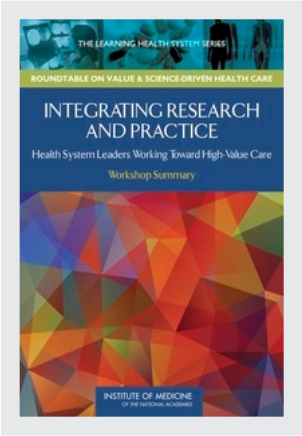

Integrating Research and Practice: Health System Leaders Working Toward High-Value Care: Workshop Summary

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INTEGRATING RESEARCH AND PRACTICE

Health System Leaders Working Toward High-Value Care

Workshop Summary

Joe Alper and Claudia Grossmann, *Rapporteurs*

Roundtable on Value & Science-Driven Health Care

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"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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Institute of Medicine
Roundtable on Value & Science-Driven Health Care
Charter and Vision Statement

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, 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information and will reflect the best available evidence. We believe 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 that 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 health care 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 Institute of Medicine 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 the 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 policy makers alike—will be grounded in 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 the medical care delivered; building constant measurement into our health care investments; the establishment of health care 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.

Reviewers

This workshop summary has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published workshop summary as sound as possible and to ensure that the workshop summary meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this workshop summary:

Robert M. Califf, Duke University Medical Center
Rainu Kaushal, Weill Cornell Medical College
Michael Johns, University of Michigan Health System

Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the workshop summary before its release. The review of this workshop summary was overseen by **Stephen Shortell,** University of California, Berkeley, School of Public Health. Appointed by the Institute of Medicine, he was responsible for making certain that an independent examination of this workshop summary was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this workshop summary rests entirely with the rapporteurs and the institution.

Contents

Acronyms and Abbreviations

ABIM	American Board of Internal Medicine
ACO	accountable care organization
AHRQ	Agency for Healthcare Research and Quality
CDC	Centers for Disease Control and Prevention
CDRN	clinical data research network
CEO	chief executive officer
CER	comparative effectiveness research
CMS	Centers for Medicare & Medicaid Services
EHR	electronic health record
FDA	U.S. Food and Drug Administration
GHRI	Group Health Research Institute
HCA	Hospital Corporation of America
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
ICU	intensive care unit
IOM	Institute of Medicine
IRB	institutional review board
MRSA	methicillin-resistant *Staphylococcus aureus*

NIH	National Institutes of Health
OHRP	Office for Human Research Protections
ONC	Office of the National Coordinator for Health Information Technology
PCMH	patient-centered medical home
PCORI	Patient-Centered Outcomes Research Institute
PCORnet	National Patient-Centered Clinical Research Network
PORTAL	Patient Outcomes Research to Advance Learning
PPRN	patient-powered research network
RCT	randomized controlled trial
REDUCE	Randomized Evaluation of Decolonization vs. Universal Clearance to Eliminate
UCSF	University of California, San Francisco
VA	U.S. Department of Veterans Affairs
VHA	Veterans Health Administration

1

Introduction and Overview[1]

Health care has been called one of the most complex sectors of the U.S. economy. Driven largely by robust innovation in treatments and interventions, this complexity has created an increased need for evidence about what works best for whom in order to inform decisions that lead to safe, efficient, effective, and affordable care. At the same time, traditional approaches to clinical research are straining to keep pace with these demands. Calls for approaches that draw from and better inform real-world practice, that leverage the increasingly available vast amounts of digital health data, and that are more cost-effective have been on the rise. These approaches are at the foundation of a learning health system, one that continuously and seamlessly generates knowledge from the practice of health care to answer important questions that matter to patients, their health care providers, and stakeholders system-wide.

As health care becomes more digital, clinical datasets are becoming larger and more numerous. These data, many of them gathered through the normal course of health care, offer great potential for extracting useful knowledge to achieve the "triple aim"—improved care, better health for populations, and reduced health care costs. In a continuously learning health system, data from sources such as electronic health record (EHR)

[1] The planning committee's role was limited to planning the workshop, and the workshop summary has been prepared by the workshop rapporteurs as a factual summary of what occurred at the workshop. Statements, recommendations, and opinions expressed are those of individual presenters and participants and are not necessarily endorsed or verified by the Institute of Medicine, and they should not be construed as reflecting any group consensus.

systems used to manage patient care, claims data necessary for billing purposes, and increasingly patient-generated sources of data such as patient portals, surveys, and online communities are used to inform questions of operations, to guide care, to further scientific understanding, and to power innovation. This approach differs from traditional approaches to clinical research, which are often removed from the clinical experience both in terms of the questions asked and the environment in which they are carried out, require large amounts of additional data collection, can take several years to complete, can be very expensive, and are often criticized for producing evidence that is not easily generalizable to broader populations or easily implementable in real-world settings.

By realizing the potential of knowledge generation that is more closely integrated with the practice of care, it should be possible not only to produce more usable evidence to inform decisions but also to increase the efficiency and decrease the costs of doing clinical research. Delivering on this promise will depend on certain technical capabilities, but, more important, ensuring the sustainability of this approach will require the delivery of value to stakeholders who are engaged in these processes. Among these stakeholders are the patients whose experiences are captured; clinicians who deliver care, collect routine information, and implement results; researchers who are experts at using routinely collected data to answer questions; and system leaders who allocate resources and set institutional priorities and culture.

All of these groups of critical stakeholders have potentially different value propositions for participating in or supporting practice-integrated knowledge generation. For health system leaders, the current trends of increasing complexity and paucity of the proper evidence to inform care coincide with heightened pressures to reduce unsustainable health care costs. Health delivery system leaders are facing shrinking operating margins and pressure to do more with less, while at the same time contending with the resource- and knowledge-intensive demands of moving to value-based reimbursement approaches that emphasize population management. Additionally, as is the case with clinicians and patients, system leaders are often faced with a lack of evidence on which to base their operational decisions. This can be the result of a misalignment of priorities among leaders, researchers, and funders or of differences in the timeliness requirements for results.

Digital health data are increasingly being used by organizations to manage patient populations, to fulfill reporting requirements, to carry out local quality improvement activities, to support externally funded research projects, and to share with other organizations in inter-organizational collaborations for quality improvement and research. What underlie all of these activities are robust informatics capabilities that are often designated for clinical, operational, or research purposes. However, in some cases the

infrastructure is common across activities and provides opportunities for greater efficiency and value in its use.

Although the effort to use clinical and patient-generated data to answer important research questions is still in its infancy, investigators have already demonstrated the potential for using routinely collected clinical information to detect and respond to disease outbreaks (Al-Samarrai et al., 2013), to target medical services to those who need them most (Stephens et al., 2014), to help patients and clinicians make better decisions (Ray et al., 2012), to avoid errors that can harm patients (Zhou et al., 2014), and to speed medical research (Borch et al., 2011). Many of these efforts are done locally within a single health system, but there have been a number of efforts to share information across systems in order to compare data for quality improvement purposes and benchmarking, such as the Minnesota Community Measurement initiative; for public health and drug safety surveillance, such as Mini-Sentinel; for the conduct of pragmatic clinical trials, such as the Health Systems Research Collaboratory of the National Institutes of Health (NIH); and, most recently, for the conduct of comparative effectiveness research (CER) through the National Patient-Centered Clinical Research Network, or PCORnet.

