiency, and safety of available and emerging interventions. Improving the value of the return on our healthcare investment is a vital imperative that will require much greater capacity to evaluate high priority clinical interventions, stronger links between clinical research and practice, and reorientation of the incentives to apply new insights. We must quicken our efforts to position evidence development and application as natural outgrowths of clinical care—to foster health care that learns.

Approach: The IOM Roundtable on Value & Science-Driven Health Care serves as a forum to facilitate the collaborative assessment and action around issues central to achieving the vision and goal stated. The challenges are myriad and include issues that must be addressed to improve evidence development, evidence application, and the capacity to advance progress on both dimensions. To address these challenges, as leaders in their fields, Roundtable members work with their colleagues to identify the issues not being adequately addressed, the nature of the barriers and possible solutions, and the priorities for action, and marshal the resources of the sectors represented on the Roundtable to work for sustained public-private cooperation for change.

Activities include collaborative exploration of new and expedited approaches to assessing the effectiveness of diagnostic and treatment interventions, better use of the patient care experience to generate evidence on effectiveness and efficiency of care, identification of assessment priorities, and communication strategies to enhance provider and patient understanding and support for interventions proven to work best and deliver value in health care.

Core concepts and principles: For the purpose of the Roundtable activities, we define science-driven health care broadly to mean that, to the greatest extent possible, the decisions that shape the health and health care of Americans—by patients, providers, payers and policymakers alike—will be grounded on a reliable evidence base, will account appropriately for individual variation in patient needs, and will support the generation of new insights on clinical effectiveness. Evidence is generally considered to be information from clinical experience that has met some established test of validity, and the appropriate standard is determined according to the requirements of the intervention and clinical circumstance. Processes that involve the development and use of evidence should be accessible and transparent to all stakeholders.

A common commitment to certain principles and priorities guides the activities of the Roundtable and its members, including the commitment to: the right health care for each person; putting the best evidence into practice; establishing the effectiveness, efficiency and safety of medical care delivered; building constant measurement into our healthcare investments; the establishment of healthcare data as a public good; shared responsibility distributed equitably across stakeholders, both public and private; collaborative stakeholder involvement in priority setting; transparency in the execution of activities and reporting of results; and subjugation of individual political or stakeholder perspectives in favor of the common good.

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Clinical Effectiveness Research Innovation Collaborative

Methods innovation and practice-based approaches

Issue. The constantly increasing diversity and sophistication of healthcare interventions hold great promise for gains in patient health, but also raise substantial challenges to the pace and nature of research about the effectiveness of treatments. Clinical research is straining to keep up with the rapid and iterative evolution of medical interventions and the innovation that occurs in clinical practice. It has become clear that, while trials are key especially to pre-market assessment of safety and efficacy, depending on trials is impractical—in both time and cost—for the information needed on effectiveness and efficiency. Recent enhancements in the nation’s capacity for clinical effectiveness research (CER), and the characterization of the broad range of CER questions of national priority, underscore the need to accelerate the development and use of innovative approaches for learning about what works best for whom and under what circumstances. Such information is critical for clinical and policy decisions and requires more nimble and efficient approaches that take advantage of emerging statistical tools and techniques, research designs and analytic models that can be applied across broader population groups, and information developed as a natural byproduct of the care process. Accelerated initiative within the research community is essential for progress—particularly to improve the targeting, tailoring, sequencing of approaches to develop a totality of evidence. Efforts to enhance the use of genomic information, probability and other models that accelerate the timeliness and level of research insights gained, and the development of virtual intervention studies also offer increased prospects for transformative change in clinical outcomes research.

Collaborative. An *ad hoc* convening activity under the auspices of the IOM Roundtable, the Clinical Effectiveness Research Innovation Collaborative (CERIC) provides a venue for information exchange and knowledge sharing among researchers working to develop and apply innovative approaches to evidence generation for healthcare decisions. Work focuses on identifying key barriers to and opportunities for advancing the pace and progress of CER.

CO-CHAIRS



Ralph I. Horwitz, M.D.
SVP, GlaxoSmithKline

“Only with a high-performing clinical research system will patients and providers be able to make informed decisions based on sound evidence.”



Richard Platt, M.D., M.S.
Professor, Harvard University

“CERIC participants take on the important charge of developing a clinical research enterprise that will drive continuous learning in health care.”

STAFF CONTACT

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Participants. Individual researchers with research innovation interests, capacity, and activities from public and private organizations, leading academic research institutions, insurers, health product manufacturing companies, and product assessment companies. The aim is for an inclusive Collaborative—without walls—and participation in individual projects is structured according to interest, need, and practicality.

Activities. Projects completed, under way, or under consideration by CERIC include:

- *Field advancement mapping.* Cooperative development of a White Paper exploring the major institutional, organizational, and regulatory challenges and opportunities for expediting clinical effectiveness research.
- *Engaging health system leadership in CER.* A program of work that begins by engaging health system leadership on issues and opportunities to transform how evidence is generated and used to improve health and the value of delivered care as a fundamental part of their institutional processes, and provides a neutral forum to discuss and share insights from ongoing evidence application and development efforts.
- *Eliminating disparities.* An exploration of how features of a continuously learning health system can best address and close the gaps for our most salient health and health care disparities, with particular focus on opportunities from innovation in clinical effectiveness research.

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Bristol-Myers Squibb
Cedars-Sinai Medical Center
Center for Medical Technology Policy
Duke Clinical Research Institute
Harvard Medical School
Harvard School of Public Health
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University of Pennsylvania School of Nursing
University of Pittsburgh
Vanderbilt University Medical Center
World Health Information Science Consultants

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– Agency for Healthcare Research and Quality
– Centers for Medicare & Medicaid Services
– Food and Drug Administration
– National Institutes of Health
– Office of the Secretary
U.S. Department of Veterans Affairs

Digital Learning Collaborative

Advancing the digital infrastructure for
the learning health system

Issue. With more components—testing, diagnosis, records, and patient-clinician communication—shifting to digital platforms, there exists enormous potential for increasing the efficiency, convenience, and effectiveness of health care. Digitalizing health care processes and information provides the foundation necessary to drive a continuously improving health system in which knowledge from past events is used to guide decisions. A health information technology infrastructure that supports a continuously improving, learning health care system requires consideration of the capabilities, technical and policy approaches, and operating principles needed to allow data from multiple areas of clinical health care, population health, clinical, biomedical, and translational research to be leveraged while protecting patients' privacy. In 2010, the IOM, with support from the Office of the National Coordinator for Health Information Technology, held a series of workshops to explore the current efforts and opportunities to accelerate progress in improving health and health care with information technology. The resulting report—*Digital Infrastructure for the Learning Health System: The Foundation for Continuous Improvement in Health and Health Care*—highlighted several areas for follow up activities in developing the digital infrastructure such as data stewardship, quality monitoring, research capabilities, and coordinating requirements around leadership, policies, and sustainability.

Collaborative. Formerly the Electronic Health Records Innovation Collaborative (EHRIC), the Digital Learning Collaborative (DLC) is an *ad hoc* convening activity under the auspices of the IOM Roundtable on Value & Science-Driven Health Care. It was created to provide a venue for joint activities that can accelerate progress towards the digital infrastructure necessary for continuous improvement and innovation in health and health care. This includes fostering a new culture of collaborative action among participants in the learning process—e.g. patients, clinicians, researchers, and product developers.

CO-CHAIRS



Jonathan B. Perlin, M.D., Ph.D.
Chief Medical Officer
Hospital Corporation of America
"DLC participants work on the projects necessary to ensure that the staggering advances in health IT translate to improved health."



Reed Tuckson, M.D.
Managing Director
Tuckson Health Connections
Former EVP, UnitedHealth Group
"A smarter digital infrastructure is essential for using clinical data to make better health decisions."

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Participants. Participants include experts from public and private organizations with prominent activities and leadership responsibilities related to development and application of digital technology important to continuous improvement in health and health care. The aim is for an inclusive Collaborative—without walls—and participation in individual projects is structured according to interest, need, and practicality.

Activities. Projects completed, under way, or under consideration by the DLC include:

- *Workshop series and report on the Digital Infrastructure for the Learning Health System.* Cooperative work involving DLC participants with the Office of the National Coordinator and related government agencies to explore strategic considerations in accelerating learning from healthcare delivery.
- *PEDSNet.* A consortium of 15 leading pediatric care institutions, working together to create an organization providing networked clinical data from electronic health records for use in accelerating clinical research in pediatrics.
- *Aligning health reform data needs and priorities.* Engaging leaders from key federal health reform initiatives on strategies and opportunities to leverage health IT for program and monitoring alignment, across initiatives and in the support of population health.
- *Data quality and learning from the digital health utility.* Workshop to explore the data quality issues and strategies central to the increasing capture and use of digital clinical and patient-reported data for knowledge development.

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Children's Hospital of Wisconsin
Cincinnati Children's Hospital Medical Center
Cleveland Clinic
Duke University Health System
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Google, Inc.
Harvard Medical School
Harvard Pilgrim Health Care
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– National Institutes of Health
– National Library of Medicine
– Office of the National Coordinator for HIT
U.S. Department of Defense (Health Affairs)
U.S. Department of Veterans Affairs

PCORnet: The National Patient-Centered Clinical Research Network

The Vision

Patients, their families, and healthcare providers frequently must make crucial healthcare decisions while lacking key information about which preventive, diagnostic, or treatment approach would be best, given a patient's preferences and circumstances. The Patient-Centered Outcomes Research Institute (PCORI) was created to fund comparative clinical effectiveness research (CER) that will provide needed evidence to help patients and their caregivers make better-informed decisions. However, the nation's capacity to conduct CER rapidly and efficiently remains extremely limited.

To facilitate more efficient CER that could significantly increase the amount of information available to healthcare decision makers and the speed at which it is generated, PCORI has invested more than \$100 million in the development of **PCORnet: The National Patient-Centered Clinical Research Network**.

PCORnet will be a large, highly representative, national network for conducting clinical outcomes research. PCORnet will foster a range of observational and experimental CER by establishing a resource of clinical data gathered in "real-time" and in "real-world" settings, such as clinics. Data will be collected and stored in standardized, interoperable formats under rigorous security protocols, and data sharing across the network will be accomplished using a variety of methods that ensure confidentiality by preventing patient identification.

To develop the key components of PCORnet, PCORI has approved awards to 29 health data networks and a coordinating center:

- 11 Clinical Data Research Networks (CDRNs), which are system-based networks that originate in healthcare systems, such as hospitals, health plans, or practice-based networks, and securely collect health information during the routine course of patient care;
- 18 Patient-Powered Research Networks (PPRNs), which are networks operated and governed by groups of patients and their partners and are focused on a particular condition and interested in sharing health information and participating in research; and
- A Coordinating Center, led by Harvard Pilgrim Health Care Institute and Duke Clinical Research Institute, which will provide technical and logistical support to the data networks and assist in program evaluation.

Details about the awardees are available [here](#). More information about PCORnet and its constituent networks and components is available at www.pcornet.org.

A Network to Promote Research Done Differently and More Efficiently

PCORI's distinct approach to research seeks to involve patients and other stakeholders in all aspects of the research process, from determining which research topics and outcomes should be studied to helping to develop and conduct the studies to sharing the results.

A hallmark of PCORnet is its requirement that the patients, clinicians, and healthcare systems that provide the research data housed in each constituent network be actively involved in the governance and use of the data. PCORnet aims to advance the shift in clinical research from investigator-driven to patient-centered studies.

PCORnet will establish a functional research network that is nationally representative of health information and will significantly reduce the amount of time and effort required to start studies and build the necessary infrastructure to conduct them. It will support a range of study designs, including large, simple clinical trials and studies that combine an experimental component, such as a randomized trial, with a complementary observational component.

Because PCORnet will enable studies to be conducted using “real-time” data drawn from “real-world” settings, it should increase the relevance of the kinds of questions that can be studied and the usefulness of the study results.

Phase I: Building PCORnet

During an 18-month development phase, PCORI is working with the PPRNs, CDRNs, Coordinating Center, and other stakeholders to refine the capabilities and capacity of the individual constituent networks. Through the work of the Coordinating Center Task Forces and a steering committee, PCORnet will develop policies governing data sharing, security, and protection of patient privacy across the overarching network. By the end of this phase, PCORI expects a functional research network to be in place and ready to support CER studies.

Functioning as an advisory group to PCORI leadership, the PCORnet Steering Committee will review proposed policies and recommendations from the Coordinating Center Task Forces. Collectively, the policies, operations, and products of the Steering Committee and Task Forces will support the development of a robust infrastructure for the efficient conduct of patient-centered clinical research. In addition, the Steering Committee will play an important role in exploring uses of the network by all funders of research.

The Steering Committee will include representatives from each CDRN and PPRN, the Coordinating Center, and federal and private sector funders of research and providers of clinical data. The Task Forces will focus on developing PCORnet policies, procedures, and infrastructure.



Why PCORnet Exists

PCORnet, the National Patient-Centered Clinical Research Network, will transform clinical research by engaging patients, care providers, and health systems in collaborative partnerships to improve healthcare and advance medical knowledge. By bringing research and patient care together, this innovative health data network will be able to explore the questions that matter most to patients and their families.

Vast amounts of valuable health information are created every day during routine patient visits. But opportunities to use this information for research are often missed because the networks that hold this information cannot easily communicate or collaborate with each other. However, by building clinical research into the healthcare process and by working directly with patients and their advocates, PCORnet will be able to provide the answers that patients need quickly, efficiently, and at a lower cost than previously possible. Furthermore, PCORnet's unique focus on collaboration means that patients will be directly involved in making decisions about research priorities and efforts that will protect patient privacy and ensure data security.

PCORnet represents a unique opportunity to make a real difference in the lives of patients and their families. Until now, we have been unable to answer many of the most important questions affecting health and healthcare. But by combining the knowledge and insights of patients, caregivers, and researchers in a revolutionary network with carefully controlled access to rich sources of health data, we will be able to respond to patient's priorities and speed the creation of new knowledge to guide treatment on a national scale.

Biographies and Meeting Logistics

HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH

Planning Committee Biographies

Raymond J. Baxter, PhD, is Kaiser Permanente's senior vice president for Community Benefit, Research and Health Policy. As a member of Kaiser's National Executive Team, Dr. Baxter leads the organization's activities to fulfil its social mission, including care and coverage for low income people, community health initiatives, health equity, environmental stewardship and support for community-based organizations. He also leads Kaiser Permanente's work in research, health policy and diversity, and serves as President of KP International. Dr. Baxter has more than 35 years of experience managing public health, hospital, long-term care and mental health programs, including heading the San Francisco Department of Public Health and the New York City Health and Hospitals Corporation. Dr. Baxter also led The Lewin Group, a noted health policy firm. Dr. Baxter holds a doctorate from the Woodrow Wilson School of Public and International Affairs, Princeton University. He serves on the Advisory Boards of the UC Berkeley School of Public Health and the Duke University Institute for Health Innovation, the Board of the CDC Foundation, the Global Agenda Council on Health of the World Economic Forum, the Board of Archimedes, Inc. and is a member of the Institute of Medicine's Roundtable on Population Health Improvement. In 2001 the University of California, Berkeley, School of Public Health honored him as a Public Health Hero for his service in the AIDS epidemic in San Francisco. In September 2006 he received the CDC Foundation Hero Award for addressing the health consequences of Hurricane Katrina in the Gulf Coast, and for his longstanding commitment to improving the health of communities.