PCORnet (see Box 1-1) is a nationwide patient-centered clinical research network funded by the Patient-Centered Outcomes Research Institute (PCORI), which consists of clinical data research networks (CDRNs), each spanning at least two health care delivery systems, and patient-powered research networks (PPRNs), whose focus is the collection and use of patient-generated information. Together these networks are intended to form a resource of clinical, administrative, and patient data that can be used to carry out observational and interventional research studies and enhance the use of clinical data to advance the learning health care system. The primary goal of the first phase of PCORnet will be to establish the data infrastructure necessary to do such research. This includes getting to harmonized, comparable, and consistent data; working out privacy and security issues; and establishing the trust needed to work out data-sharing agreements across participants. In order to achieve this, the network has made robust stakeholder engagement a priority, including requiring the involvement of health system leadership in CDRN governance.

PCORnet symbolizes a new approach to clinical research, one that is integrated into the delivery of care and that leverages its experiences, rather than creating a set of parallel infrastructures and processes. Critical to the long-term sustainability of such a network of networks will be demonstrating its value to its many stakeholders. For health system leaders, such demonstrations may include building or improving their systems' data infrastructure to help with data-intensive functions such as reporting and identifying variation and areas for improvement; enabling health systems

BOX 1-1
PCORnet

To facilitate more efficient comparative-effectiveness research that could significantly increase the amount of information available to health care decision makers and also increase the speed at which this information is generated, the Patient-Centered Outcomes Research Institute (PCORI) has invested more than $100 million in the development of the National Patient-Centered Clinical Research Network (PCORnet).

PCORnet will be a large, highly representative national network of health care information networks that will be used to conduct large-scale clinical outcomes research by establishing a resource of clinical data gathered in real time and in real-world setting such as hospitals and 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. 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.

During an 18-month development phase, 29 health data networks—11 clinical data research networks (CDRNs) and 18 patient-powered research networks (PPRNs)—will work closely with a national coordinating center and other stakeholders to refine the capabilities and capacity of the individual constituent networks. By the end of this first phase PCORI expects that a fully functional research network will be in place and ready to support comparative-effectiveness research. PCORnet, even in its formative phase, is creating 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 and by working directly with patients and their advocates, PCORnet will be able to provide the answers that patients need quickly, efficiently, and at lower costs than previously possible.

(www.pcori.org)

to leverage their data to be more active partners in generating the evidence used by their providers and patients to inform care; and helping health systems better manage their populations toward higher-value care.

SCOPE AND OBJECTIVES OF THE WORKSHOPS

In April and June 2014 the Institute of Medicine's (IOM's) Roundtable on Value & Science-Driven Health Care convened two workshops aimed at accelerating progress toward real-time knowledge generation through the seamless integration of clinical practice and research, one of the funda-

BOX 1-2
Statement of Task

An ad hoc committee will plan two workshops to explore the engagement of health system leaders as active proponents of greater integration of research activities with clinical care processes and discuss specific insights for advancing a learning health care system through the work of the Patient-Centered Outcomes Research Institute's (PCORI's) National Patient-Centered Clinical Research Network (PCORnet). The first workshop will integrate issues, opportunities, and strategic options by bringing together health care system leaders, both administrative and clinical, and researchers, including those from PCORnet grantee institutions, the NIH Health Systems Research Collaboratory, and the Innovation Collaboratives of the IOM Roundtable on Value & Science-Driven Health Care. The workshop will consider issues and strategic priorities for building a successful and durable PCORnet and facilitating progress toward a continuously learning health care system more broadly, including issues related to science, technology, ethics, business, regulatory oversight, sustainability, and governance. A follow-on workshop focusing on implementation approaches will convene health system CEOs to consider strategic priorities and explore approaches to implementation. Discussions will inform the decisions of field leaders moving forward, including PCORI, the PCORnet steering committee, and PCORnet grantees (Phase 1 and 2). An individually authored workshop summary of the workshop series presentations and discussions will be prepared by a designated rapporteur in accordance with institutional guidelines.

mental concepts of a continuously learning health system, centered on the development of the PCORnet (see Box 1-2).

The first workshop brought together health care system leaders, both administrative and clinical, and researchers, including those from CDRN and PPRN grantees, the NIH Health Systems Research Collaboratory, and the IOM Innovation Collaboratives, to identify and consider the issues and strategic priorities for facilitating progress toward sustainably integrating PCORnet into a continuously learning health care system, including issues related to science, technology, ethics, business, regulatory oversight, sustainability, and governance. The goals of this workshop, developed by the planning committee, were

1. Broaden and deepen health systems' leadership awareness of the prospects for and from a continuously learning health system.
2. Foster the development of a shared commitment, vision, and strategy among health system leaders building a national clinical research network.

3. Identify common applications in meeting health systems' responsibilities for science, technology, ethics, regulatory oversight, business, and governance.
4. Consider and learn from models and examples of productive integration of research with care delivery programs.
5. Explore strategic opportunities for executive, clinical, and research leaders to forge working partnerships for progress.
6. Consider the approach and desirable outcomes of a meeting of chief executive officer (CEO) leadership in building, growing, and making full use of the infrastructure necessary.

The second workshop convened health system CEOs to consider strategic priorities and explore approaches to implementation that will inform the decisions of field leaders moving forward. The goals for the second workshop, developed by the planning committee, were

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 in 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.

A major premise that served as the foundation for the two workshops is that the continuous and seamless assessment of the effectiveness and efficiency of care is basic to a continuously learning and constantly improving health care system. Advancements in the digital infrastructure and the development of innovative methods for research and learning now make this aim achievable in health care, as it has already been achieved in many other sectors of the economy. PCORI and its Methodology Committee are committed to accelerating this progress, including prior work with the IOM in conducting a workshop exploring the role of observational studies in continuous learning (IOM, 2013). A foundational focus for PCORI's PCORnet (see Box 1-1) is developing a large, highly representative, nationally linked, and coordinated clinical research program with multiple

collaborating large-system networks to improve the nation's capacity to conduct comparative clinical-outcomes research. The issues are complex, including matters of ethics, governance, sustainability, and stakeholder engagement. PCORI is committed to active stakeholder engagement, and these two workshops were aimed, in particular, at informing and engaging health system leaders as essential partners in building the necessary and sustainable infrastructure to power a continuously learning health system. As Joe Selby, PCORI's executive director, said at the opening of the first workshop, "The entire premise of creating PCORnet is that it does make sense to engage health care systems, their clinicians, and their patients in a process of putting data together, standardizing it, and using it for quality improvement and clinical research."

In his introductory remarks to the first workshop, IOM president Harvey Fineberg said that his hope is that the domains of medical practice and medical research will be seen not as parallel, independent enterprises, but rather as tightly integrated efforts. "This is a way in which we can reduce the traditional distinction between research that shows what could work and research that demonstrates what does work in practice," Fineberg said. "If we can bring those more tightly together over time, I believe we have the opportunity not only to make faster progress, but to make the kind of progress in health care that really pays dividends immediately and over the long term for the health consequences of our population."

At the start of the second workshop, IOM president-elect Victor Dzau, who previously served as the CEO of the Duke University Health System, said that he believes that the health care system is now positioned to finally join other industries as an enterprise of continuous learning, but that this will not happen without the seamless integration of research and practice. He noted, too, that the main challenge that he faces as a health system CEO is to bring together learning and innovation that can disrupt the way things are done today and at the same time create standards for more effective and efficient health care.

A learning health system can create an ideal environment in which to take advantage of the advent of "big data" and to conduct the type of outcomes research that the health care system needs in order to become both more efficient and more effective. The challenge, Selby said, will be to develop a learning health care system that is sustainable so that the data infrastructure that PCORI is helping establish to enable large-scale outcomes research will not require continuous infusions of funds to maintain operations. Doing so will require establishing a business case, not only for the delivery system and for funders but also for patients and the clinicians who will populate the data infrastructure with their patients' data. Speaking about the business case for a learning health system, Selby said that there are many advantages for a health care system in supporting this kind of

research. "The experience of collaborating across institutions can bring a lot of value and insight, and the entire process can position delivery systems well for driving towards value-focused payments," he said.

THE ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

The 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. The Roundtable explores concerns that, despite the world's best care being available in the United States, 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, including clinicians, patients, health care institutions, employers, manufacturers, insurers, health information technology companies, 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.

The Roundtable's vision is that the nation will develop a continuously learning health system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation. In this continuously learning health system, best practices will be seamlessly embedded in the care process, patients and families will be active participants in all elements of the health system, and new knowledge will be captured as an integral byproduct of the care experience. This vision includes an "afferent" arm of data collection, analysis and learning, as well as an "efferent" arm of dissemination and implementation of learning and best practices. The Roundtable's goal is to promote collective action and progress so that by the year 2020, 90 percent of clinical decisions will reflect the best available evidence. The Roundtable aims to meet this goal through stakeholder workshops and meetings designed to accelerate understanding and progress toward the vision of a continuously learning health system and through joint projects conducted by affinity-group Innovation Collaboratives focused on best clinical practices, clinical effectiveness research, the communication of medical evidence, digital technology for health, incentives for value in health care, and systems engineering for health improvement.

ORGANIZATION OF THE SUMMARY

This publication summarizes the presentations and discussions that occurred during the two workshops (see Appendix A for the agendas), highlighting the key lessons presented, practical strategies, and the needs and opportunities for future leadership. The perspectives included in this summary reflect the experience of the workshop attendees, who included a preponderance of system leaders committed to developing learning systems in their organizations. Their perspectives may not represent other stakeholder groups or of all system leaders. Chapter 2 offers examples of organizations that are on the leading edge of integrating care delivery and research in a way that leads to greater efficiency, better value, and improved health care. Chapter 3 provides a brief introduction to the vision for a continuously learning health system, including a description of the value proposition for various constituencies, and Chapter 4 explores the business and financial issues and opportunities that arise as organizations move toward continuous learning and improvement. Chapter 5 looks at the challenges and opportunities surrounding the legal and ethical oversight of integrating care and research opportunities, and Chapter 6 focuses on issues of institutional governance of continuous learning activities. Chapter 7 discusses the challenges and opportunities that come with efforts to engage clinicians, patients, families, and the public in integrating care and research efforts. Chapter 8 identifies and prioritizes the key issues for health systems leadership in moving toward greater integration of care and knowledge-generating activities. Chapter 9 discusses infrastructure needs for a continuous learning health system and how that infrastructure can have several uses within an organization's operations, and Chapter 10 explores how continuous learning can become an executive agenda priority. Chapter 11 provides a summary of key points made by speakers from the two workshops.

2

Continuous Learning and Improvement in Health Care

KEY SPEAKER POINTS

- Michael McGinnis noted that, when asked to reflect on their experiences, virtually all successful corporate CEOs in the country would speak to the centrality of continuous learning to their effectiveness and efficiency—even to their survival.
- "We are aware that among the needs that our systems have from research at this point are speed, relevance, precision, and methods that really fit the kinds of questions, decisions, and actions that are needed by us as delivery system leaders, as patients, and as clinicians," said Raymond Baxter.
- Baxter also noted that PCORnet's success will not only accelerate the pace of change, but it will also change the culture of research for the better by bringing patients, clinicians, and delivery system leaders into the research enterprise.
- Rainu Kaushal said that she applauds the foresight of large health care system CEOs who, despite the fragmentation and competitive pressures, see that sharing data is the right thing to do for their health systems, for clinical care, and for populations.
- Kaushal said, too, that there is a tension between research interests and organizational priorities and that she believes that the key to resolving those tensions rests with good communication and alignment of priorities.

As was noted in the previous chapter, the vision of the Roundtable on Value & Science-Driven Health Care—which is in line with the goals of PCORI—is that the nation will develop a continuously learning health system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation. In a session designed to serve as a backdrop for further discussion, Michael McGinnis, senior scholar at the IOM, provided a brief introduction to the concepts of a learning health system, and Joe Selby, PCORI's executive director, gave an overview of PCORnet. The workshop also heard presentations describing two of the CDRNs that are participating in PCORnet. Raymond Baxter, senior vice president for community benefit research and health policy at Kaiser Permanente, and Elizabeth McGlynn, director of Kaiser Permanente's Center for Effectiveness and Safety Research, spoke about the Patient Outcomes Research to Advance Learning (PORTAL) Network, while Rainu Kaushal, Chair of Healthcare Policy and Research at Weill Cornell Medical College, discussed the New York City Clinical Data Research Network (CDRN). Afterward Eric Larson, vice president for research at Group Health, executive director of the Group Health Research Institute, and the workshop planning committee chair, moderated an open discussion.

THE LEARNING HEALTH SYSTEM

To start his short overview of the IOM and work that has been done to date to conceptualize and advance a continuously learning health care system, McGinnis recounted a discussion that the workshop planning committee had had concerning whom it might ask to provide a perspective on how other sectors view a learning system in comparison with how the health care system operates today. He suggested, for example, that Jeff Bezos from Amazon might reflect on what his company's situation might be if it captured as little of its customers' experience—and of its own experience—as is often the case in health care. Or Mary Barra, the new CEO of General Motors, could have something to say about the importance in a competitive market of investing in an employee culture of continuous quality and the consequences when that does not happen. Michael Huerta, the administrator of the Federal Aviation Administration, could reflect on what airline safety might look like if the airline industry had the level of nonstandard work procedures in air safety that often exists in health care. William Dudley, CEO of the construction giant Bechtel, could comment on how well his company would operate if the plumbers, architects, carpenters, and electricians were all working from different blueprints. And Dee Hock, founder and former CEO of the Visa Credit Card Association, could reflect on the likely condition of the credit card industry if it suffered the same scale of electronic disconnect as currently exists in health care.