Barbara E. Bierer, MD, is Senior Vice President for Research at the Brigham and Women's Hospital and Professor of Medicine at Harvard Medical School. Dr. Bierer, a graduate of Harvard Medical School, completed her internal medicine residency at the Massachusetts General Hospital and her hematology and medical oncology training at the Brigham and Women's Hospital and the Dana-Farber Cancer Institute. Dr. Bierer maintained a research laboratory in the Department of Pediatric Oncology at Dana-Farber Cancer Institute and was appointed Director of Pediatric Stem Cell Transplantation at Dana-Farber Cancer Institute and Children's Hospital in 1993. In 1997, she was named Chief of the Laboratory of Lymphocyte Biology at the National Heart, Lung and Blood Institute at the National Institutes of Health in Bethesda, MD, where she received the Director's Award in 1999. She returned to the Dana-Farber Cancer Institute in July 2002, as Vice President of Patient Safety and Director of the Center for Patient Safety. In 2003, Dr. Bierer moved to the Brigham and Women's Hospital to assume her current position. In 2006, Dr. Bierer established the Center for Faculty Development and Diversity at the Brigham and Women's Hospital and now serves as its first director. For these efforts, she was the first recipient of the HMS Harold Amos Faculty Diversity Award in 2008. In addition, Dr. Bierer is the Co-Chair of the Partners HealthCare Committee on Conflict of Interest and the Program Director of the Regulatory Domain of the Harvard Catalyst, the Harvard Clinical and Translational Science Award. Dr. Bierer maintained until recently a research laboratory focusing on the biochemistry of T cell activation and immunosuppression. She has authored or co-authored over 150 publications and is on the editorial boards of a number of journals including Current Protocols of Immunology. In addition to her academic responsibilities, Dr. Bierer was elected to the Board of Directors of the Association for Accreditation of Human Research Protection Programs (AAHRPP), serving as its President from 2003-2007 and was on the Board of Directors of the Federation of American Societies for Experimental Biology (FASEB). She was a member of the Medical and Scientific Advisory Board and, later, the Board of Directors of ViaCell,

Inc. She is currently a member of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Clinical Research, on the National Academies of Sciences Committee on Science, Technology and the Law, and on the Secretary's Advisory Committee for Human Research Protections, Department of Health and Human Services, for which she serves as chair.

Mary Brainerd, MBA, has been a leader in health care since 1984. Prior to joining HealthPartners in 1992, Brainerd held senior level positions with Blue Cross and Blue Shield of Minnesota, including senior vice president and chief marketing officer. She was also senior vice president and chief executive officer of Blue Plus. Before that, she was a marketing instructor in the graduate program at Metropolitan State University. Mary is one of the founding CEOs of the Itasca Project, a group of 40 government, civic and business leaders addressing the issues that impact long-term economic growth, including jobs, education, transportation and economic disparities. She also serves on the boards of Minnesota Life/Securian, Minnesota Council of Health Plans, The St. Paul Foundation, Minneapolis Federal Reserve and SurModics.

Meighan Girus, MBA, has been Chief Mission Officer of the American Heart Association (AHA) since 2009. In this role, she oversees all AHA efforts in preventative health, science operations, emergency cardiovascular care, global strategies, communications, brand content, stroke and multicultural marketing, patients, healthcare innovations, health quality, mission aligned businesses, advocacy and field health strategies. Prior to being named Chief Mission Officer, Meighan served for seven years as the AHA's Executive Vice President of Healthcare. She has more than two decades of experience in healthcare marketing and administration. Meighan has spent much of her career dedicated to helping change the care delivery system and has been integrally involved in multiple national panels and writing groups dedicated to fighting cardiovascular disease. She was a co-author of the groundbreaking "Recommendations for the Establishment of Primary Stroke Centers," published in JAMA, which was the precedent for a radical shift in stroke care in the United States and the premise for The Joint Commission's primary stroke center certification program. She was a co-author of the "Recommendations for Improving the Quality of Care through Stroke Centers and Systems: An Examination of Stroke Center Identification Options," which was published in Stroke and has been instrumental in redefining the type of care that is provided to stroke patients. She was a writing group member for the CDC's "A Public Health Action Plan to Prevent Heart Disease," and an expert panel member for its workgroup which published "Establishment of Data Elements for the Paul Coverdell National Acute Stroke Registry" in Stroke. Meighan participated in the NHLBI Workgroup on Peripheral Artery Disease: Developing a Public Awareness Campaign and on the National Institute of Neurological Diseases and Stroke, Stroke Progress Review Group. Most recently, she is a co-author of "Translating Research into Practice for Healthcare Providers: The American Heart Association's Strategy for Building Healthier Lives Free of Cardiovascular Disease and Stroke," and "Partnering to Reduce Risks and Improve Cardiovascular Outcomes - American Heart Association Initiatives in Action for Consumers and Patients," both published in the journal Circulation. Additionally, she recently completed a three-year term on the Board of Trustees for the Certification Commission for Healthcare Information Technology under the direction of Dr. Mark Leavitt. Meighan received her undergraduate degree from the University of Texas at Austin, her Masters in Business Administration from Southern California University, and completed her Graduate Marketing Certification at Southern Methodist University.

Regina Holliday is an activist, artist, speaker and author. You might see her at a health conference painting the content she hears from the patient view. She is part the movement known as participatory medicine. She and others in this movement believe that the patient is a partner with their provider and both should work together as a team. Regina, like her friend Dave deBronkart, is also an e-patient. She utilizes the tools of technology and social media to better understand the patient condition and the landscape of medicine. Regina is a mother and a widow; she speaks about the benefits of HIT and timely

data access for patients due to her family loss. In 2009, she painted a series of murals depicting the need for clarity and transparency in medical records. This advocacy mission was inspired by her late husband Frederick Allen Holliday II and his struggle to get appropriate care during 11 weeks of continuous hospitalization at 5 facilities. Her paintings became part of the national debate on health care reform and helped guide public policy. She also began an advocacy movement called “The Walking Gallery.” The Gallery consists of medical providers and advocates who wear patient story paintings on the backs of business suits. Paint and patients, pills and policy all come together within The Walking Gallery of Healthcare. This “walking wall” of 200 individuals who wear personal patient narrative paintings on their backs is changing minds and opening hearts. They are attending medical conferences where often there isn’t a patient speaker on the dais or in the audience. They are providing a patient voice, and by doing so, are changing the conversation. Regina has delivered 80 speeches in the last two years as a patient speaker focusing on range of issues such as patient data access, social media in medicine, end of life care and the power of the visual image. She has spoken before Kaiser Permanente, Stanford Medicine X, The White House Summit on Blue Button, Leap Frog Group, AHDI, HIMSS, AHIMA, AHRQ, HHS, Microsoft and Cerner. She travels the nation as a patient speaker and encourages others to speak as well. She worked with TMIT (Texas Medical Institute of Technology) to create a resource called SpeakerLink.org to help venues find passionate patient speakers. She published a book with the help of the Health Informatics Society of Australia (HISA) entitled: “The Walking Wall: 73 Cents to the Walking Gallery.”

Brent C. James, MD, MStat, Executive Director of the Institute for Health Care Delivery Research and Vice President of Medical Research and Continuing Medical Education at Intermountain Healthcare, has championed the standardization of clinical care through data collection and analysis on a wide variety of treatment protocols and complex care processes. He has devoted himself to using quality improvement tools to better understand the cause and effect relationship between various practice and environmental factors. Today, nearly 100 years after his mentors’ groundbreaking discoveries, Dr. James firmly believes that the practice of medicine and delivery of health care stands at another critical crossroads. If the health care field is to successfully bridge the quality chasm defined by the Institute of Medicine, a new and innovative approach to the practice of health care is mandatory. Dr. James feels strong that the time has come to shift from the “craft-based” practice to evidence-directed teams focused on patient care. In addition to his duties at Intermountain Health Care, Dr. James is adjunct professor at the University of Utah School of Medicine, Department of Family and Preventive Medicine. He also holds a Visiting Lectureship in the Department of Health Policy and Management at the Harvard School of Public Health. He is a member of a number of national taskforces and committees that examine health care quality and cost control, including AHRQ and his most recent appointment by the Federal Comptroller to an advisory group on making American health care more accessible and affordable. In 2005, Dr. James also received an award from the National Committee for Quality Assurance (NCQA) recognizing his vision and energy in making the U.S. health care system better.

Uma R. Kotagal, MBBS, MSc, is senior vice president for quality, safety and transformation and executive director of the James M. Anderson Center for Health Systems Excellence at Cincinnati Children’s Hospital Medical Center. As director of the Anderson Center, Dr. Kotagal oversees the development of disease management teams and development and institution of evidence-based clinical practice guidelines. Dr. Kotagal was director of the neonatal intensive care units at the University Hospital and at Cincinnati Children’s. She received her Master of Science in Clinical Epidemiology and Clinical Effectiveness from the Harvard School of Public Health, and refocused her clinical efforts on quality transformation at a systems level. She served as a visiting scholar at the Center for Risk Analysis at the Harvard School of Public Health and a visiting professor at the Tufts New England Medical Center, in the Division of Clinical Decision Making, completing further training in the field of decision and cost effectiveness analyses. Dr. Kotagal was born in Bombay, India, where she received her

undergraduate and her MBBS from the University of Bombay. She completed rotating internships at the University of Bombay and at Detroit General Hospital. At Children's Hospital of Michigan, Dr. Kotagal completed her pediatric residency and went on to do a fellowship in neonatology. She completed a fellowship in neonatal physiology at the University of Cincinnati. Dr. Kotagal is President of the Academy of Healthcare Improvement and a faculty member of the Institute for Healthcare Improvement. She also serves on the Board of Directors and as chair of the quality steering team of the Ohio Children's Hospital Association, as a member of the advisory committee of the Toronto Patient Safety Center, as an associate editor of BMJ Quality and Safety and as a member of the Institute of Medicine.

David Labby, MD, PhD, is Chief Medical Officer of Health Share of Oregon, a Coordinated Care Organization (CCO) with over 160,000 enrollees in the tri-county area (Multnomah, Clackamas, and Washington), encompassing Portland and including all major hospital and health systems along with providers including those in safety net practices. Previously, he served as Medical Director for CareOregon, the state's largest Medicaid Managed Care Plan. During his career, Dr. Labby has practiced in Primary Care and was Medical Director of both Primary Care and Multi-Specialty settings before coming to CareOregon in 2000. He received his PhD in Cultural Anthropology.

Eric B. Larson, MD, MPH, MACP, is Vice President for Research, Group Health and Executive Director of the Group Health Research Institute. A graduate of Harvard Medical School, he trained in internal medicine at Beth Israel Hospital, in Boston, completed a Robert Wood Johnson Clinical Scholars and MPH program at the University of Washington, and then served as Chief Resident of University Hospital in Seattle. He served as Medical Director of University of Washington Medical Center and Associate Dean for Clinical Affairs from 1989-2002. His research spans a range of general medicine topics and has focused on aging and dementia, including a long running study of aging and cognitive change set in Group Health Cooperative - The UW/Group Health Alzheimer's Disease Patient Registry/Adult Changes in Thought Study. He has served as President of the Society of General Internal Medicine, Chair of the OTA/DHHS Advisory Panel on Alzheimer's Disease and Related Disorders and was Chair of the Board of Regents (2004-05), American College of Physicians. He is an elected member of the National Academy of Sciences Institute of Medicine.

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI, is President, Clinical Services and Chief Medical Officer of Nashville, Tennessee-based HCA (Hospital Corporation of America). He provides leadership for clinical services and improving performance at HCA's 166 hospitals and more than 800 outpatient centers and physician practices. Current activities include implementing electronic health records throughout HCA, improving clinical "core measures" to benchmark levels, and leading patient safety programs to eliminate preventable complications and healthcare-associated infections. Before joining HCA in 2006, "the Honorable Jonathan B. Perlin" was Under Secretary for Health in the U.S. Department of Veterans Affairs. Nominated by the President and confirmed by the Senate, as the senior-most physician in the Federal Government and Chief Executive Officer of the Veterans Health Administration (VHA), Dr. Perlin led the nation's largest integrated health system. At VHA, Dr. Perlin directed care to over 5.4 million patients annually by more than 200,000 healthcare professionals at 1,400 sites, including hospitals, clinics, nursing homes, counseling centers and other facilities, with an operating and capital budget of over \$34 billion. A champion for implementation of electronic health records, Dr. Perlin led VHA quality performance to international recognition as reported in academic literature and lay press and as evaluated by RAND, Institute of Medicine, and others. Dr. Perlin has served previously on numerous Boards and Commissions including the National Quality Forum and the Joint Commission, and currently serves on the Boards of the National Patient Safety Foundation and Meharry Medical College. He chairs the U.S. Department of Health and Human Services Health IT Standards Committee and has been elected chair of the American Hospital Association for 2015. Recognized perennially as one

of the most influential physician executives in the United States by Modern Healthcare, Dr. Perlin has received numerous awards including Distinguished Alumnus in Medicine and Health Administration from his alma mater, Chairman's Medal from the National Patient Safety Foundation, the Founders Medal from the Association of Military Surgeons of the United States, and is one of a dozen honorary members of the Special Forces Association and Green Berets. Broadly published in healthcare quality and transformation, Dr. Perlin is a Fellow of the American College of Physicians and the American College of Medical Informatics. He has a Master's of Science in Health Administration and received his Ph.D. in pharmacology (molecular neurobiology) with his M.D. as part of the Physician Scientist Training Program at the Medical College of Virginia of Virginia Commonwealth University (VCU). Dr. Perlin has faculty appointments at Vanderbilt University as Adjunct Professor of Medicine and Biomedical Informatics and at VCU as Adjunct Professor of Health Administration.

Lewis G. Sandy, MD, is Executive Vice President, Clinical Advancement, UnitedHealth Group (a Fortune 25 diversified health and well-being company dedicated to helping people live healthier lives). At UnitedHealth Group he focuses on clinical innovation, payment/delivery reforms to modernize our health care system, and physician collaboration. He also is a Principal in the UnitedHealth Center for Health Reform and Modernization, with a focus on payment/delivery innovation and policy. From 2003 to 2007, he was EVP and Chief Medical Officer of UnitedHealthcare, UnitedHealth Group's largest business focusing on the employer/individual health benefits market. From 1997 to 2003, he was EVP of The Robert Wood Johnson Foundation. At RWJF, he was responsible for the Foundation's program development and management, strategic planning and administrative operations. Prior to this, Dr. Sandy was a program VP of the Foundation, focusing on the Foundation's workforce, health policy, and chronic care initiatives. An internist and former health center medical director at the Harvard Community Health Plan in Boston, Massachusetts, Dr. Sandy received his B.S. and M.D. degrees from the University of Michigan and an M.B.A. degree from Stanford University. A former RWJF Clinical Scholar and Clinical Fellow in Medicine at the University of California, San Francisco, Dr. Sandy served his internship and residency at the Beth Israel Hospital in Boston. He is a Senior Fellow of the University of Minnesota School of Public Health, Department of Health Policy and Management.

Joe V. Selby, MD, MPH, is the first Executive Director of the Patient-Centered Outcomes Research Institute (PCORI). A family physician, clinical epidemiologist and health services researcher, he has dedicated his career to patient care, clinical research and administration. At PCORI, he works to identify and address strategic issues and opportunities for PCORI and to implement and administer the research agenda authorized by the PCORI Board of Governors. Building on the foundational work of the Board, Selby leads the continuing development of PCORI as a research organization, overseeing the implementation of its research agenda, its external communications, and its work to establish effective on-going, two-way engagement channels with each of PCORI's key stakeholder groups, beginning with patients. Selby joined PCORI from Kaiser Permanente, Northern California, where he was a researcher for 27 years, serving as Director of the Division of Research for the last 13 years. In this role, he led a department of more than 50 investigators and 500 research staff working on more than 250 ongoing studies. An accomplished researcher, Selby has authored more than 220 peer-reviewed articles, primarily in the areas of primary care delivery; diabetes mellitus outcomes and quality improvement; colorectal cancer screening strategies; population management for chronic conditions; and quality measurement. Selby was elected to membership in the Institute of Medicine in 2009. A native of Fulton, Missouri, Selby received his medical degree from Northwestern University; his training in family medicine from Contra Costa County Family Medicine Program, Martinez, CA, and his master's in public health from the University of California, Berkeley. He served as a commissioned officer in the Public Health Service with the National Health Services Corp from 1976-1983 and received the Commissioned Officer's Award in 1981. Dr. Selby was appointed PCORI executive director on May 16, 2011.