Virtually all successful corporate CEOs in the country, McGinnis said, would speak to the centrality of continuous learning to their effectiveness and efficiency—even to their survival. With this in mind, McGinnis said he would provide an overview of the possibilities and concepts for continuously learning health care and ask the workshop participants to imagine the kinds of changes that can occur in a truly transformed health system.

The perspectives that the above-mentioned CEOs might have provided were noted in the opening pages of the 2012 IOM report *Best Care at Lower Cost*: *The Path to Continuously Learning Health Care in America*, which, McGinnis said, "looked very carefully at the state of play with respect to quality, cost, science, technology, and culture in health care and said, in effect, we're well past the time when health care should be lagging so far behind the best practices in other sectors and even in our own sector." McGinnis added, "We can do much better in terms of delivering the efficiency and effectiveness that the American people deserve." According to McGinnis, the committee that authored the report was saying that the health care system needs to transition away from a linear system in which learning opportunities are substantively lost (see Figure 2-1) to one characterized by a continuous feedback loop in which science yields evidence that is then applied to care and that care experience is captured to generate new knowledge.

Today, however, McGinnis noted, the translation from evidence to care is often lacking with respect to the extent of its application, and the care experience itself is, for the most part, poorly captured, which limits the opportunity for feedback that could further inform and improve care. What the nation needs instead is to bring the practice and culture of science into the networked age and create a virtuous cycle of learning, one that

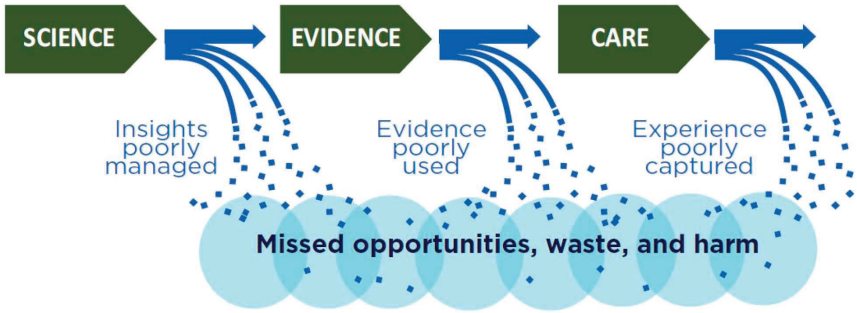

FIGURE 2-1 Learning opportunities are lost in today's linear system.
SOURCE: IOM, 2012.

aligns science, informatics, incentives, and culture to produce continuous improvement and innovation, and one that embeds best practices seamlessly into the delivery process and that captures new knowledge as an integral by-product of the delivery experience. McGinnis said that many of the workshop participants could testify to the value of creating such a system.

McGinnis also reminded the workshop participants that the *Best Care at Lower Cost* report had been revisiting the ground laid by two earlier IOM reports: *To Err Is Human: Building a Safer Health System* and *Crossing the Quality Chasm: A New Health System for the 21st Century*, which were issued in 1999 and 2001, respectively. The 2012 report, McGinnis said, provided an update on these two earlier reports in the context of the increasing complexity and cost of health care and also in the context of the new tools and levers that had become available for continuous quality improvement, through the provisions of the Health Information Technology for Economic and Clinical Health Act and the Affordable Care Act, as well as in the context of the overall increase in learning capacity stemming from advances in research methods and in the nation's digital infrastructure. The 2012 report called for ramping up real-world and real-time learning strategies that employ data science to engage both structured and spontaneous learning. The report noted that work that is patient participatory in nature is an untapped resource for the learning process. The goal should be to create a learning infrastructure that is research-ready, multiuse, focused on both quality and knowledge generation, and patient accessible.

McGinnis mentioned, too, that the context of the 2012 report also reflected the 15 reports that the Roundtable had developed over the previous 7 years. These reports explore various elements of the multiple issues involved in creating a continuously learning health care system, such as effectiveness research, the implications of the growing complexity of care, the value proposition, and the digital platform needed for a learning health system. McGinnis also noted the work that the IOM has done with the Office of the National Coordinator for Health Information Technology in laying out the vision for the digital platform for continuous learning in health and health care (see Figure 2-2).

McGinnis then noted several assumptions underlying the structure of the workshops. The first assumption was that the workshop participants did not need to be convinced about the value of a learning health care system; these are CEOs who are leading the field on behalf of continuous learning. The second assumption was that developing a learning health system is fundamentally not a technical problem. Yes, there are technical complexities, McGinnis acknowledged, but he said that experts in the software and hardware development arenas do not see these complexities as fundamentally impossible technical challenges. The third assumption was that culture need not be an obstacle, given that patients understand the

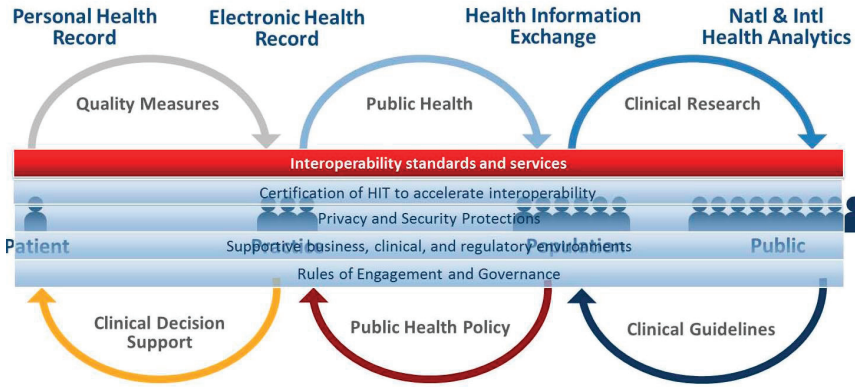

FIGURE 2-2 The Office of the National Coordinator's vision of a learning health system.
NOTE: HIT = health information technology.
SOURCE: Reprinted with permission from Douglas Fridsma.

value of research, that clinicians believe that knowledge generates pride, and that CEOs want a culture that creates value at speed and allows them to stay ahead of the curve. The fourth assumption was that this is not an economic problem at heart, given the sizable investment in health information technologies, which is estimated to be some $34.5 billion in 2014. The fifth and final assumption was that this is not a political problem: Democrats and Republicans agree on the importance of developing an evidence-based learning health care system. What this is, McGinnis said in closing, "is fundamentally a commons problem," or one in which the behavior of individual actors is contrary to the best interest of the group.