Jonathan N. Tobin, PhD, FACE, FAHA, is President/CEO of Clinical Directors Network (CDN), a NYC-based practice-based research network (PBRN) dedicated to improving clinical and population health outcomes for low income/medically underserved communities by creating community-academic partnerships around research, education and service. He holds a BA in Sociology/Anthropology from Haverford College, and an MA, MPhil, PhD from Columbia University in Epidemiology and Sociomedical Sciences. He is an elected fellow of the American Heart Association (Council on Epidemiology and Prevention) and the American College of Epidemiology. Dr. Tobin is a clinical epidemiologist and is Co-Director for Community-Engaged Research and Adjunct Professor in the Allen and Frances Adler Laboratory of Blood and Vascular Biology at the Center for Clinical and Translational Science at The Rockefeller University. Dr. Tobin is also a Professor in the Department of Epidemiology & Population Health at Albert Einstein College of Medicine of Yeshiva University, and was the Interim Director of Education/Training at Albert Einstein College of Medicine where he developed Certificate and Master of Public Health (MPH) programs. He has extensive experience in the design, administration and analysis of large-scale observational and experimental clinical and translational studies. Dr. Tobin serves as the Principal Investigator for the AHRQ-funded Center of Excellence (P30) for Practice-based Research and Learning (2012), which is a network of eight safety-net PBRNs in NYC, Boston, Chicago, Oakland and Portland, and includes 600 sites and over 4 million patients, and is the PI of a mental health/cancer prevention RCT funded by PCORI (2013). Dr. Tobin has served as Principal/Co-Principal Investigator on grants funded by NIMH, NHLBI, NCI, NCATS, NIAID, NIDDK, NIDCR, NIDA, SAMHSA, EPA, CDC, AHRQ, HRSA and PCORI, related to dissemination and implementation research and effectiveness trials in behavior, stress, clinical preventive services, cardiovascular disease, diabetes, cancer and HIV, all designed to translate research into practice for the improvement of public health.

P. Jon White, MD, directs the Health Information Technology (Health IT) Portfolio at the Agency for Healthcare Research and Quality (AHRQ). Dr. White sets the programmatic direction of AHRQ's Health IT projects, and leads a team of diverse and skilled individuals. Under his leadership, AHRQ programs have fueled and informed the tremendous expansion of health IT to improve health care quality. He is also a leading contributor to AHRQ's other key initiatives and is an active partner to health IT programs across the federal government, including the Office of the National Coordinator, the Centers for Medicare & Medicaid Services, and the Veteran's Health Administration. Dr. White has implemented provisions of a number of major federal health care initiatives during his service at AHRQ. He participates in several national initiatives to improve the quality of American health care. Dr. White trained in family medicine at the University of Virginia and Lancaster General Hospital in Pennsylvania. He is a recipient of the national AAFP Award for Excellence in Graduate Education.

HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF RESEARCH AND PRACTICE

Participant Biographies

Steve Allen, MD, has been CEO of Nationwide Children's Hospital since July 2006. Dr. Allen is credited to driving the hospital's national prominence resulting in recognition as one of the best children's hospitals by both U.S. News and World Report and Parent magazine. Prior to coming to Columbus, Steve was a physician, scientist, teacher and executive in the Texas Medical Center in Houston for 24 years. He has published almost 100 articles and more than 20 book chapters on a variety of medical topics. He is board-certified in Anesthesiology and Critical Care Medicine and awarded an MBA. He serves on a number of community boards, as well as the Children's Hospital Association board.

Joel T. Allison, FACHE, is CEO of Baylor Scott & White Health, a fully integrated healthcare system headquartered in Dallas, Texas providing services to a network of acute care hospitals and related healthcare entities that provide patient care, medical education, research and community service. Mr. Allison's career includes more than 40 years in healthcare management. He serves on the Healthcare Leadership Council, the United Surgical Partners, International Board and is a Regent for Baylor University. In addition, he serves on the Texas Institute of Health Care Quality and Efficiency Board and is involved in many other state and local organizations, including the Texas Business Leadership Council, Texas Association of Voluntary Hospitals and the Dallas Citizens Council. He received a bachelor's degree in journalism and religion from Baylor University in 1970, a master's degree in healthcare administration from Trinity University in 1973 and is a graduate of the Harvard Business School Advanced Management Program. He is a Fellow of the American College of Healthcare Executives.

Scott Armstrong is president and CEO of Group Health Cooperative, one of the nation's largest consumer-governed health care systems. He has been with Group Health since 1986 in positions ranging from assistant hospital administrator to chief operating officer. He became president and CEO in January 2005. He joined Group Health from Miami Valley Hospital in Dayton, Ohio, where he was the assistant vice president for hospital operations. He received a bachelor's degree from Hamilton College in New York and a master's degree in business with a concentration in hospital administration from the University of Wisconsin–Madison. Armstrong is a commissioner of the Medicare Payment Advisory Commission, board member of the Alliance of Community Health Plans, and a board member of America's Health Insurance Plans. He is also a fellow of the American College of Healthcare Executives.

David Bailey, MD, MBA, was named President and Chief Executive Officer of The Nemours Foundation by the Board of Directors in 2006. With the goal of establishing Nemours as a pre-eminent voice for children, Dr. Bailey has sharpened Nemours' strategic focus and concentrated its investments on four overarching strategic goals: Care for every child as we would our own; be a leader in improving children's health through Nemours' integrated system; be a great place to work; be effective stewards of all of our assets, continually improving them to advance Nemours' mission. In furtherance of these goals, Nemours has improved operating efficiency, execution, and financial performance. An intense focus on addressing the health needs of families and children has led to the construction of a new children's hospital in Florida and plans for complete refurbishment of the inpatient facilities of the Nemours/Alfred I. duPont Hospital for Children in Delaware. Dr. Bailey graduated in 1973 from West Virginia University magna cum laude, Phi Beta Kappa in Biology. After earning his medical degree from

The Pennsylvania State University in 1977, he completed an internship and residency program in Pediatrics at Walter Reed Army Medical Center in Washington, D.C. Dr. Bailey's Army Medical Corps service included duty as a pediatrician at Fort Rucker, Alabama; a clinical professor appointment to the Uniformed Services Medical School as director for medical student pediatric clinical training; completion of a fellowship in Pediatric Gastroenterology at the University of Florida; and appointment as Chief of Pediatric Gastroenterology at Tripler Army Medical Center in Honolulu, HI. After leaving the military in 1987, Dr. Bailey established the Division of Pediatric Gastroenterology at the Arnold Palmer Hospital for Children in Orlando. With a burgeoning interest in health care administration, Dr. Bailey pursued a Masters of Business Administration at the University of South Florida, earning his degree in 1996. In 1997, he joined Nemours when the Nemours Children's Clinic in Orlando opened. Dr. Bailey became familiar with all the Nemours campuses as he moved to Pensacola, FL in 1999 to become Chief Executive of the Practice and returned to Orlando in 2002 as Chief Executive for all physician practices in Florida, overseeing Nemours operations in Pensacola, Orlando and Jacksonville. In 2003, he was appointed the first Chief Operating Officer of Nemours at which time he moved to Jacksonville with responsibility for day-to-day operations for all Nemours entities in the Delaware Valley and Florida.

Theresa M. H. Brennan, MD, FACC, the John W. Colloton Associate Professor and Chief Medical Officer of UI Health Care, received her medical degree from Northwestern University Feinberg School of Medicine in 1992. She completed her Internal Medicine residency, cardiology fellowship, and interventional cardiology fellowship training at the University of Iowa. Her clinical interests include prevention of cardiovascular disease, cardiovascular disease in women, treatment of peripheral arterial disease, and interventional cardiology. Her research interests include the study of the use of novel devices for catheter-based treatment of cardiovascular disease, treatment of patients with non-revascularizable cardiovascular disease including angiogenesis, and medical and interventional therapy for patients with peripheral arterial disease.

Tom Carton, MS, PhD, is the PI and Steering Committee representative for Louisiana CDRN (LACDRN). Dr. Carton is the Director of Analytics at the Louisiana Public Health Institute (LPHI), where he conceives, manages, and coordinates a variety of projects, namely the Greater New Orleans Health information Exchange (GNOHIE), the New Orleans Community Health Database (CHDB), and the Louisiana Tobacco Free Living (TFL) campaign. Prior to joining LPHI, Dr. Carton worked for the Tulane University Prevention Research Center and consulted for international organizations, non-governmental organizations, and private companies on a variety of diverse research projects. He teaches Doctoral-level courses in introductory and intermediate econometrics at the Tulane University School of Public Health, where he is an Adjunct professor.

Steven Clauser, PhD, MPA, is the Program Director of the Improving Healthcare Systems Research Program at the Patient-Centered Outcomes Research Institute (PCORI). He is a health services and outcomes researcher with over 25 years of research management experience. Dr. Clauser is responsible for developing PCORI's research program that evaluates comparisons among alternative health system strategies to improve patient outcomes in a broad range of clinical and organizational domains. Dr. Clauser previously held the positions of Associate Director for the National Cancer Institute's (NCI) Community Oncology Research Program, as well as Chief of NCI's Outcomes Research Branch. He also was co-director of NCI's Community Cancer Centers Program where he developed and managed a variety of research projects related to system strategies to improve cancer care delivery, including methods to increase adherence to evidence based practice and models of multidisciplinary treatment planning for patients requiring multi-modal cancer treatment. He has expertise in a broad range of research methodologies used for assessing patient reported outcomes and quality improvement programs. Before coming to NCI, Dr. Clauser served in a number of senior research management positions at the Centers for Medicare and Medicaid Services. His most recent position was Director of

the Quality Measurement and Health Assessment Group in the Office of Clinical Standards and Quality, where he directed CMS quality measurement research initiatives in support of Medicare's consumer quality reporting programs in managed care organizations, hospitals, nursing homes, home health agencies, and renal dialysis centers. Dr. Clauser has over 60 peer reviewed publications related to quality of care and outcomes research, and has participated in several national committees and advisory groups on these topics. He speaks regularly on patient centered outcomes research topics related to improving healthcare systems. Dr. Clauser received his bachelor's degree from Michigan State University, a Ph.D. degree from the University of Minnesota, and a Master in Public Affairs from the Hubert H. Humphrey Institute in Minneapolis, Minnesota.

Patrick Conway, MD, MSc, is the Deputy Administrator for Innovation and Quality & CMS Chief Medical Officer. He leads the Center for Clinical Standards and Quality (CCSQ) and the Center for Medicare and Medicaid Innovation (CMMI) at CMS. CCSQ is responsible for all quality measures for CMS, value-based purchasing programs, quality improvement programs in all 50 states, clinical standards and survey and certification of Medicare and Medicaid health care providers across the nation, and all Medicare coverage decisions for treatments and services. The center's budget exceeds \$2 billion annually and is a major force for quality and transformation across Medicare, Medicaid, CHIP, and the U.S. health care system. The CMS Innovation Center is responsible for testing numerous new payment and service delivery models across the nation. Models include accountable care organizations, bundled payments, primary care medical homes, state innovation models, and many more. Successful models can be scaled nationally. The CMS Innovation Center budget is \$10 billion over 10 years. Previously, he was Director of Hospital Medicine and an Associate Professor at Cincinnati Children's Hospital. He was also AVP Outcomes Performance, responsible for leading measurement, including the electronic health record measures, and facilitating improvement of health outcomes across the health care system. Other relevant experience includes previous work as the Chief Medical Officer at the Department of Health and Human Services (HHS) in the Office of the Assistant Secretary for Planning and Evaluation. In 2007-08, he was a White House Fellow assigned to the Office of Secretary in HHS and the Director of the Agency for Healthcare Research and Quality. He also served as Executive Director of the Federal Coordinating Council on Comparative Effectiveness Research coordinating the investment of the \$1.1 billion for CER in the Recovery Act. He was a Robert Wood Johnson Clinical Scholar and completed a Master's of Science focused on health services research and clinical epidemiology at the University of Pennsylvania and Children's Hospital of Philadelphia. Previously, he was a management consultant at McKinsey & Company, serving senior management of mainly health care clients on strategy projects. He has published articles in journals such as JAMA, New England Journal of Medicine, Health Affairs, and Pediatrics and given national presentations on topics including health care policy, quality of care, comparative effectiveness, hospitalist systems, and quality improvement. He is a practicing pediatric hospitalist and was selected as a Master of Hospital Medicine from the Society of Hospital Medicine. He completed pediatrics residency at Harvard Medical School's Children's Hospital Boston, graduated with High Honors from Baylor College of Medicine, and graduated summa cum laude from Texas A&M University.

Steven J. Corwin, MD, was named Chief Executive Officer of NewYork-Presbyterian Hospital on September 6, 2011. In this role, he is responsible for developing and implementing the Hospital's next capital and fundraising plan; advocating for academic medicine under health care reform; further integrating electronic information systems across the care continuum; collaborating with the Hospital's medical school partners and Healthcare System to support patient care, education, and research; and continuing to improve community health status. Previously, Dr. Corwin served as Executive Vice President and Chief Operating Officer for NewYork-Presbyterian Hospital, a position he held since 2005. In addition to overseeing the day-to-day operations across all five campuses of the Hospital, Dr. Corwin was responsible for advancing the institution's strategic initiatives to fulfill its commitment to

We Put Patients First, at the core of its mission. This included an intense focus on quality and patient safety, cultivating the organization's people and talent, advancing clinical and technological innovation, building physician and institutional partnerships across the NewYork-Presbyterian enterprise, ensuring service to the Hospital's underserved communities, and maintaining the Hospital's financial and operational strength. Key accomplishments under Dr. Corwin's leadership include marked improvements in quality and safety across the institution, improved patient and employee satisfaction, significant program growth and ranking among the top six hospitals in the nation, advancement of major construction projects, joint information systems planning with the Hospital's partner medical schools, and robust financial and operating results. Dr. Corwin has been at the Hospital since 1979. He joined the former Columbia-Presbyterian Medical Center's management team in 1991 and served in various management capacities. From 1998 to 2005 Dr. Corwin served as Senior Vice President and Chief Medical Officer for NewYork-Presbyterian, leading the development and implementation of 13 clinical service lines, an initiative that was critical to the success of the newly merged Hospital. In this role, he forged strong clinical collaborations across the institution to foster a solid partnership among physicians and Hospital management. A cardiologist and internist, Dr. Corwin obtained his undergraduate and medical degrees from Northwestern University, graduating summa cum laude and as a member of the Alpha Omega Alpha honors society. He completed both his internal medicine residency and cardiology training at Columbia-Presbyterian Medical Center. Dr. Corwin is a member of the Board of Directors of the Greater New York Hospital Association Foundation and serves as Assistant Treasurer. He is a Fellow at the New York Academy of Medicine, a member of the Association of American Medical Colleges Council of Teaching Hospitals Administrative Board, a member of the Health Management Academy, and a member of the Advisory Board for the Morgan Stanley Institute for Sustainable Investing. Dr. Corwin has received numerous awards. He was a 2013 recipient of the Our Town Thanks You (OTTY) Award for his efforts in improving Manhattan's Upper East Side community. He was also a 2013 recipient of the Northwestern Alumni Award. His other previous awards include the Hope and Heroes Award, the VHA Award for Clinical Quality, the Health Care Industry Good Scout Award, and an Honorary Physician-of-the-Year Award presented to him by the NewYork-Presbyterian/Columbia Division of Nursing.

John Couk, MD, is Chief Medical Officer of the Louisiana State University Health Care Services Division (HCSD) and is an Assistant Professor of Emergency Medicine at LSU Health Sciences Center in New Orleans. Dr. Couk leads the LSU HCSD Clinical Coordination Committee and the LSU HCSD Healthcare Effectiveness Team. These teams oversee the HCSD Accountable Care Services including Disease Management, Population Health, and Informatics. He has been the lead for Emergency Department improvement, Physician Champion for EHR implementation, and has extensive experience in research and education of clinical translation and quality improvement. Dr. Couk's expertise also includes electronic support of clinical functions and clinical workflows, clinical data warehousing and federation of data, and development and deployment of innovative and integrated IT systems. Dr. Couk is Board Certified by the American Board of Emergency Medicine.

Wyatt W. Decker, MD, is Mayo Clinic Vice President and Chief Executive Officer of Mayo Clinic in Arizona. As a Vice President of the largest not-for-profit integrated multi-specialty group practice in the nation, Dr. Decker helps direct Mayo Clinic's research, education, and clinical operations in Arizona, Florida, and Minnesota. Dr. Decker is directly responsible for Mayo Clinic operations in Arizona which includes launching Mayo Medical School Arizona in conjunction with Arizona State University; constructing state-of-the-art NCI designated Cancer Center with proton beam therapy; pioneering the use of telemedicine technologies to provide healthcare expertise to affiliated practices nationwide; and, providing healthcare for 95,000 patients each year at Mayo's four locations in greater Phoenix. Research from the Dartmouth Health Policy Institute indicates that the Mayo Clinic model of care lowers healthcare expenditures by approximately 30 percent in the Medicare patient population. Mayo Clinic

Hospital in Arizona was ranked by Consumer Reports as the nation's #1 safest teaching hospital in 2012, while all 3 of Mayo Clinic's flagship hospitals nationally were ranked in the top 10. Dr. Decker is a Professor of Emergency Medicine at the Mayo Clinic College of Medicine. He developed and subsequently directed the Emergency Medicine Residency training Program at Mayo Clinic, served as the inaugural Chair of the Department of Emergency Medicine in Minnesota, and Chair of Emergency Medicine at Mayo Clinic in Florida. Dr. Decker has held numerous leadership positions at Mayo Clinic in Rochester which has included the oversight of hospital operations; public affairs; and the recruitment, retention and leadership development of staff physicians. As an Emergency Physician, Dr. Decker chaired the Clinical Policy Committee of American College of Emergency Physicians, and served as the founding editor-in-chief of the International Journal of Emergency Medicine. He has published numerous peer-reviewed research articles and lectures internationally on topics including syncope and atrial fibrillation, hospital management, team building, change management and leadership. He has received numerous leadership and team-building awards from Mayo Clinic and the prestigious Heroes of Emergency Medicine award from the American College of Emergency Physicians for his work in Haiti following the earthquake of 2009. Prior to his medical career, Dr. Decker worked as a mountaineering guide in the western United States for the National Outdoor Leadership School. Dr. Decker holds an M.B.A. from Kellogg School of Management, Northwestern University, an M.D. from Mayo Medical School, and a B.S. from the University of California-Santa Cruz. He completed internal medicine residency training at Mayo Clinic Graduate School of Medicine and Emergency Medicine training at Denver Health and Hospitals.

Ronald A. DePinho, MD, is President of The University of Texas MD Anderson Cancer Center in Houston. His research program has focused on the molecular underpinnings of cancer, aging and degenerative disorders and the translation of such knowledge into clinical advances. Dr. DePinho's independent scientific career began at the Albert Einstein College of Medicine, where he was the Feinberg Senior Faculty Scholar in Cancer Research. He then joined the Department of Medical Oncology at the Dana-Farber Cancer Institute and the Department of Medicine and Genetics at the Harvard Medical School. He was the founding Director of the Belfer Institute for Applied Cancer Science at the Dana-Farber Cancer Institute and a Professor of Medicine and Genetics at Harvard Medical School. Dr. DePinho is a former member of the Board of Directors of the American Association for Cancer Research, and has served on numerous advisory boards in the public and private sectors, including co-chair of advisory boards for the NCI Mouse Models of Human Cancers Consortium and for The Cancer Genome Atlas Project. Dr. DePinho studied biology at Fordham University, where he graduated class salutatorian, and received his M.D. degree with distinction in microbiology and immunology from the Albert Einstein College of Medicine. For his fundamental contributions to cancer and aging, he has received numerous honors and awards including the March of Dimes Basil O'Connor Scholar Award, the James S. McDonnell Foundation Scholar Award, the Cancer Research Institute Investigator Award, the Melini Award for Biomedical Excellence, the Irma T. Hirschl Career Scientist Award, the Kirsch Foundation Investigator Award, and the Richard P. and Claire W. Morse Scientific Award. He is the recipient of the 2002 American Society for Clinical Investigation Award, the 2003 AACR G.H.A. Clowes Memorial Award, the 2007 Biomedicum Helsinki Medal and the 2009 Albert Szent-Györgyi Prize. He is a member of the Institute of Medicine of the National Academies of Science. In 2010, Dr. DePinho was elected to membership in the American Academy of Arts and Sciences. In 2012, he was elected as a member of the National Academy of Sciences. He is a founder of a number of biopharmaceutical companies focused on cancer therapies and diagnostics.

Jennifer DeVoe, MD, DPhil, is a practicing family physician and health services researcher in the Oregon Health & Science University (OHSU) Department of Family Medicine and also serves as the Chief Research Officer at OCHIN, a community health center information network. Dr. DeVoe studies access to health care, disparities in care, and how transformations in primary care affect patients' health

outcomes. She has pioneered the use of electronic health record (EHR) data, reviewing primary care utilization by uninsured and underinsured populations, which has garnered her national attention, particularly relating to the Affordable Care Act. She leads a multidisciplinary team of community and academic researchers with expertise in informatics, sociology, epidemiology, biostatistics, economics, primary care, health services research, clinical medicine, health care disparities, and psychology. Her team's research findings inform community, practice and policy interventions that help to improve the delivery of care for vulnerable populations and eliminate health disparities. Dr. DeVoe is currently the Principal Investigator (PI) on five large research studies funded by the Patient-Centered Outcomes Research Institute, the Agency for Healthcare Research and Quality, the National Institutes of Health. This includes serving as PI of the ADVANCE Clinical Data Research Network of PCORnet. She is an author on more than 100 peer-reviewed publications. Since 2006, Dr. DeVoe has built collaborations with investigators at Kaiser Permanente Northwest Center for Health Research, the State of Oregon, and OCHIN, Inc. (a national collaboration of community health centers) to develop the OCHIN EHR database. Dr. DeVoe has led or supported over 30 studies at OCHIN since 2006, spanning across 300 clinic practice sites, with over \$20 million in grant funding. She sees patients at the OHSU Gabriel Park Family Health Center, precepts medical students and residents, and mentors graduate students, fellows and junior faculty members. She holds joint appointments in the Department of Medical Informatics and Clinical Epidemiology at OHSU and at Kaiser Permanente Northwest Center for Health Research. Dr. DeVoe is an Puffer/American Board of Family Medicine Anniversary Fellow at the Institute of Medicine. Dr. DeVoe graduated from Harvard Medical School in 1999, obtained an MPhil (1998) and DPhil (2001) from Oxford University, and completed her Family Medicine residency at Oregon Health & Science University in 2004.

Susan DeVore is president and CEO of Premier, Inc., one of the nation's leading healthcare performance improvement companies. An alliance of approximately 3,000 U.S. community hospitals and 110,000+ other providers, Premier uses the power of collaboration to lead the transformation to high-quality, cost-effective healthcare. DeVore is an industry-leading thinker who was named to Modern Healthcare's top 100 most influential people in healthcare and Top 25 Women in Healthcare lists. She serves on the boards of the Healthcare Leadership Council, the Coalition to Protect America's Healthcare, and the Medicare Rights Center. She also serves as a member of the Institute of Medicine's Roundtable on Value & Science-Driven Healthcare. Under DeVore's leadership, Premier has built an industry-leading code of ethics, been named seven times as one of the World's Most Ethical Companies by Ethisphere, won the Malcolm Baldrige National Quality Award, been named four times to InformationWeek's 500 top technology innovators in the nation and won IBM's CTO innovation award for advanced analytics in healthcare.

Victor J. Dzau, MD, is Chancellor for Health Affairs and James B. Duke Professor of Medicine at Duke University and the past President and CEO of Duke University Health System. Previously, Dr. Dzau was the Hersey Professor of Theory and Practice of Medicine and Chairman of Medicine at Harvard Medical School's Brigham and Women's Hospital and formerly the Chairman of Department of Medicine at Stanford University. On July 1, 2014 he will become the 8th President of the Institute of Medicine. Dr. Dzau has made a significant impact on medicine through his seminal research in cardiovascular medicine and genetics, his pioneering in the discipline of Vascular Medicine, and recently his leadership in Healthcare Innovation. His important work on the renin angiotensin system (RAS) paved the way for the contemporary understanding of RAS in cardiovascular disease and the development of RAS inhibitors as therapeutics. Dr. Dzau also pioneered gene therapy for vascular disease, and his recent work on stem cell "paracrine mechanism" and the use of microRNA in direct reprogramming provide novel insight into stem cell biology and regenerative medicine. In his role as a leader in health care, Dr. Dzau has led efforts in health care innovation. His vision is for academic health sciences centers to lead the transformation of medicine through innovation, translation and

globalization. Leading this vision at Duke, he and colleagues developed the Duke Translational Medicine Institute, the Duke Global Health Institute, the Duke-National University of Singapore Graduate Medical School and the Duke Institute for Health Innovation. These initiatives create a seamless continuum from discovery & translational sciences to clinical care, and promote transformative innovation in health. As one of the world's preeminent academic health leaders, Dr Dzaou advises governments, corporations and universities worldwide. He has served as a member of the Council of the Institute of Medicine (IOM) and the Advisory Committee to the Director of the National Institutes of Health (NIH), and as Chair of the NIH Cardiovascular Disease Advisory Committee and of the Association of Academic Health Centers. Currently he is a member of the Board of Directors of the Singapore Health System, Governing Board of Duke-National University Singapore Medical School and Senior Health Policy Advisor to Her Highness Sheikha Moza (the Chair of Qatar Foundation). He is also on the board of Health Governors of the World Economic Forum and chaired of its Global Agenda Council on Personalized and Precision Medicine. In 2011, he led a partnership between Duke University, World Economic Forum and McKinsey, and founded the nonprofit organization: "International Partnership for Innovative Healthcare Delivery" and chairs its Board of Directors. Among his honors and recognitions are the Gustav Nylin Medal from the Swedish Royal College of Medicine; the Max Delbruck Medal from Humboldt University, Charite and Max Planck Institute; the Commemorative Gold Medal from Ludwig Maximilian University of Munich; the Inaugural Hatter Award from the Medical Research Council of South Africa; the Polzer Prize from the European Academy of Sciences and Arts; the Novartis Award for Hypertension Research; the Distinguished Scientist Award from the American Heart Association (AHA) and the 2010 AHA Research Achievement Award for his contributions to cardiovascular biology and medicine. He has received 6 honorary doctorates.

Philip Fasano is executive vice president and chief information officer of Kaiser Permanente, the nation's largest not-for-profit health plan and health care provider, with annual operating revenue in excess of \$42 billion. Often referred to as the model for the future of health care, Kaiser Permanente serves more than 9.3 million members, focusing on prevention and affordable health care for the members and communities it serves through the use of evidence-based medicine and industry-leading technology. A nationally recognized leader, Fasano was named one of Computerworld's Top 100 IT Leaders for 2010 for exceptional technology leadership and effectively managed IT strategies. Since joining Kaiser Permanente in 2007, Fasano has been directing the 6,000 employees of the IT organization in support of a vision of real-time, personalized health care for its members. Under Fasano's leadership, the company creates better tools and platforms to deliver smarter, more connected care that is also preventative and affordable. The centerpiece of the technology platform is Kaiser Permanente HealthConnect®, the world's largest civilian electronic health record. KP HealthConnect gives the organization's 14,600 physicians immediate access to patients' status and medical history, as well as support for making decisions using evidence-based practice guidelines and the latest medical research. Kaiser Permanente's members can easily make and reschedule appointments, check lab results, and send e-mails to care providers via My Health Manager, the online personal health record that connects directly with KP HealthConnect. Passionate about using transformative technology to make lives better, Fasano serves as co-chair for CIO Leadership Network's San Francisco CIO Executive Summit, a community developed for the specific needs of chief information officers and senior IT leaders. Fasano also provides technology and health care industry leadership as a member the board of directors of NICRE-Veterans Health Research Institute, the Oracle CIO Customer Advisory Board, and Sierra Ventures CIO Advisory Board. Prior to joining Kaiser Permanente, Fasano served in information technology leadership roles in some of the nation's top finance companies, including Capital One Financial Group, JP Morgan, and Deutsche Financial Services, a division of Deutsche Bank. Fasano earned his master's in business administration from Long Island University and his bachelor's degree in computer science from the New York Institute of Technology.

Rachael Fleurence, PhD, is Program Director of the CER Methods and Infrastructure Program at the Patient-Centered Outcomes Research Institute (PCORI). In this role, she leads the research prioritization initiative to help identify important patient- and stakeholder-generated questions and establish a rigorous research prioritization process to rank these questions. A methodologist with experience in systematic reviews and evidence synthesis, health technology assessment, and research prioritization methods, Fleurence has 15 years of experience in the field of health outcomes research, including seven years in the life sciences consulting industry, where she held senior leadership positions at United BioSource Corporation and ICON plc. From 1995 to 1999, she was a program officer at the World Health Organization for the revision of the International Classification of Disabilities. Fleurence co-chaired the 2011 ISPOR issue panel review committee for the 16th annual meeting and was an associate editor for the journal *Health Outcomes Research in Medicine* in 2011 and 2012. She is currently co-editing a volume on *Comparative Effectiveness* for Springer's upcoming handbook on health services research. Fleurence received a BA from Cambridge University, an MA in business management from the Ecole Supérieure des Sciences Economiques et Commerciales (ESSEC)-Paris, and an MSc and PhD in health economics from the University of York in the United Kingdom.

John Gallin, MD, was appointed director of the NIH Clinical Center in 1994. The Clinical Center serves the clinical research needs of 17 NIH institutes and is the largest hospital in the world totally dedicated to clinical research. During his tenure, Dr. Gallin has overseen the design and construction of a new research hospital for the Clinical Center, the Mark O. Hatfield Clinical Research Center, which opened to patients in 2005; the establishment of a new curriculum for clinical research training now offered globally; and development of new information systems for biomedical translational and clinical research. In 2011, under Dr. Gallin's leadership, the Clinical Center received the Lasker~Bloomberg Public Service Award. While serving as Clinical Center director, Dr. Gallin has continued to be an active clinician and researcher. His primary research interest is in a rare hereditary immune disorder, chronic granulomatous disease (CGD). His laboratory described the genetic basis for several forms of CGD and has done pioneering research that has reduced life-threatening bacterial and fungal infections in CGD patients. A New York native, Dr. Gallin attended public school in New Rochelle, New York; graduated cum laude from Amherst College; and earned an MD degree at Cornell University Medical College. After a medical internship and residency at New York University's Bellevue Hospital, he received postdoctoral training in basic and clinical research in infectious diseases at NIH from 1971 to 1974. He then went back to New York University's Bellevue Hospital as senior chief medical resident from 1974-1975 before returning to NIH. In 1985, Dr. Gallin began a nine-year period as scientific director for intramural research activities at the National Institute of Allergy and Infectious Diseases (NIAID). Dr. Gallin was the founding chief of the NIAID Laboratory of Host Defenses, served as chief of the laboratory for 12 years, and continues as chief of the lab's clinical pathophysiology section. He has published more than 325 articles in scientific journals and has edited two textbooks – "Inflammation, Basic Principles and Clinical Correlates" (Lippincott, Williams, and Wilkins, 1999, now in 3rd edition) and "Principles and Practice of Clinical Research" (Academic Press, now in 3rd edition, 2012). Dr. Gallin is a member of the American Society for Clinical Investigation, the Association of American Physicians, the Institute of Medicine of the National Academy of Sciences, and he is a Master of the American College of Physicians.