AN INTRODUCTION TO PCORNET

As a preamble to his remarks about PCORnet, Joe Selby commented that in his experience, sometimes randomized interventions are the only way to learn, with enough certainty to justify implementation, whether something works better than an alternative. However, he said there are concerns within the community of people working toward the development of a learning health care system that, on the one hand, many interesting questions concerning effectiveness are not amenable to randomization, and on the other hand, observational study designs are limited and can be biased. Additionally, there is also some concern that joining a network that includes multiple institutions or a network of networks such as PCORnet will retard

rather than accelerate local progress. In addressing those concerns, Selby said that networks such as the CDRNs and PCORnet will enable observational studies that "look for all the world like randomized trials," as well as drive innovation in the use of randomized approaches. One of the keys features of PCORnet, he said, is that consolidating data from multiple systems and multiple clinical units within those systems provides enough variation in practice to provide statistical power and rigor and to reduce the chances of bias. "So I would say one advantage of PCORnet as it matures could in fact be to have a broader range of variation in practice that could be studied," he said.

The prevailing view in Washington, Selby said, is that the nation's clinical research system is in trouble—that it is well-intentioned but flawed. According to this view, the current system is not generating the evidence needed to support most clinical decisions, there are health outcomes and disparities that are not by and large improving, and the current clinical research system is too slow and too expensive and it does not answer the questions that worry most patients, clinicians, and health system leaders. PCORnet envisions a "community of research" that addresses these concerns by uniting systems, patients, clinicians, and research in a national infrastructure for patient-centered clinical research. Toward that end, PCORnet has created a network of networks comprising 11 CDRNs, clinical data networks spanning at least two health systems, and 18 PPRNs, disease-specific networks focused on the collection and use of patient-generated data, that are distributed across all 50 states and the District of Columbia (see Figure 2-3). Selby said that he sees the patient-powered networks as "the really radical portion of PCORnet, those groups of activated patients who are charged to grow and to interact with the CDRNs."

The overall goal of PCORnet, Selby explained, is to achieve a single functional research network through the following actions:

- **Create** a secure national research resource that will enable teams of health researchers, patients, and their partners to work together on studying questions of shared interest.
- **Utilize** multiple rich data sources, such as EHRs, insurance claims data, and data reported directly by patients, to support research.
- **Engage** patients, clinicians, and health system leaders throughout the research cycle from idea generation to implementation.
- **Support** observational and interventional research studies that compare how well different treatment options work for different people.
- **Enhance** the use of clinical data to advance the learning health care system.

- **Enable** external partners to collaborate with PCORI-funded networks.
- **Sustain** PCORnet resources for a range of research activities supported by PCORI and other sponsors.

A steering committee consisting of a representative of each of the CDRNs and PPRNs along with patient advocates and representatives of medical product and device manufacturers, various agencies in the U.S. Department of Health and Human Services, and PCORI oversees a coordinating center that manages 11 task forces, each of which in turn oversees a mission-critical activity (see Figure 2-4). PCORnet, Selby said, needs to phase in those 11 activities over the 15 months remaining in Phase 1 of this initiative. He said, too, that agencies such as the NIH, the U.S. Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), and the Centers for Disease Control and Prevention (CDC) as well as the pharmaceutical and devices industries could prove to be interesting partners for and funders of future research. "This research would bring together delivery systems, payers, the research community, the

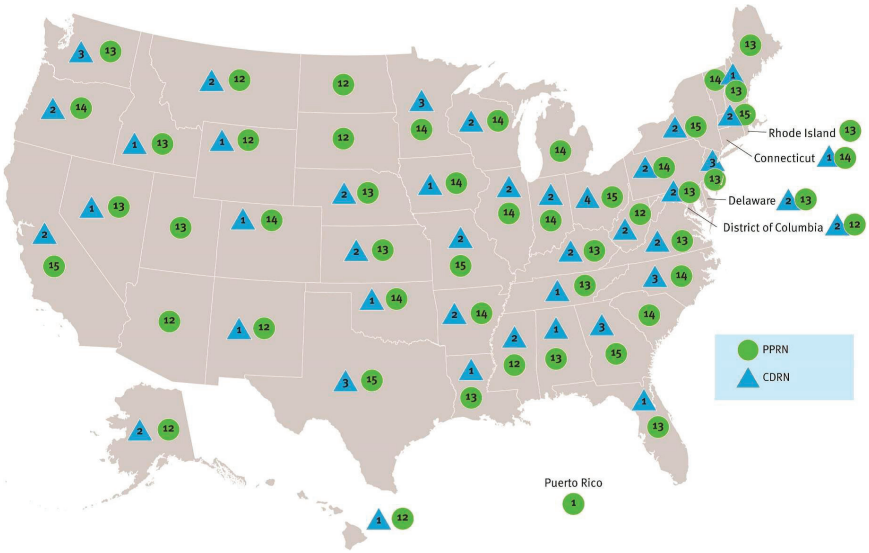

FIGURE 2-3 Geographic coverage of the PPRNs and CDRNs that have joined PCORnet.
SOURCE: Reprinted with permission from the Patient-Centered Outcomes Research Institute.

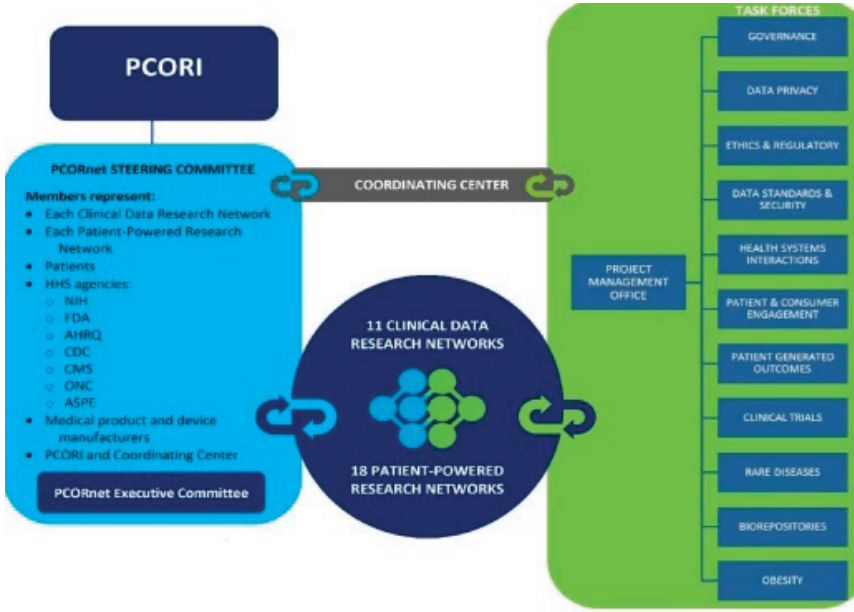

FIGURE 2-4 PCORnet's operational structure.
SOURCE: Reprinted with permission from the Patient-Centered Outcomes Research Institute.

sponsors of the research, and patients to fund research that is of interest to all groups," Selby said. "So we have a hope that we will find research being funded through PCORnet that brings these stakeholders in the enterprise together at the beginning, not at the end of the research," when someone may bring in a result that could upset the system.