Sarah Greene, MPH, is a Senior Program Officer with the CER Methods and Infrastructure Program at the Patient-Centered Outcomes Research Institute (PCORI). She is responsible for providing intellectual and organizational leadership for the program, primarily working with awardees on PCORI's National Patient-Centered Clinical Research Network. For the past two decades, Greene has worked in patient-centered communication, health literacy, quality of cancer care, and optimization of multi-site collaboration. Most recently, as a healthcare strategy consultant for Group Health Cooperative, she led initiatives on improving patient service, cancer outcomes measurement, and branding. At the Group

Health Research Institute, she served leadership roles on federally funded consortium projects, including the Cancer Research Network, Cancer Communication Research Center, and the HMO Research Network. As a member of the Clinical & Translational Science Awards consortium, Greene chaired the national Community Partners Integration work group. Greene has authored numerous manuscripts focused on development and implementation of multicenter research, and she created ResearchToolkit.org, which focuses on resources related to conduct of health research studies. She received a BA in psychology and Italian, and an MPH with an emphasis in epidemiology, from Indiana University.

Jeffrey Grossman, MD, is a career long faculty member at the University of Wisconsin. He serves as the Senior Associate Dean for Clinical Affairs at the University of Wisconsin School of Medicine and Public Health and as President and CEO of the University of Wisconsin Medical Foundation, the group practice organization for more than 1300 faculty physicians. In these roles he has responsibility for the quality of clinical care delivered by the faculty of the UW Medical School, the financial health of the clinical enterprise, and the interface between patient care and the Medical School's other missions of research and education. He has served in other administrative positions for the UW Health, including Vice President for Medical Affairs at University of Wisconsin Hospital and Clinics, Physician-in-Chief, Chair of the Department of Medicine, and Medical Director of the Trauma and Life Support Center. Over the past decade, Dr. Grossman has been involved, from a variety of perspectives, in trying to foster the evolution of a traditional Department-based academic health center practice model toward a more integrated practice model with roots in the community as well as in academia. This is a transition that he believes will be critical to the future viability of many academic health centers, and which he is working to sustain and nurture at the University of Wisconsin. He is committed to the idea that the successful academic health center of the future will play a central role in translating knowledge into improved healthcare organization, policy, delivery, and population health. He has cultivated and promoted the idea of applied health services research through the development of the Health Innovations Program at the University of Wisconsin School of Medicine and Public Health. Working at the interface between hospitals, physician group and school, he is trying to promulgate an enterprise model of collaboration that supersedes the interests of any one part of the organization. He remains an active clinician and teacher, with particular interests in the pathophysiology of critical illness, the ethics and practice of end-of-life care, and transformation of our model of medical care.

Scott J. Hamlin became the Executive Vice President and Chief Operating Officer of Cincinnati Children's Hospital Medical Center in February of 2012. For the previous 14 years, he had served Cincinnati Children's as its Senior Vice President and Chief Financial Officer. Hamlin joined Cincinnati Children's in 1988 as its Director of Finance. Prior to joining Cincinnati Children's, Hamlin specialized in healthcare practices at Arthur Anderson & Co. Hamlin earned a BBA in accounting, graduating cum laude at the University of Cincinnati in 1983. He was also a member of Beta Alpha Psi (Accounting Honorary). He received his CPA in the state of Ohio in 1987. Hamlin serves as member of the Cincinnati USA Regional Chamber Board of Directors, and as First Vice Chair of the Executive Committee. Hamlin also serves on the Board of Trustees of River City Insurance Company, Convalescent Hospital for Children and the Children's Hospital Foundation. Hamlin has also served on the Board of the Cincinnati Zoo Foundation, Advisory Board of the Mariemont Board of Education, Joy Outdoor Education Center, Greater Cincinnati Foundation and Ronald McDonald Charities. He also serves on the Finance and Management Oversight Committees of the Board of Uptown Consortium, Inc.

Lisa E. Harris, MD, has practiced medicine for 30 years at nationally recognized Eskenazi Health (formerly Wishard Health Services). Today, Dr. Harris serves as Eskenazi Health's chief executive officer (CEO), leading one of America's largest essential health care systems where roughly half of Indiana's

physicians have trained through the health system's partnership with the Indiana University School of Medicine. In addition to her leadership role at Eskenazi Health, Dr. Harris is engaged in research and teaching as the John F. Williams, Jr., M.D. scholar; associate professor of medicine; and associate dean for the IU School of Medicine. Long before national health care reform took shape in America, Dr. Harris concentrated Eskenazi Health's resources on primary care, prevention and health promotion, asserting that this is the greatest opportunity to impact the health of a community – keeping people well in the first place. She is intensely focused on improving access to patient-centered, comprehensive, community-based primary care and mental health care, effective chronic disease management and health promotion programs. And, as past chair of America's Essential Hospitals (formerly the National Association of Public Hospitals and Health Systems), Dr. Harris has nurtured the organization's strong presence on Capitol Hill, advocating for our nation's most vulnerable populations. Also an active and engaged leader in the local community, Dr. Harris serves as medical director and president-elect of the board of directors of the American Red Cross of Greater Indianapolis, as well as on the boards of directors for the Regenstrief Institute, Julian Center, MESH (formerly Managed Emergency Surge for Healthcare), and the inaugural board of directors of the Patachou Foundation, focused on providing healthful food to homeless children. She also serves on the executive committee of United Way of Central Indiana and is serving as the 2015 chair of the American Heart Association's Go Red for Women initiative. In 2009, Dr. Harris helped successfully lead a campaign seeking voter approval for a new Wishard Hospital campus. Prior to the 2009 special election calling upon voters to approve the construction, Dr. Harris built a coalition of community and business leaders and participated in more than 200 meetings to share information about the project. An astounding 85 percent of voters said yes to the referendum; in 33 precincts, not one opposing vote was cast. In 2011, the organization received a \$40 million gift from Indianapolis couple Sidney and Lois Eskenazi, in honor of whom Health & Hospital Corporation of Marion County named the new hospital facilities. The Sidney & Lois Eskenazi Hospital and Eskenazi Health campus opened in December 2013 and, designed to demonstrate the impact of the built environment on the health and well-being of patients and those who care for them, is on track to be the only newly built hospital campus in the country to achieve United States Green Building Council (USGBC) Leadership in Energy and Environmental Design (LEED®) Silver certification.

John M. Hauptert, FACHE, is President and CEO of Grady Health System in Atlanta, GA. Hauptert began his tenure at Grady in October 2011. Grady Health System is the safety net healthcare system serving Fulton and DeKalb Counties in Georgia. Grady is the primary Level I trauma center and burn center for the Atlanta metropolitan area. In addition, Grady is home to many nationally recognized clinical services including the Marcus Neuroscience and Stroke Center, the Correll Cardiac Center, the Georgia Cancer Center and Grady EMS. Grady also serves as the primary training site for the Morehouse and Emory Schools of Medicine. A native of Ft. Smith, Arkansas, he is a graduate of Trinity University in San Antonio where he earned a Master of Science Degree in Health Care Administration. He also received a Bachelor of Science in Business Administration from Trinity. His career in healthcare management began at Methodist Health System in Dallas, Texas in 1992 where he served for fourteen years in various roles including President of one of the system's hospitals and as Executive Vice President for Corporate Services and Business Development. In October 2006 Hauptert left the Methodist Health System to become the Chief Operating Officer at Parkland. Hauptert is a Fellow in the American College of Healthcare Executives and recipient of the ACHE Regent's Leadership Award. In Atlanta, John is a member of the Rotary Club of Atlanta and serves as a member of the Board of Directors of Central Atlanta Progress, The American Heart Association, The Atlanta Committee for Progress and The Atlanta Women's Foundation. John is also a member of the Advisory Boards for The Healthcare Institute at Georgia State University and the Department of Community Health. Nationally, John serves on the Health Advisory Committee to the Pew Charitable Trusts, on the Board of Directors of Americas Essential Hospitals and on the Member Board of the University Health System Consortium.

Rachel Hess, MD, MS, is an Associate Professor of Medicine, Epidemiology, and Clinical and Translational Sciences at the University of Pittsburgh and a Professor of Medicine and the founding director of the Health System Innovation and Research (HSIR) program at the University of Utah Schools of the Health Sciences. She is the principal investigator of the PaTH clinical data research network within PCORnet. As a clinician and Health Services Researcher, Dr. Hess brings a unique perspective of translating research into clinical and policy practice. Dr. Hess's research aims to improve patient-centered outcomes in clinical care. In service of this mission, she seeks to understand determinants of quality of life, including sexual function, and how health-related quality of life affects health and cost outcomes. She has conducted cohort studies in midlife women to examine the impact of menopause on health-related quality of life, including sexual functioning. She is currently following a cohort of adults over 50 to characterize the roles of intrapersonal resources, interpersonal relationships, and individual lifestyle in shaping quality of life across transitions; and the health and healthcare-cost outcomes of quality of life. Dr. Hess's implementation work uses health information technology to engage patients in their care. She has examined the impact of providing patients with guideline-based feedback regarding their health behaviors and health-related quality of life on patient activation and behavior change. Dr. Hess has overseen the development and successful implementation of multiple technology-based programs in primary care, including UPMC's efforts in the electronic collection of patient-reported information as part of routine clinical care throughout the health system. As the director of HSIR, she brings together individuals from across the University of Utah to develop, test, and implement novel approaches that improve health outcomes for the population. Dr. Hess completed her undergraduate work in mathematics at Washington University, received her medical degree from the University of New Mexico, completed her residency training at Temple University, and completed her general internal medicine and women's health fellowships at the University of Pittsburgh.

Susan Hildebrandt, MA, is the Director of Stakeholder Engagement for the Patient-Centered Outcomes Research Institute (PCORI). She is responsible for leading PCORI's engagement with clinicians, policy makers, professional audiences, and the broader healthcare community. Hildebrandt is an experienced government relations professional with longstanding knowledge of patient-centered research. She has more than 25 years of communications, public policy, and healthcare advocacy experience. Most recently, Hildebrandt was assistant director for government relations at the American Academy of Family Physicians (AAFP), where she worked on policy issues including comparative effectiveness research, healthcare reform, delivery system reform, research, and health information technology. She also oversaw the AAFP's grassroots program to engage family physicians on health policy issues. Hildebrandt has also held policy positions at the American College of Obstetricians and Gynecologists and on Capitol Hill. Hildebrandt earned her BS in political science and German from the University of Michigan and her MA from the University of Pennsylvania.

Rodney F. Hochman, MD, serves as president and CEO of Providence Health & Services, leading the five state health system. Before serving as group president and now president and CEO of Providence, Dr. Hochman was president and chief executive officer of Swedish Health Services. He and his team helped transform Swedish and positioned the organization for a strong, stable future. In his five years at Swedish he strengthened the community safety net, created a strong culture of safety and re-invented their business model from a downtown hospital focus to a regional system of care. Knowing that greater collaboration among providers was the future of health care, Dr. Hochman and the Swedish board conducted an exhaustive search over the course of his tenure and aligned Swedish with the right partner – Providence. Prior to joining Swedish, Dr. Hochman had been executive vice president since 2004 of Sentara Healthcare – a major medical system based in Norfolk, Virginia. In that role, he was responsible for the operation of five hospitals, as well as the organization's medical group, legal and corporate compliance divisions. Prior to that position, he had served as Sentara's chief medical officer and senior

vice president since 1998. Before joining Sentara, Dr. Hochman held numerous executive-level positions during five years with the Health Alliance of Greater Cincinnati and he spent nearly 10 years with Guthrie Healthcare System in Sayre, Pennsylvania. His medical background is in rheumatology and internal medicine and he has served as a clinical fellow in internal medicine at Harvard Medical School and Dartmouth Medical School. In addition, Dr. Hochman is a Fellow of the American College of Physicians, a Fellow of the American College of Rheumatology and a member of the American College of Healthcare Executives. He is the recipient of the 2001 Physician Executive Award of Excellence, sponsored by Modern Physician magazine and under his leadership, 569-bed Sentara Norfolk General Hospital won the American Hospital Association's prestigious Quest for Quality national award in 2002. In May 2009, Dr. Hochman was honored for the second time by Modern Physician magazine as number eleven of the 50 Most Powerful Physician Executives in Healthcare. He earned his medical degree from Boston University School of Medicine and his bachelor's degree from Boston University.

Robert L. Jesse, MD, PhD, was appointed Principal Deputy Under Secretary for Health in the Department of Veterans Affairs (VA) on July 4, 2010. Prior to his appointment, Dr. Jesse had served as the Acting Principal Deputy Under Secretary for Health since March 7, 2010. In this position, Dr. Jesse leads clinical policies and programs for the Veterans Health Administration (VHA), the Nation's largest integrated health care system. In addition to its medical care mission, VHA is the Nation's largest provider of graduate medical education and a major contributor to medical and scientific research. Previously, Dr. Jesse was the Chief Consultant for Medical Surgical Services in the VA's Office of Patient Care Services, also serving as the National Program Director for Cardiology. In this capacity, he implemented broad reforms in the delivery of specialty, sub-specialty and emergency care that have significantly improved the quality of care provided across the VA health care system. Dr. Jesse received his Bachelor of Science degree in Biochemistry from the University of New Hampshire in 1974 and later worked as a research associate at the Harvard School of Public Health. In 1980, he earned his Ph.D. in Biophysics at the Medical College of Virginia, followed by his M.D. in 1984, completing both his Residency and Cardiology fellowship there. Dr. Jesse began his career as the Director of the Acute Cardiac Care Program at Virginia Commonwealth University's Health System. Prior to assuming national leadership positions in VHA, Dr. Jesse was the Chief of the Cardiology Section at the Richmond VA Medical Center in Virginia. Dr. Jesse has published widely in areas of acute cardiac care, systems management and quality in health care. His basic research has focused on platelet physiology and cardiac biomarkers. Dr. Jesse is a diplomate of the American Board of Internal Medicine with specialty boards in Cardiovascular Medicine. He is a Fellow of the American College of Cardiology, and has served as a Governor for the College. He is also a Fellow of the American Heart Association and is currently the President of the Richmond Metro Chapter of the American Heart Association. In addition, he holds the rank of tenured Professor of Internal Medicine/Cardiology within the Virginia Commonwealth University Health System.

Robert M. Kaplan, PhD, became Chief Science Officer at the Agency for Health Care Research and Quality (AHRQ) in May of 2014. From 2011 to 2014, he was in the National Institutes of Health (NIH) Office of the Director as an Associate Director of for Behavioral and Social Sciences and Director of the Office of Behavioral and Social Sciences Research (OBSSR). Prior to working for government, Kaplan was Distinguished Professor of Health Services at UCLA and Distinguished Professor of Medicine at the UCLA David Geffen School of Medicine where he was PI of the California Comparative Effectiveness and Outcomes Improvement Center. He led the UCLA/RAND health services training program and the UCLA/RAND CDC Prevention Research Center. He was Chair of the Department of Health Services from 2004 to 2009. From 1997 to 2004 he was Professor and Chair of the Department of Family and Preventive Medicine, at the University of California, San Diego. He is a past President of several organizations, including the American Psychological Association Division of Health Psychology, Section J of the American Association for the Advancement of Science (Pacific), the International Society for

Quality of Life Research, the Society for Behavioral Medicine, and the Academy of Behavioral Medicine Research. He is a Past Chair of the Behavioral Science Council of the American Thoracic Society. Dr. Kaplan is a former Editor-in-Chief of two different academic journals: Health Psychology and the Annals of Behavioral Medicine. He is the author, co-author or editor of more than 18 books and over 500 articles or chapters. His work has been cited in more than 25,000 papers and the ISI includes him in the listing of the most cited authors in his field (defined as above the 99.5th percentile). In 2005 he was elected to the Institute of Medicine of the National Academies of Sciences.

John N. Kastanis, FACHE, is President and CEO of Temple University Hospital (TUH) in Philadelphia, Pa., an internationally renowned academic medical institution which trains future physicians and is extensively involved in academic research. Mr. Kastanis is a seasoned hospital administrator in a wide range of healthcare settings, and has served for nine years as President and CEO of the Hospital for Joint Diseases Orthopaedic Institute, part of the Mt. Sinai-NYU Health System in New York City. As a consultant and transitional contractor, Mr. Kastanis has also served as Interim President and CEO of Quincy Medical Center, in Quincy, Massachusetts; Caritas Health Care, part of Brooklyn-Queens Health Care, Inc., in Queens, NY; and Southampton Hospital, in Southampton, NY. He has also held permanent leadership positions at Bayley Seton Hospital, in Staten Island, NY; New Rochelle Hospital Medical Center; and the Manhattan Eye, Ear & Throat Hospital. In addition to health system leadership, Mr. Kastanis has also served as a healthcare consultant to hospital boards, investment banking, and management firms. Mr. Kastanis is a Fellow of the American College of Healthcare Executives (FACHE), earned his MBA from Baruch College-Mt. Sinai School of Medicine's Health Administration Program, and his B.A. in Political Science from Queens College.

Rainu Kaushal, MD, MPH, Chairman of the Department of Healthcare Policy and Research at Weill Cornell Medical College, is an international expert and leader in the clinical effectiveness, cost effectiveness, and comparative effectiveness of healthcare delivery interventions and models. Dr. Kaushal is also Executive Director of the Center for Healthcare Informatics and Policy (CHiP) and the Frances and John L. Loeb Professor of Medical Informatics at Weill Cornell Medical College, and Chief of Healthcare Policy and Research at New York-Presbyterian Hospital/Weill Cornell Medical Center. Dr. Kaushal's extensive research portfolio covers topics central to healthcare delivery and reform, including health information technology, health information exchange, and novel models of health care delivery and provider payment. She studies the effects of these healthcare interventions on outcomes related to health care quality, safety, costs, value, provider adoption, provider usage, and patient satisfaction. These studies include those conducted by the Health Information Technology Evaluation Collaborative (HITEC), which she leads and which has played an instrumental role in New York State's health reform program. Dr. Kaushal also currently leads a \$7 million grant from the Patient-Centered Outcomes Research Institute to establish a Clinical Data Research Network involving 22 New York City organizations. The consortium will develop a data infrastructure to support a wide variety of research studies and the recruitment of patients into clinical trials. Dr. Kaushal was recently selected as a Fellow in the 2014-15 class of the prestigious Hedwig van Ameringen Executive Leadership in Academic Medicine (ELAM) Program for Women at Drexel University College of Medicine. She has published more than 125 scholarly publications, served on numerous national and international advisory committees, formally consulted with other researchers as well as with policy makers, and served on editorial boards for health care journals as well as on several study sections for the Agency for Healthcare Research and Quality. Dr. Kaushal is a frequent invited national and international speaker.

Darrell G. Kirch, MD, is president and CEO of the Association of American Medical Colleges (AAMC), which represents the nation's medical schools, teaching hospitals, and academic societies. A distinguished physician, educator, and medical scientist, Dr. Kirch speaks and publishes widely on the need for transformation in the nation's health care system and how academic medicine can lead that

change across medical education, medical research, and patient care. Prior to becoming AAMC president in 2006, Dr. Kirch served as the dean and academic health system leader of two institutions, the Medical College of Georgia and the Penn State Milton S. Hershey Medical Center. He has co-chaired the Liaison Committee on Medical Education, the accrediting body for U.S. medical schools, and now serves as chair of the Washington Higher Education Secretariat and the Department of Veterans Affairs Special Medical Advisory Group. Dr. Kirch also is a member of the Institute of Medicine of the National Academies. A psychiatrist and clinical neuroscientist by training, Dr. Kirch began his career at the National Institute of Mental Health, becoming the acting scientific director in 1993 and receiving the Outstanding Service Medal of the United States Public Health Service. A native of Denver, he earned his B.A. and M.D. degrees from the University of Colorado.

Jerry A. Krishnan, MD, PhD, is Professor of Medicine (Section of Pulmonary, Critical Care, Sleep, and Allergy) and Public Health (Division of Epidemiology and Biostatistics), and Associate Vice President for Population Health Sciences in the Office of the Vice President for Health Affairs at the University of Illinois Hospital & Health Sciences System. He is also a practicing pulmonologist specialized in the management of patients with chronic obstructive pulmonary disease (COPD), an expert in clinical investigation in asthma and COPD, and a leader in the field of comparative effectiveness research. He is the Chair of the Steering Committee for the COPD Outcomes-based Network for Clinical Effectiveness and Research Translation (CONCERT) and a Principal Investigator in the NHLBI-sponsored AsthmaNet consortium. Dr. Krishnan leads Patient Centered Outcomes Research Institute (PCORI)-funded multi-investigator groups examining the effectiveness of interventions to improve outcomes after hospital discharge (PARTNER), use of supplemental oxygen (PELICAN), and care of children with presenting to the emergency department with uncontrolled asthma (the CHICAGO Trial). He is also an investigator in PCORnet (the National Patient-Centered Clinical Research Network), including CAPriCORN and the COPD Patient-Powered Research Network.

Stephen T. Lawless, MD, MBA, earned his BS in biology from Fordham University and his medical degree from UMDNJ Robert Wood Johnson Medical School. He completed a pediatric residency at St. Christopher's Hospital for Children and a pediatric critical care fellowship at Children's Hospital of Pittsburgh. Dr. Lawless subsequently earned an MBA from the Wharton School of Business at the University of Pennsylvania. Since 2006, he has served in the role of the Vice-President of Quality and Safety for Nemours. In this role, Dr. Lawless is charged with the oversight and coordination of quality and safety within all of Nemours. In addition, he seeks to use Nemours' combined technologies and knowledge to make systems simpler and error-free, whether those systems are used for business or healing. Dr. Lawless is also a Professor of Pediatrics at Thomas Jefferson University and Staff Intensivist in the Department of Anesthesiology and Critical Care Medicine at the Alfred I. duPont Hospital for Children. He holds certifications in Pediatrics from the American Board of Pediatrics (ABP) and Pediatric Critical Care; he is a Fellow in the American College of Critical Care Medicine. He has authored numerous publications and has spoken nationally on a range of subjects primarily focusing on aspects of quality improvement and safety in medical care especially as the electronic medical record and other technologies impact it.

Steven H. Lipstein, president and Chief Executive Officer of BJC HealthCare, oversees one of the nation's largest health care organizations, with annual net revenues of \$4 billion and more than 28,000 employees in the greater St. Louis, southern Illinois and mid-Missouri regions. BJC HealthCare serves patients and their families in urban, suburban and rural communities through its 13 hospitals and other health-service organizations. Its teaching hospitals, Barnes-Jewish Hospital and St. Louis Children's Hospital, are affiliated with internationally renowned Washington University School of Medicine, consistently ranked among the nation's best medical schools and research institutions. Lipstein serves on the St. Louis Regional Health Commission and sits on the Board of the Missouri Hospital Association.

At Washington University in St. Louis, Lipstein serves on the Board of Trustees, on the School of Medicine National Council, and is chair of the Institute of Public Health National Advisory Council. Lipstein serves on the Board of Directors of Ameren, an electrical utility company with assets of \$24 billion, on the Teach for America -- St. Louis Regional Advisory Board and on the Board of Trustees at Emory University. In 2010, he was appointed by the United States Comptroller General as vice chair of the Board of the Patient Centered Outcomes Research Institute (PCORI), established under the Patient Protection and Affordable Care Act. Lipstein is a former chairman of the Board of Directors of the St. Louis Federal Reserve Bank. Spanning three decades, Lipstein's education and professional career has taken him from Emory University to Duke University for college and graduate school respectively, to Massachusetts General Hospital, Johns Hopkins Hospitals and Health System, the University of Chicago Hospitals and Health System, and now to BJC HealthCare, where he has served as president and chief executive officer since 1999.

Bryan R. Luce, PhD, is Chief Science Officer at the Patient-Centered Outcomes Research Institute. He is responsible for leading the development and implementation of PCORI's patient-centered comparative clinical effectiveness research (CER) agenda. Luce previously founded the outcomes research firm MEDTAP® International, serving as its chairman, president, and chief executive officer and was the senior vice president for science policy at the United BioSource Corporation. Earlier, Luce was director of Battelle's Centers for Public Health Research and Evaluation; director of the Office of Research and Demonstrations, Centers for Medicare and Medicaid Services; and a senior analyst at Office of Technology Assessment of the United States Congress. Luce's research has focused on improving methods and related policies for more efficient healthcare decision making. He has authored more than 100 scientific publications, including three textbooks on health technology assessment, health policy, and health economics. In 2008, Luce founded the Pragmatic Approaches to Comparative Effectiveness (PACE) Initiative, which studies novel methods to conduct analytical efficiency comparative effectiveness trials. Previously, he founded the Bayesian Initiative in Health Economics and Outcomes Research. He has been an advisor to numerous government and nonprofit agencies, as well as pharmaceutical and device firms worldwide; a member or chair of socioeconomic and public health policy advisory boards for leading biopharmaceutical companies; and a member of the Medicare Evidence Development & Coverage Advisory Committee (MedCAC). Luce is also a past president of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and in 2008 received the Society's Avedis Donabedian Outcomes Research Lifetime Achievement Award. He has held adjunct faculty positions in the Department of Health Policy at Jefferson Medical College, the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California, and the Department of Pharmacy at the University of Washington. A former Special Forces Officer, Luce is a Lieutenant Colonel (Retired), US Army Reserves. He holds MS (public health) and MBA degrees from the University of Massachusetts at Amherst, and a PhD in health services research from the University of California at Los Angeles.

Kenneth D Mandl, MD, MPH, Boston Children's Hospital Chair in Biomedical Informatics and Population Health, pioneered the use of IT and big data for population health, discovery, patient engagement and care redesign through scholarship intersecting epidemiology and informatics. Mandl leads the transformative SMART Platforms initiative to design the "app store for health" and is principal investigator of the Scalable Collaborative Infrastructure for a Learning Health System across Boston hospitals and nationally. Recognized for research and teaching, Mandl received the Presidential Early Career Award for Scientists and Engineers and the Clifford A. Barger Award for top mentors at Harvard Medical School. He was advisor to two Directors of the CDC and chairs the Board of Scientific Counselors of the NIH's National Library of Medicine. His clinical training and experience is in pediatrics and pediatric emergency medicine. Dr. Mandl has been elected to multiple honor societies

including the American Society for Clinical Investigation, Society for Pediatric Research, American College of Medical Informatics and American Pediatric Society.

Terry Mazany is President and CEO of The Chicago Community Trust, one of the nation's largest community foundations with assets of more than \$2 billion and grant making exceeding \$150 million that annually benefits more than a thousand not-for-profit organizations in metropolitan Chicago. Terry was selected as the sixth Executive in The Chicago Community Trust's ninety-eight year history in 2004. In 2011 Terry served as the interim chief executive officer of Chicago Public Schools, a district of more than 400,000 students and over 650 schools with a budget of \$6 billion. In addition, Terry is a member of the board of directors of the Federal Reserve Bank of Chicago and the Council on Foundations, as well as past chair of its Community Foundation Leadership Team representing the nation's 700 community foundations. He was also appointed by Secretary of Education Arne Duncan to serve on the National Assessment Governing Board that oversees the National Assessment of Education Progress, known as our Nation's Report Card. In recognition of the 100th anniversary of the first community foundation, Terry and his colleague, David Perry, co-edited a recently published book entitled *Here for Good: Community Foundations and the Challenges of the 21st Century*. His work in philanthropy is based on fifteen years experience in public education, working in several districts across the country including Detroit, Chicago, Baltimore, Oakland, and San Francisco. Preceding his work in the public sector, Terry Mazany enjoyed his first career as an archaeologist and dendrochronologist – using tree-ring chronologies to date human settlements and develop past climate records. Terry earned Master's degrees in Anthropology and Business Administration at the University of Arizona and a Master's in Education Policy from the University of Illinois at Chicago. He has also been awarded Honorary Doctorate degrees from DePaul University and Lewis University.

J. Michael McGinnis, MD, MPP, is a physician, epidemiologist, and long-time contributor to national and international health programs and policy. An elected Member of the Institute of Medicine (IOM) of the National Academies, he has since 2005 also served as IOM Senior Scholar and Executive Director of the IOM Roundtable on Value & Science-Driven Health Care. He founded and stewards the IOM's *Learning Health System* Initiative, and, in prior posts, also served as founding leader for the Robert Wood Johnson Foundation's (RWJF) Health Group, the World Bank/European Commission's Task Force for Health Reconstruction in Bosnia, and, in the U.S. government, the Office of Research Integrity, the Nutrition Policy Board, and the Office of Disease Prevention and Health Promotion. In the latter post, he held continuous policy responsibilities for prevention through four Administrations (Presidents Carter, Reagan, Bush, Clinton), during which he conceived and launched a number of initiatives of ongoing policy importance, including the *Healthy People* national goals and objectives, the U.S. Preventive Services Task Force, the *Dietary Guidelines for Americans*, and development of the *Ten Essential Services of Public Health*. At RWJF, he founded the *Health & Society Scholars* program, the *Young Epidemiology Scholars* program, and the *Active Living* family of programs. Early in his career he served in India as epidemiologist and State Director for the World Health Organization's Smallpox Eradication Program. Widely published, he has made foundational contributions to understanding the basic determinants of health (e.g. "Actual Causes of Death", *JAMA* 270:18 [1993] and "The Case for More Active Policy Attention to Health Promotion", *Health Affairs* 21:2 [2002]). National leadership awards include the Arthur Flemming Award, the Distinguished Service Award for public health leadership, the Health Leader of the Year Award, and the Public Health Hero Award. He has held visiting or adjunct professorships at George Washington, UCLA, Princeton, and Duke Universities. He is a graduate of the University of California at Berkeley, the UCLA School of Medicine, and the John F. Kennedy School of Government at Harvard University, and was the graduating commencement speaker at each.

Elizabeth A. McGlynn, PhD, is the Director of Kaiser Permanente's Center for Effectiveness and Safety Research (CESR). She is responsible for the strategic direction and scientific oversight of CESR, a

virtual center designed to improve the health and well-being of Kaiser's 9 million members and the public by conducting comparative effectiveness and safety research and implementing findings in policy and practice. She is the Principal Investigator for the Kaiser Permanente-led clinical data research network, PORTAL, an infrastructure development contract that is part of PCORnet, funded by PCORI. Dr. McGlynn is an internationally known expert on methods for evaluating the appropriateness, quality and efficiency of health care delivery. She has conducted research in the U.S. and in other countries. Dr. McGlynn has also led major initiatives to evaluate health reform options under consideration at the federal and state levels. She received AcademyHealth's Distinguished Investigator Award in 2012. Dr. McGlynn is a member of the Institute of Medicine. She is vice-chair of the American Board of Internal Medicine Foundation Board of Trustees. She is on the Board of AcademyHealth (former chair), the Institute of Medicine Board of Health Care Services, and the Reagan-Udall Foundation for the FDA. She chairs the Scientific Advisory Group for the Institute for Healthcare Improvement. She co-chairs the Coordinating Committee for the National Quality Forum's Measures Application Partnership. She serves on the editorial boards for Health Services Research and The Milbank Quarterly and is a regular reviewer for many leading journals. Dr. McGlynn received her B.A. in international political economy from The Colorado College, her MPP from the University of Michigan's Gerald R. Ford School of Public Policy, and her Ph.D. in public policy analysis from the Pardee RAND Graduate School.