In reviewing the activities of the 11 issue-focused task forces that form part of the PCORnet coordinating center, Selby explained that the governance task force is concerned with issues such as who owns the data collected by the members of the networks, who can use the data, who can access the data, what is required to be a member of PCORnet, and what the expectations are regarding members securing additional funding to support PCORnet activities. Privacy is a critical activity, as it could prove to be either PCORnet's Achilles' heel or, as Selby put it, "a real triumph if we are able to bring patients, patient organizations, and delivery systems together with ethicists to discuss the benefits and the potential risks of big data and using big data to address questions of importance to patients."

The ethics and regulatory oversight task force is looking at issues concerning informed consent and how to balance the concerns of institutional

review boards (IRBs) and the need to streamline and accelerate research. The data standards task force is not concerned with establishing a new set of standards but is looking at ways of encouraging electronic health record vendors to make greater and more consistent use of the nationally agreed-upon standards that already exist. The task force on health systems interactions is working to maintain, strengthen, and nurture PCORnet's relationships with health care delivery systems, while the patient and consumer engagement task force is doing the same for patient groups. The patient-generated outcomes task force is working from the premise that getting patient-generated outcomes is another area that could greatly enhance clinical care and could also enhance clinical and outcomes research, Selby said.

Regarding clinical trials, Selby said that PCORnet's philosophy is that they will be done only when needed. Occasionally, he said, it will be necessary to run small, randomized trials to find small differences in effectiveness. "I'd totally agree though that most of the time you can't do randomization and you'd prefer not to," he said. Rare diseases will be something that PCORnet tackles because the network will have data from more than 25 million people, and, in fact, the legislation that created PCORI specifically charges the institute with studying rare diseases. The goal for the biorepository task force is to work to strengthen the biorepositories associated with the CDRNs and PPRNs and to bring them into clinical outcomes research.

Shelby explained that the CDRNs (see Table 2-1) include a number

TABLE 2-1 The 11 Clinical Data Research Networks

CDRN Name	Lead Organization	Principal Investigator
ADVANCE	Oregon Community Health Information Network	Jennifer DeVoe
CAPriCORN	The Chicago Community Trust	Terry Mazany
Great Plains Collaborative	University of Kansas Medical Center	Lemuel Waitman
Louisiana Clinical Data Research Network	Louisiana Public Health Institute	Thomas Carton
Mid-South CDRN	Vanderbilt University	Russell Rothman
NYC-CDRN	Weill Medical College of Cornell University	Rainu Kaushal
PEDSNet	The Children's Hospital of Philadelphia	Christopher Forrest
PORTAL	Kaiser Foundation Research Institute	Elizabeth McGlynn
pSCANNER	University of California, San Diego	Lucila Ohno-Machado
P2ATH	University of Pittsburgh	Rachel Hess
SCIHLS	Harvard University	Kenneth Mandl

SOURCE: Reprinted with permission from the Patient-Centered Outcomes Research Institute.

of networks of two or more health care systems, networks of nonprofit integrated health systems, networks of federally qualified health centers, and networks that have leveraged previous NIH and AHRQ investments. At least 54 of the 61 Clinical and Translational Science Award winners are involved in one of PCORnet's 11 CDRNs, and many of them include large populations of underserved individuals. The Louisiana CDRN, Selby said, is built substantially on the state's health information exchange. Among the PPRNs in PCORnet (see Tables 2-2 and 2-3), whose focus is the collection and use of patient-generated information, about half are devoted to rare diseases.

Selby concluded his introduction to PCORnet by recapping some early observations. "We are convinced that we've got to establish priorities that patients, clinicians, health systems, payers, manufacturers—as well as researchers—share and consider important," he said. "We think if we can find that sweet spot that the findings are much more likely to be listened to, taken up, and implemented and to change practice." PCORnet has a great deal of work to do, much of it around governance and issues about data ownership and privacy, to facilitate the trust that will support collaborations between networks.

Selby said that it is going to be critical to embed research, including randomized research, as intimately as possible within the practice setting

TABLE 2-2 The Patient-Powered Research Networks Devoted to Common Diseases

Organization	PI	Condition	Population Size
Accelerated Cure Project for Multiple Sclerosis	Robert McBurney	Multiple sclerosis	20,000
American Sleep Apnea Association	Susan Redline	Sleep apnea	50,000
Cincinnati Children's Hospital Medical Center	Peter Margolis	Pediatric Crohn's disease and ulcerative colitis	15,000
COPD Foundation	Richard Mularski	Chronic obstructive pulmonary disease	50,000
Crohn's and Colitis Foundation of America	R. Balfour Sartor	Inflammatory bowel disease (Crohn's disease and ulcerative colitis)	30,000
Global Healthy Living Foundation	Seth Ginsberg	Arthritis (rheumatoid arthritis; spondyloarthritis), musculoskeletal disorders (osteoporosis), and inflammatory conditions (psoriasis)	50,000
Massachusetts General Hospital	Andrew Nierenberg	Major depressive disorder and bipolar disorder	50,000
University of California, San Francisco	Mark Pletcher	Cardiovascular health	100,000
University of South Florida	Rebecca Sutphen	Hereditary breast and ovarian cancer	17,000

NOTE: PI = primary investigator.
SOURCE: Reprinted with permission from the Patient-Centered Outcomes Research Institute.

TABLE 2-3 The Patient-Powered Research Networks Devoted to Rare Diseases

Organization	PI	Condition	Population Size
ALD Connect, Inc.	Florian Eichler	Adrenoleukodystrophy	3,000
Arbor Research Collaborative for Health	Bruce Robinson	Primary nephrotic syndrome; focal segmental glomerulosclerosis; minimal change disease; and membranous nephropathy multiple sclerosis	1,250
Duke University	Laura Schanberg	Juvenile rheumatic disease	9,000
Epilepsy Foundation	Janice Beulow	Aicardi syndrome; Lennox-Gastaut syndrome; Phelan-McDermid syndrome; hypothalamic hamartoma; Dravet syndrome; tuberous sclerosis	1,500
Genetic Alliance, Inc.	Sharon Terry	Alström syndrome; dyskeratosis congenital; Gaucher disease; hepatitis; inflammatory breast cancer; Joubert syndrome; Klinefelter syndrome and associated conditions; psoriasis; metachromatic leukodystrophy; pseudoxanthoma elasticum	50 to 50,000
Immune Deficiency Foundation	Kathleen Sullivan	Primary immunodeficiency diseases	1,250
Parent Project Muscular Dystrophy	Holly Peay	Duchenne and Becker muscular dystrophy	4,000
Phelan-McDermid Syndrome Foundation	Megan O'Boyle	Phelan-McDermid syndrome	737
University of Pennsylvania	Peter Merkel	Vasculitis	500

SOURCE: Reprinted with permission from the Patient-Centered Outcomes Research Institute.

without disrupting clinical operations. In order to achieve this, he said that it will be crucial to develop ethical oversight procedures and human subject procedures that protect patients while minimizing redundancy, wasted effort, and the barriers that prevent participation. It is also apparent that PCORnet will have to engage individuals and organizations beyond the initial awardees, and, toward that end, Phase 2 of the effort will open the network to broader participation. Finally, Selby said, PCORnet must strive for simplicity in a very complex and multilayered environment.