Randall L. O'Donnell, PhD, president and chief executive officer of Children's Mercy Hospitals and Clinics in Kansas City, Missouri, brings over 30 years experience as a CEO in children's hospitals. He earned his bachelor's degree magna cum laude from California Lutheran College and his doctorate in hospital and health administration from the University of Iowa. Before coming to Kansas City in 1993, he spent 13 years as chief executive officer of Arkansas Children's Hospital in Little Rock and previously was associate administrator of The Children's Hospital of Buffalo, New York. Dr. O'Donnell is a national leader in the field of psychosocial services within pediatric health care and led the effort in Congress to obtain federal funding for children's teaching hospitals such as Children's Mercy. He is actively representing the needs of children in the health care reform debate in Washington, D.C. Dr. O'Donnell has been active for more than 30 years in children's hospital organizations nationally, including the Children's Hospital Association, and serves on many local and regional boards. He was one of the first chairmen of the Osmond Foundation Board (which operates the Children's Miracle Network, an international fund-raising organization for pediatric hospitals.) In addition to numerous presentations and publications, he has also authored a book entitled, *Nurturing Leadership*. He has volunteered for various organizations devoted to children's health care, which includes volunteer service in China, Russia, Romania, Cambodia, Jamaica and Ireland.

Lucila Ohno-Machado, MD, PhD, received her medical degree from the University of Sao Paulo and her doctoral degree in medical information sciences and computer science from Stanford. She is Associate Dean for Informatics and Technology, and the founding chief of the Division of Biomedical Informatics at UCSD, where she leads a group of faculty with diverse backgrounds in biomedicine, informatics, and computer science. Prior to her current position, she was faculty at Brigham and Women's Hospital, Harvard Medical School and at the MIT Division of Health Sciences and Technology. She is former director of a training program involving a consortium of biomedical informatics laboratories from Harvard, MIT, Tufts, and Boston University. Dr. Ohno-Machado is an elected fellow of the American Institute for Medical and Biological Engineering, the American College of Medical Informatics, the American Society for Clinical Investigation, and serves as editor-in-chief for the *Journal of the American Medical Informatics Association*.

C. Wright Pinson, MBA, MD, is the Deputy Vice-Chancellor for Health Affairs at Vanderbilt University Medical Center and serves as Chief Executive Officer of the Vanderbilt Health System. This includes 2,000 academic clinical physicians, 4 hospitals with 62,000 admissions/yr, 62,000 operations/yr,

100 outpatient clinics with 2 million visits/yr, and a budget of \$3.0 billion/yr. Recently, he helped organize and became Chairman of the Board of the Vanderbilt Health Affiliated Network, a system covering the state of Tennessee. Previously positions include Chief Medical Officer, Chief of Staff of the Vanderbilt Hospitals, H. William Scott Professor and Chairman of the Department of Surgery and Director of the Vanderbilt Transplant Center. Dr. Pinson attended Miami University and the University of Colorado, graduating with distinction in Physics. While an engineer for IBM, he completed a Master's in Business Administration. A 1980 graduate of the Vanderbilt University School of Medicine, he trained in general and transplant surgery and is boarded in surgery and in critical care. He now chairs the Board of Directors for the Governor's Foundation for the Health and Wellness of Tennessee.

Richard Platt, MD, MS, is Professor and Chair of the Harvard Medical School Department of Population Medicine, at the Harvard Pilgrim Health Care Institute. Dr. Platt is principal investigator of PCORI's PCORnet coordinating center, a newly established consortium of 29 networks that will use electronic health data to conduct comparative effectiveness research. He is also Principal Investigator of the FDA Mini-Sentinel program, which performs post-marketing safety surveillance using the electronic health data from over 125 million people. He co-leads the coordinating center of the NIH Health Care System Research Collaboratory and leads a CDC Prevention Epicenter. He co-chairs the CER Innovation Collaborative of the IOM Roundtable on Value and Science-Driven Healthcare, and is a member of the American Medical Colleges Advisory Panel on Research.

David R. Posch is Chief Executive Officer of Vanderbilt University Hospital and Clinics and Executive Director for the Vanderbilt Medical Group, overseeing the adult clinical enterprise. He also leads the clinical strategic planning office for the Vanderbilt University Medical Center. Vanderbilt is among the nation's premier institutions of academic medicine, and includes Vanderbilt University Hospital, Monroe Carell Jr. Children's Hospital, Vanderbilt Stallworth Rehabilitation Hospital, The Vanderbilt Clinic, Vanderbilt Health One Hundred Oaks, and affiliate hospitals, clinics and physician practices in more than 31 counties throughout Tennessee and Kentucky. Vanderbilt employs more than 20,000 people and is Tennessee's largest private employer. More than 2,500 faculty (MDs, PhDs) make up the 155 medical disciplines and sub-specialties offering more than 57,000 annual surgical procedures. Vanderbilt is also a National Center of Excellence for Heart, Trauma, Neurosurgery, Diabetes, Transplant, Children's Care, and many other disciplines. Mr. Posch joined Vanderbilt in July of 1999 in the capacity of Chief Operating Officer of the Vanderbilt Medical Group and Clinics, and became CEO in 2007. His role was expanded to include CEO for Vanderbilt University Hospital in October of 2011. Additionally, Mr. Posch serves as President for Vanderbilt Integrated Providers and is a member of the Board of Directors for several Vanderbilt subsidiary organizations to include joint venture companies for an inpatient rehabilitation hospital, imaging, and ambulatory surgery centers. He currently serves on the governing boards for both the Tennessee Hospital Association and the University Healthsystem Consortium. He formerly worked at Ochsner Clinic in New Orleans for 8 years, leading the group practice and serving on the board of the Ochsner Health Plan. Previously, Mr. Posch spent 16 years at Cleveland Clinic Foundation in a number of administrative and leadership roles. He is a past member of the Board of Directors for the American Medical Group Association (AMGA). He has served as Chairman of the Group Practice Improvement Network. Mr. Posch has a Bachelor's Degree in Psychology from Miami University of Ohio, and a Master of Science Degree in Organization Analysis and Development from Case Western Reserve University.

Fred D. Rachman, MD, received his Bachelor of Arts degree in Biology from Johns Hopkins University, Baltimore, Maryland, his Doctor of Medicine degree from Temple University, Philadelphia, Pennsylvania and completed his residency in Pediatrics at Albert Einstein Medical Center, Philadelphia, Pennsylvania. He is Board Certified in Pediatrics, and completed post graduate courses in Ethics, Economics and Health Care Management at Harvard University School of Public Health. Dr. Rachman

has almost 30 years experience in primary health care delivery and administration, and extensive experience in Community Health Center leadership. He is presently serving as Chief Executive Officer of the Alliance of Chicago Community Health Services, a HRSA funded Health Center Controlled Network which supports a centrally hosted electronic health record system shared by 32 Safety Net Health Centers and is one of 4 research nodes for community based patient centered outcomes research. He also serves as Co-Director of the Chicago Health Information Technology Regional Extension Center. Dr. Rachman is Attending Physician in Pediatrics at Children's Memorial Hospital and Northwestern Memorial Hospital and sees patients as a Pediatrician at Erie Family Health Center, a Community Health Center in Chicago. He serves on the Board of Directors of the Health Information Management Systems Society, and serves on the Illinois Health Information Exchange Advisory Committee. Dr. Rachman previously served as Medical Director at Howard Brown Health Center and Erie Family Health Centers, and was a field representative for the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) conducting accreditation surveys and providing field education.

Russell Rothman, MD, MPP, is an Associate Professor of Internal Medicine and Pediatrics at Vanderbilt, and serves as the Director of the Vanderbilt Center for Health Services Research and Chief of the Internal Medicine/Pediatrics Section. Dr. Rothman's current research focuses on improving care for adult and pediatric patients with diabetes, obesity and other chronic diseases. He has been funded by the NIH, American Diabetes Association, and other sources to examine the role of literacy and numeracy in patients with diabetes and obesity. He has been the Principal Investigator on over \$20 million in extramural funding and has authored over 90 manuscripts. He is currently the Principal Investigator on several NIH funded studies addressing literacy and health communication in obesity prevention and diabetes. He is also the Principal Investigator of the PCORI funded Mid-South Clinical Data Research Network which engages over 50 hospitals and 1,000's of ambulatory practices reaching patients across the nation. Dr. Rothman currently serves on the PCORI Health Disparities Advisory Board and the PCORnet Executive Steering Committee. He is also on the Board of Directors for the American Academy on Communication in Healthcare. Dr. Rothman has served as a reviewer on multiple NIH study sections, including the NIH Special Emphasis Panel on Health Literacy and has been a Pfizer Visiting Professor in Health Literacy at several academic institutions. As Director of the Vanderbilt Center for Health Services Research, Dr. Rothman oversees a Center that engages over 120 faculty across the University engaged in health services research, implementation science, behavioral research, health disparities research, quality improvement research and other areas aimed at improving health outcomes. Dr. Rothman also currently serves as Co-Director of the Vanderbilt Community Engaged Research Core of the Vanderbilt Institute of Clinical and Translational Research (VICTR), and the Associate Director of the Vanderbilt Center for Diabetes Translational Research.

Steven M. Safyer, MD, is President and Chief Executive Officer of Montefiore Health System. Montefiore is the University Hospital and academic medical center for Albert Einstein College of Medicine and an integrated academic health system serving the New York metropolitan region. An accomplished physician leader and highly respected healthcare executive, Dr. Safyer has been at Montefiore since 1982, previously serving as Senior Vice President and Chief Medical Officer. Throughout his career at Montefiore, Dr. Safyer has been a leader in advancing Montefiore's position as a preeminent, innovative and equitable healthcare system. He has been a strong advocate for delivering a single standard of excellence to all, regardless of social or economic circumstances. He began his career with a deep commitment to improving health care for the underserved and early on galvanized a city-wide effort to stem the burgeoning epidemics of HIV and TB that were taking the greatest toll on the poor. Dr. Safyer then assumed a more senior role at Montefiore and lead the expansion of Montefiore's ambulatory healthcare network and developed innovative business and clinical strategies to provide care management under prepayment arrangements. He championed the early adoption of physician order entry clinical information systems and created nationally recognized quality and safety programs. In his

position as President and CEO, he has strengthened Montefiore's partnership with Einstein, the results of which have included exceptional research and treatment being provided through the creation of Montefiore's notable Centers of Excellence in the areas of heart, transplant, cancer, child health, neurosciences and others. Dr. Safyer received his Bachelor of Science degree from Cornell University and his medical degree from Albert Einstein College of Medicine. He completed his internship and residency in Social Medicine at Montefiore. He is board certified in Internal Medicine and a Professor of Medicine in the Department of Medicine and Professor of Epidemiology and Population Health in the Department of Epidemiology and Population Health at Einstein. He is a fellow of the New York Academy of Medicine, founding member of The Health Management Academy and a member of the Healthcare Institute. Dr. Safyer currently serves as Chair of the League of Voluntary Hospitals and Homes and the immediate past chairman of the Board of Governors for the Greater New York Hospital Association (GNYHA). He is a board member of the Hospital Association of New York State (HANYS); Association of American Medical Colleges' Council of Teaching Hospitals (COTH) Administrative Board; Josiah Macy Jr. Foundation; New York eHealth Collaborative (NYcE); Coalition to protect America's Health Care; and University HealthSystem Consortium (UHC). He is an active participant on committees for organizations such as the Association of American Medical Colleges; New York State Council on Graduate Medical Education; Medicaid Redesign Team; and Chase Regional Advisory Board. He was the previous founder and Chair of the Bronx Regional Health Information Organization, an independent organization for health information sharing. A frequent lecturer on topics including the history of healthcare reform, healthcare transformation and academic medical centers, population-based medicine and public health, Dr. Safyer has authored and co-authored numerous articles in peer-reviewed journals, covering subjects ranging from electronic medical records to managing the health of a population, to the emergence of tuberculosis in correctional settings.

Abby Sears, Chief Executive Officer, is responsible for the overall strategy and executive leadership at OCHIN. Abby has been with OCHIN since its inception and has helped grow the organization into a national company focused on building a learning company. A prominent national speaker and HIT advisor with over 15 years of healthcare expertise, she is focused on building a premier information and technology network leveraging Health IT products, services, and the use of practice-based research to help community practices nationwide achieve federal and industry standards for healthcare delivery, quality, cost control. She holds a MBA with a focus on Finance, and a MHA, both from the University of Minnesota.

Jonathan Silverstein, MD, MS, FACS, FACMI, is Vice President and Davis Family Chair of Informatics at NorthShore and heads the Center for Biomedical Research Informatics (CBRI), whose mission is to preserve and improve human life through innovative collection and use of biomedical data. CBRI builds upon NorthShore's award-winning Electronic Medical Record (EMR) and extensive data warehouse to be a nationally recognized leader in informatics for healthcare and research. Dr. Silverstein joined NorthShore in 2011 after serving as the associate director of the Computation Institute at the University of Chicago and Argonne National Laboratory. He is internationally known for his expertise, and federally funded research, in the application of advanced computing architectures to biomedicine; and on the design, implementation and evaluation of high-performance collaboration and visualization environments for anatomic education and surgery. Dr. Silverstein is recognized as one of three founding scientific directors of the Chicago Biomedical Consortium. He was an attending general surgeon for seven years while he was a lead physician informatician for enterprise EMR deployments at the University of Chicago and the University of Illinois at Chicago. Dr. Silverstein earned his medical degree from Washington University in St. Louis and his Master of Science from the Harvard School of Public Health. Additionally, he is a Fellow of the American College of Surgeons and a Fellow of the American College of Medical Informatics.

Jean R. Slutsky, PA, MSPH, is the Chief Engagement and Dissemination Officer at the Patient-Centered Outcomes Research Institute (PCORI). She leads PCORI's Engagement Program and growing dissemination and implementation planning efforts. She also serves as Director of PCORI's Communication and Dissemination Research Program. Before joining PCORI, Slutsky directed the Center for Outcomes and Evidence at the Agency for Healthcare Research and Quality, where she conceived and implemented the Effective Health Care program. The Effective Health Care program is an integrated program of research, stakeholder engagement, research training, and dissemination and implementation of comparative effectiveness research. Slutsky is particularly interested in pragmatic user-driven research and its implementation into healthcare decision making. Slutsky received her baccalaureate degree from the University of Iowa, trained as a Physician Assistant at the University of Southern California, and received a MSPH in health policy from the University of North Carolina at Chapel Hill.