PATIENT OUTCOMES RESEARCH TO ADVANCE LEARNING (PORTAL) NETWORK

In the first of two presentations highlighting specific PCORNet CDRNs, Raymond Baxter and Elizabeth McGlynn described the PORTAL network developed by Kaiser Permanente and its principal partners Group Health Cooperative, HealthPartners, and Denver Health. These organizations, Baxter said, share the aim of being true learning health care organizations and see research as a critical part of the strategy to realize that aim rather than merely an interesting sideline activity. All four organizations are also

grappling not only with the transformation of care but also with the transformation of research to serve that transformation of care, he added. "We are aware that among the needs that our systems have from research at this point are speed, relevance, precision, and methods that really fit the kinds of questions, decisions, and actions that are needed by us as delivery system leaders, as patients, and as clinicians," Baxter said. "At least for Kaiser Permanente, that translates into a sense that we now see the need for a broad continuum of research and analytic capabilities in the organization, in order to answer the critical questions that we have." Among the other members of the PORTAL CDRN are three patient groups—the Adult Congenital Heart Association, Fight Colorectal Cancer, and Smart Patients—that Baxter said play a critical role in driving the activities of the PORTAL network.

PORTAL members see their network as being able to contribute quickly to PCORnet, thanks to the internal resources that PORTAL puts at their disposal, the connection between their delivery systems, and their research and analytic activities. They also see that belonging to PCORnet will help with the work that they each are doing in their individual organizations. "PCORnet represents a model and a discipline that we think can help us push faster the changes we need to make within our own systems in terms of the relationships between research and analytics and care delivery change," Baxter explained. "It also offers us a network that gives us the opportunity not only to share what we are learning, not only to share our data and our capabilities, but to understand what we think we have been learning is actually generalizable in a broader way to the field. We also see PCORnet as something that will be self-reinforcing for us, if it is successful."

In concluding his comments, Baxter said that if PORTAL can contribute to PCORnet and if PORTAL's members are able to integrate findings from PCORnet into their own care delivery systems, that would serve as a proof point not only for the importance of research but also for the importance of engaging with others in a collaborative manner to speed the development and adoption of knowledge on a broad scale. In his opinion, he said, PCORnet's success will not only accelerate the pace of change, but it will also change the culture of research for the better by bringing patients, clinicians, and delivery system leaders into the research enterprise.

McGlynn then described some of PORTAL's accomplishments over its first 3 months of operation. Though PORTAL is relatively new, this is not Kaiser Permanente's first experience in working within the structure of a network (see Figure 2-5). In 1994, she said, her organization joined the HMO Research Network, which demonstrated the importance of developing a common data model and strong governance provisions. "What we have learned and honed and perfected is the ability to write code in one place and distribute it and run it in lots of different places with really minor

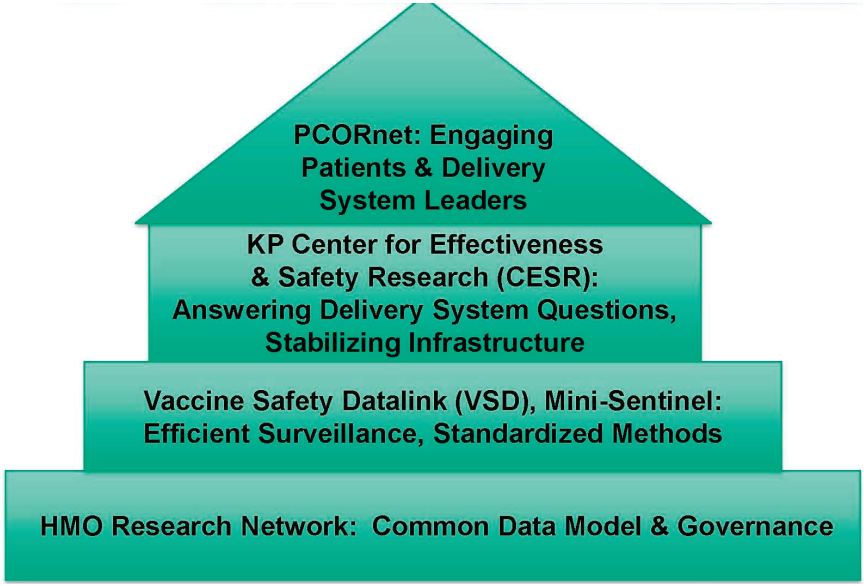

FIGURE 2-5 Kaiser Permanente's experience in working with data networks.
SOURCE: Reprinted with permission from Ray Baxter and Elizabeth McGlynn.

tweaks," she said. "The opportunity to answer more questions and move more quickly is really facilitated by this common data model." She added that given the size, complexity, and multitude of stakeholders involved, PCORnet has the components of a great social experiment, noting that, as such, strong governance will be critical for its success.

From its experience as part of the CDC's Vaccine Safety Datalink and the FDA's Mini-Sentinel networks, Kaiser Permanente learned the value of listening to its customers and how to do surveillance more efficiently with standardized methods. Through its interactions with these two networks, McGlynn said, she and her colleagues also learned the value of not reinventing the wheel as it joined each of these networks. These lessons informed Kaiser Permanente's investment in its Center for Effectiveness and Safety Research, which the organization established in 2009 to answer delivery system questions and to help stabilize the organization's data infrastructure so that it could answer a wide range of questions without having to rework the organization's central data model for every new research project. PCORnet is the "roof on the house that we are building," McGlynn said. "For us, the real opportunity here is learning how to more effectively engage patients and system leaders in the conversation in the development of questions."

Stakeholders are at the heart of PORTAL's organizational structure, McGlynn said. A patient engagement council includes representatives from the three patient groups that are PORTAL members as well as individual patients from the four member health systems. In addition, PORTAL is developing a large online community using the Smart Patients online platform, which allows the network to invite everyone who would be eligible from one of its cohorts to participate in an online community conversation with an even broader reach than its patient engagement council can provide. PORTAL is also working through its community benefit group to reach out to community-based organizations, which will enable it to have conversations with stakeholders who, as McGlynn said, "may not be as online savvy and that represent some of the underserved populations that we don't always hear from."

PORTAL's clinician engagement council aims to broadly engage physicians in the conversation and to help determine the best ways to integrate research and research findings with the care delivery system. An operational engagement council brings together the people whom McGlynn described as the ones who have to get the work done: the information technology groups, the compliance groups, and those who have to manage workflows within these large health care systems. "The idea here is that we are building infrastructure that lets us develop systems, so that we are not making these things up each and every time we set out to do a research project," she said. "We are exercising them with the PCORnet dollars to find out how to make them work and then improve them as we go along." Toward that end, she said, "I think that having this kind of engagement with our critical stakeholders really at the center of what we are doing is going to be critical."