Glenn D. Steele Jr., MD, PhD, is President and Chief Executive Officer of Geisinger Health System, an integrated health services organization in central and northeastern Pennsylvania nationally recognized for its innovative use of the electronic health record and the development and implementation of innovative care models. Dr. Steele previously served as the dean of the Biological Sciences Division and the Pritzker School of Medicine and vice president for medical affairs at the University of Chicago, as well as the Richard T. Crane Professor in the Department of Surgery. Prior to that, he was the William V. McDermott Professor of Surgery at Harvard Medical School, president and chief executive officer of Deaconess Professional Practice Group, Boston, Mass., and chairman of the department of surgery at New England Deaconess Hospital (Boston, Mass.). Dr. Steele is past Chairman of the American Board of Surgery. His investigations have focused on the cell biology of gastrointestinal cancer and pre-cancer and most recently on innovations in healthcare delivery and financing. A prolific writer, he is the author or co-author of more than 483 scientific and professional articles. Dr. Steele received his bachelor's degree in history and literature from Harvard University and his medical degree from New York University School of Medicine. He completed his internship and residency in surgery at the University of Colorado, where he was also a fellow of the American Cancer Society. He earned his Ph.D. in microbiology at Lund University in Sweden. A member of the Institute of Medicine of the National Academy of Sciences, Dr. Steele serves as a member on the Roundtable on Value and Science-driven Healthcare, was recently appointed to the Committee on the Governance and Financing of Graduate Medical Education and previously served on the Committee on Reviewing Evidence to Identify Highly Effective Clinical Services (HECS). A fellow of the American College of Surgeons, Dr. Steele is a member of the American Surgical Association, the American Society of Clinical Oncology, and past president of the Society of Surgical Oncology. Dr. Steele also serves on the following boards and national committees: Agency for Integrated Care (AIC) Singapore, Bucknell University Board of Trustees, Cepheid Board of Directors, Congressional Budget Office Panel of Health Advisers, Harvard Medical Faculty Physicians Board at Beth Israel Deaconess Medical Center, Weis Markets Inc., Wellcare Health Plans Inc., xG Health Solutions Board of Directors, Healthcare Innovation Program (HIP) External Advisory Board (Emory University), the Peterson Center on Healthcare Advisory Board, Institute for Healthcare Optimization Advisory Board, Third Rock Ventures Business Advisory Board, the State Health Care Cost Containment Commission, and Healthcare Executives Network. Dr. Steele most recently served as Board Chairman for Premier Inc., former Trustee on the Temple University School of Medicine Board of Visitors. Dr. Steele currently serves as Honorary Chair of the Pennsylvania March of Dimes Prematurity Campaign. Former member on the Commonwealth Fund's Commission on a High Performance Health System, the National Committee for Quality Assurance's (NCQA) Committee on Performance Measurement, American Hospital Association (AHA) Board of Trustees, and also served on the Executive Committee, Systems Governing Council, Long-Range Policy, Committee on Research, and the AHA Physician Leadership Forum Advisory Committee. Dr. Steele is the recipient of several awards, including the CEO IT Achievement Award (2006); AHA's Grassroots

Champion Award (2007); 8th Annual (2010) AHA Health Research & Education Trust Award and HFMA Board of Directors' Award (2011). He has been named consecutive times to Modern Healthcare's 50.

Paul S. Viviano is chief executive officer (CEO) for UC San Diego Health System and associate vice chancellor for UC San Diego Health Sciences. Mr. Viviano brings to UC San Diego Health System a record of exceptional leadership and strategic vision with a community hospital system, an academic health center and in medical business providing health care services nationally. He was most recently Chairman of the Board and CEO of Alliance HealthCare Services — the nation's largest provider of advanced outpatient diagnostic imaging services and a national leader of radiation oncology services, serving more than 1,300 hospitals. His prior positions include president and CEO of USC University Hospital and USC/Norris Cancer Hospital, a private research and teaching hospital staffed by faculty from the Keck School of Medicine at the University of Southern California. USC/Norris is an National Institute of Health-designated comprehensive cancer center. Prior to his work at USC, Mr. Viviano served in various positions, including as executive vice president and CEO of the St. Joseph Health System in Orange, California, comprised of 14 acute hospitals, six medical practice foundations, three home-health agencies and multiple ambulatory clinics. From 1985 to 1987, he was president and CEO of the 300-bed nonprofit acute care facility, Long Beach Community Hospital, and from 1980 to 1985, served as CEO of Los Alamitos Medical Center. A Los Angeles native and University of California alumnus, Mr. Viviano earned his bachelor's degree from UC Santa Barbara and master's degree in public administration-public health at UCLA. He is a member of the Board of Trustees at Loyola Marymount University, where he also serves as chair of the governance committee, a member of the finance committee and chair of the Bioethics Institute. He is also a member and former chairman of the National Association for Quality Imaging, and will continue to serve as a member of the Board of Directors for Alliance HealthCare Services.

Russ Waitman, PhD, is an Associate Professor of Internal Medicine, Director of Medical Informatics, and Assistant Vice Chancellor for Enterprise Analytics at the University of Kansas Medical Center. Dr. Waitman received his B.S. from Washington University in Electrical Engineering. Upon graduation, he served in the United States Air Force as a Medical Service Corps officer and received training in Health Services Administration and Clinical Engineering. Subsequently he received his M.S. and Ph.D in Biomedical Engineering from Vanderbilt University and conducted research applying neural networks, rule induction, and knowledge discovery methods to critical care and perioperative environments. In 2002, Dr. Waitman took a faculty position with the newly formed Department of Biomedical Informatics in the Vanderbilt University School of Medicine and led their Computerized Provider Order Entry project, "WizOrder". During this time, the team expanded WizOrder's advanced decision support capabilities to meet the clinical needs of the Pediatric and Neonatal ICUs, the Emergency Department, the Psychiatric Hospital, and developed applications for enterprise-wide medication reconciliation and real-time adverse drug event surveillance. He furthered Vanderbilt's commercialization initiative with McKesson Corporation by leading the effort to successfully merge the project with its commercial offspring, Horizon Expert Orders, and also oversaw deployment of other McKesson inpatient clinical systems for nurse documentation (Horizon Expert Documentation) and bar-code medication administration (AdminRx). Since arriving at the University of Kansas Medical Center in 2010, he has worked with colleagues across the schools and campuses to establish a strategy for clinical and translation research informatics for Frontiers, the Kansas and Kansas City NIH Clinical and Translational Science Award. A key component was working with the University of Kansas Physicians and the University of Kansas Hospital to establish a master data sharing agreement and oversight process so they could jointly create an integrated data repository, HERON, based on the NIH funded i2b2 platform. This led to KUMC as the leading institution for the PCORNet Greater Plains Collaborative Clinical Data Research Network. His research interests are clinical decision support,

knowledge discovery, and creating information environments to support personal health, research and patient safety.

Kate Walsh became the president and CEO of Boston Medical Center (BMC) on March 1, 2010. BMC is a private, not-for-profit, 496 bed, academic medical center with a community-based focus. The primary teaching affiliate of Boston University School of Medicine, Boston Medical Center has approximately 4,500 employees, 1,200 physicians and an annual operating budget of roughly \$1.0 billion. BMC is a founder of Boston HealthNet, a network affiliation of the Medical Center, Boston University School of Medicine and 14 community health centers. Boston HealthNet is an integrated health care delivery system whose partners provide outreach, prevention, primary care, specialty care and dental services at sites throughout Boston's neighborhoods and Quincy. In addition to the Medical Center and its affiliated community health centers, BMC owns and operates the BMC HealthNet Plan, a statewide Medicaid Managed Care Organization with more than 280,000 members across the Commonwealth. Prior to her appointment at Boston Medical Center, Ms. Walsh served as executive vice president and chief operating officer of Brigham and Women's Hospital for five years. She served previously as the chief operating officer for Novartis Institutes for Biomedical Research. Ms. Walsh began her career in health care as a summer intern at Brookside Health Center in the Boston neighborhood of Jamaica Plain. Upon finishing graduate school, she held positions in a number of New York City hospitals including Montefiore, Columbia Presbyterian Medical Center, Saint Luke's – Roosevelt Hospital Center and the New York City Health and Hospitals Corporation. She relocated to Boston and joined Massachusetts General Hospital (MGH) as an assistant general director in medical services and was promoted to vice president of medical services and primary care and then to senior vice president of medical services and the MGH Cancer Center. Ms. Walsh received her bachelor's of arts degree and a master's degree in public health from Yale University. She is a member of the Boards of Trustees of Emmanuel College, the YMCA of Greater Boston, the Boston Public Health Commission, the Massachusetts Hospital Association, the Council of Teaching Hospitals, and the Dean's council of the Yale University School of Medicine. She is also a member of the Advisory Board of the National Institutes of Health Clinical Center, the Health Care Institute and the Boston Green Ribbon Commission.

John Warner, MD, MBA, is Chief Executive Officer of UT Southwestern University Hospitals and Clinics and a Professor of Internal Medicine in the Division of Cardiology. Dr. Warner holds the Jim and Norma Smith Distinguished Chair for Interventional Cardiology; the Audre and Bernard Rapoport Chair in Cardiovascular Research; and the Nancy and Jeremy Halbreich, Susan and Theodore Strauss Professorship in Cardiology. Dr. Warner received his medical degree from Vanderbilt University and his M.B.A. from the Physician Executive Program at the University of Tennessee. He completed residency training in Internal Medicine at UT Southwestern, where he served as Chief Resident. He completed fellowship training in Cardiovascular Disease and Interventional Cardiology at Duke University Medical Center, and was a member of the Duke Cardiology faculty from 2000-2002. Since joining the UT Southwestern faculty in 2003, Dr. Warner has served in many clinical and administrative leadership roles, including Chief of Staff for UT Southwestern University Hospitals, Director of the Cardiac Catheterization Laboratories and Director of the Cardiology Fellowship Training Program. Prior to being named as the Chief Executive Officer of UT Southwestern University Hospitals in 2012, he served as Medical Director of the Doris and Harry W. Bass Jr. Clinical Center for Heart, Lung and Vascular Disease and Assistant Vice President for Hospital Planning. Dr. Warner is a Fellow of the American College of Cardiology and is currently a member of the National Board of Directors of the American Heart Association, where he chairs the Advocacy Committee. He is past President of both the Dallas Division and the Southwest Affiliate of the American Heart Association.

Clayton Williams currently serves as Principal for River Group Health Solutions, and as Chief Executive Officer for the Partnership for Advancing Total Health (PATH), a supporting organization of

the Louisiana Public Health Institute, in New Orleans. In 2012-2013, Mr. Williams served as the Senior Director / Global Affairs Principal for Ascension Hospital System in St. Louis, MO. From 2010 to 2011, he served as the Assistant Secretary for the Office of Public Health within Louisiana's Department of Health and Hospitals as a gubernatorial appointee. The Louisiana Office of Public Health (OPH) is the state's principal agency concerned with the protection and promotion health of the population as a whole. From 2001-2009 Mr. Williams served as director of the Health Systems Development Division at the Louisiana Public Health Institute (LPHI) and had responsibility for leading a wide variety of local and state public health programs. Mr. Williams was received NCQA's National Health Care Quality Award for LPHI's contributions towards building sustainable, high quality primary care network in the New Orleans area post-hurricane Katrina by effectively administering a \$100 million grant from the CMS to transform the region's healthcare delivery system. Mr. Williams holds a bachelors degree from Northwestern University in Evanston, Illinois; a master of public health in International Health and Development from Tulane University; completed a post-graduate research fellowship at the US Centers for Disease Control and Prevention; and is a graduate of the National Public Health Leadership Institute.

Jonathan Woodson, MD, is the Assistant Secretary of Defense for Health Affairs. In this role, he administers the more than \$50 billion Military Health System (MHS) budget and serves as principal advisor to the Secretary of Defense for health issues. The MHS comprises over 133,000 military and civilian doctors, nurses, medical educators, researchers, healthcare providers, allied health professionals, and health administration personnel worldwide, providing our nation with an unequalled integrated healthcare delivery, expeditionary medical, educational, and research capability. Dr. Woodson ensures the effective execution of the Department of Defense (DoD) medical mission. He oversees the development of medical policies, analyses, and recommendations to the Secretary of Defense and the Undersecretary for Personnel and Readiness, and issues guidance to DoD components on medical matters. He also serves as the principal advisor to the Undersecretary for Personnel and Readiness on matters of chemical, biological, radiological, and nuclear (CBRN) medical defense programs and deployment matters pertaining to force health. Dr. Woodson co-chairs the Armed Services Biomedical Research Evaluation and Management Committee, which facilitates oversight of DoD biomedical research. In addition, Dr. Woodson exercises authority, direction, and control over the Defense Health Agency (DHA); the Uniformed Services University of the Health Sciences (USUHS); the Armed Forces Radiobiology Research Institute (AFRRI); the Defense Center of Excellence for Psychological Health and Traumatic Brain Injury (DCoE); the Armed Forces Institute of Pathology; and the Armed Services Blood Program Office. Prior to his appointment by President Obama, Dr. Woodson served as Associate Dean for Diversity and Multicultural Affairs and Professor of Surgery at the Boston University School of Medicine (BUSM), and senior attending vascular surgeon at Boston Medical Center (BMC). Dr. Woodson holds the rank of brigadier general in the U.S. Army Reserve, and served as Assistant Surgeon General for Reserve Affairs, Force Structure and Mobilization in the Office of the Surgeon General, and as Deputy Commander of the Army Reserve Medical Command. Dr. Woodson is a graduate of the City College of New York and the New York University School of Medicine. He received his postgraduate medical education at the Massachusetts General Hospital, Harvard Medical School and completed residency training in internal medicine, and general and vascular surgery. He is board certified in internal medicine, general surgery, vascular surgery and critical care surgery. He also holds a Master's Degree in Strategic Studies (concentration in strategic leadership) from the U.S. Army War College. In 1992, he was awarded a research fellowship at the Association of American Medical Colleges Health Services Research Institute. He has authored/coauthored a number of publications and book chapters on vascular trauma and outcomes in vascular limb salvage surgery. His prior military assignments include deployments to Saudi Arabia (Operation Desert Storm), Kosovo, Operation Enduring Freedom and Operation Iraqi Freedom. He has also served as a Senior Medical Officer with the National Disaster Management System, where he responded to the September 11th attack in New York City. Dr. Woodson's military awards and decorations include the Legion of Merit, the Bronze Star Medal, and the Meritorious Service

Medal (with oak leaf cluster). In 2007, he was named one of the top Vascular Surgeons in Boston and in 2008 was listed as one of the Top Surgeons in the U.S. He is the recipient of the 2009 Gold Humanism in Medicine Award from the Association of American Medical Colleges.

**HEALTH SYSTEM LEADERS WORKING TOWARDS
HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH:
OPPORTUNITIES FOR EXECUTIVE ENGAGEMENT**

Workshop Logistics

**The National Academy of Sciences
2101 Constitution Avenue, NW | Washington, DC
The Lecture Room
June 20, 2014**

The Roundtable on Value & Science-Driven Health Care is looking forward to your participation on June 20. If you have any questions regarding workshop logistics, please contact Liz Johnston at ejohnston@nas.edu or 202-334-2265.

MEETING LOCATION

The workshop will begin at **8:30am** and will end at **4:00pm on June 20** in the Lecture Room of the National Academy of Sciences building at 2101 Constitution Avenue NW in Washington, DC. Breakfast will be served on site beginning at **8:00am** on June 20, with the agenda commencing at 8:30am. While *the agenda for this meeting has not been finalized*, these times provide an accurate estimation for travel planning purposes.

LODGING

Suggested nearby hotels include:

- State Plaza Hotel / 2117 E Street, NW / 202-861-8200 (7 min walk)**
- Hotel Lombardy / 2019 Pennsylvania Avenue, NW / 202-828-2600 (12 min walk)**
- One Washington Circle Hotel / 1 Washington Circle, NW / 800-424-9671 (16 min walk)**
- The Willard Intercontinental / 1455 Pennsylvania Avenue NW / 202-628-9100 (4 min drive)**
- The Fairfax at Embassy Row / 2100 Massachusetts Ave NW / 202-293-2100 (5 min drive)**

DIRECTIONS AND GROUND TRANSPORTATION

Airports: The meeting site is approximately 5 miles from Washington National Airport (a 20-minute cab ride depending on the time of day) and approximately 25 miles from Dulles International Airport (a 45-minute cab ride).

Metro: The Foggy Bottom metro stop (Orange/Blue Line) is located at 23rd and I Streets NW. Walking from the metro to the NAS building takes approximately 12 minutes. The *C Street Entrance* to the NAS building is the closest entrance to Metro.

Parking: The parking lot for the National Academy of Sciences is located on 21st Street NW, between Constitution Avenue and C Street. However, space is very limited, so you may want to use an alternate mode of transportation. If the lot is full, there is a Colonial Parking garage near G and 18th Streets, NW (cash only). It is about 15 minutes walking distance from the NAS building.

Detailed driving and Metro directions to the National Academy of Sciences may be found at:
<http://www.nationalacademies.org/about/contact/nas.html>