PORTAL's contract with PCORnet calls for it to focus its efforts on three specific groups of its 11 million patients across its delivery systems: colorectal cancer patients, with an emphasis on treatment and how patients navigate survivorship; adolescents and adults with severe congenital heart disease, a rare condition that affects about 330 individuals across the network, with an emphasis on transitions in care as these patients not only live to be adults, but thrive; and obesity in adults. Together, these three projects aim to enhance the PCORnet health systems' ability to embed research in routine care delivery, and McGlynn listed several factors that she thinks will be key to the success of this effort. The first is the ability to ask the right questions—in particular, questions identified by the people who will be implementing the resulting answers. The second is engaging clinical champions who can help advocate for some of the changes that will have to occur to make research possible within the routine care delivery system. The third is engaging the operational teams that will do the work and make these projects happen so that, McGlynn said, "as we develop systems for

care delivery, we are thinking about how those can be used for research, as opposed to having separate and parallel systems."

The goal for each of the three projects is to produce information that will help patients and doctors make decisions together in real time. McGlynn said that the ideal would be to integrate information from research into care delivery at the point of care in a way that makes it easy for doctors and patients alike to use that information. McGlynn concluded her remarks by noting that the tools and technology pieces are largely in place and that the challenge now is getting people to collaborate in the service of answering critical questions for patients, the health care system, and the nation.

NEW YORK CITY CLINICAL DATA RESEARCH NETWORK

In providing background information for her presentation on the New York City CDRN, Rainu Kaushal said that while there are 8 million residents in New York City, the number of people who come to the city for clinical care is easily double the permanent population. There are six academic medical centers in the city, and in any given year some 40 percent of one center's inpatients will either use an emergency department or be hospitalized at another academic medical center that is also in New York City. "When you start thinking about the degree of fragmentation, including the ambulatory side of things," she said, "it is not unusual for a Medicare beneficiary in New York City, for example, to be seeing 10 or 12 different providers. That amount of fragmentation and the very tight operating margins that our health systems are under causes tremendous complexities for providing the best possible clinical care and getting the right treatment to the right person at the right time. It makes population health management exceedingly challenging."

That kind of fragmentation also creates significant challenges for sharing data among multiple institutions and for creating a learning health system, Kaushal said. As a result, she explained, when the opportunity arose to build the infrastructure to support clinical research and care and to manage health on a population basis, the 22 partners in the New York City CDRN jumped at the chance to participate, she said. The partners in this CDRN include six academic medical centers, one practice-based research network, six consumer partners, and six research infrastructure organizations, including the New York Genome Center, several information exchanges, and Cornell's new technology campus. Kaushal applauded the foresight being shown by the CEOs of the large health care systems who, despite the fragmentation and competitive pressures, see that sharing data is the right thing to do for their health systems, for clinical care, and for populations.

The New York City CDRN has four goals, Kaushal said. The first is

ensuring security and privacy. "Because of the fragmentation in our market, we are forced to centralize our data in order to perform de-duplication and then de-identification," she said. "In that context, privacy and security are our guardrails, and we are putting an incredible amount of energy right now into figuring out those guardrails and making them as secure as we possibly can." The second goal is to build a research infrastructure populated by complete comprehensive longitudinal data on a minimum of 1 million patients, although, given the populations of New York City, she said she expects that number will be higher by the end of the project. Kaushal said that the plan is to incorporate clinical data, claims data, patient-reported survey data, biospecimen data, and patient-generated data into the database. The project's third goal is to integrate the viewpoints of patients and practicing clinicians.

All of this activity has the express goal of embedding research into health care delivery so that a physician can provide the appropriate care to meet each patient's individual needs. Kaushal noted the tension between the research interests and organizational priorities and said she believes that the key to resolving those tensions rests with good communication. She also said that the New York City CDRN is putting a great deal of time into patient consent and is borrowing and sharing from the best practices across the network in order to streamline the process and make research more effective across the network.

Kaushal spoke about the value that she believes the network brings to the health systems that belong to the New York City CDRN. First and foremost is the ability to generate actionable, patient-centered knowledge that improves the delivery of health care and the conduct of research. Another contribution will lie in assuring quality and safety when quality databases are integrated with clinical and claims databases. Enabling population management in the New York City area will also be a huge contribution, she said. "If we could really understand our attributed Medicare beneficiaries, what their costs are, how their costs are accruing across our health care systems, and what the quality of care that we, as a system, are providing to them, that would be huge," she said. Another contribution will be working toward creating a citywide learning health care system.

The New York City CDRN has enjoyed tremendous support from senior leadership, Kaushal said, and partner institutions have been generous in terms of providing infrastructure and other resources. She concluded her presentation by showing a picture of her 19-month-old twins and saying that they are the reason she is involved in this project. "I feel an imperative to work on this network and to be part of PCORnet," she said, "because when I take them to a pediatrician, I want them to get antibiotics because they actually need them for an infection, or if they need a tympanostomy tube, I want that to be placed because it is surgically indicated. Those are

the types of studies that, given the scope of PCORnet, could be answered with trivial amounts of energy. I want to see those things."

DISCUSSION

In opening the discussion period, Selby said that the other nine CDRNs that are part of PCORnet could have told equally compelling stories. He also said that the original intention was to fund eight CDRNs but that the decision was made to fund 11 because the applications were so strong.

Russell Rothman of Vanderbilt University, who heads the Mid-South CDRN, said that the two preceding presentations had embodied what each of the CDRNs are doing, and he added that at this point in the PCORnet grant cycle, much of what is happening at his and other CDRNs is infrastructure development and stakeholder engagement, a point with which Selby agreed. "I just want to emphasize the point that this is a work in progress," Rothman said. "We very much want as much input as we can at this point in the process." Rothman also said that there is a grand opportunity in bringing together 11 CDRNs and 18 PPRNs under the PCORnet umbrella to collaborate and ask questions at a level that cannot be done by any single CDRN. This is particularly true for rare diseases, he said. Baxter said that another benefit of belonging to PCORnet has been that it forced him and his colleagues to make decisions and set up a structure quickly rather than debating exactly what to do for the next several years. "That is a very tangible benefit for us as a system," he said.

Steven Lipstein of BJC Health care asked Kaushal how the New York City CDRN handles IRB approvals involving multiple institutions in the network and how it handles patient recruitment, given that there may be competition among institutions and clinical trials. The New York City CDRN, Kaushal replied, has a centralized IRB that three of the member institutions had already been sharing for a decade and that all of the other partners have agreed to use. Concerning patient recruitment, she said that she and her colleagues have been thinking about this because they want to avoid multiple contacts of a single patient for research studies. Their solution, she said, has been to develop a centralized de-identified database and "use attribution logic to attribute each patient as a primary for a given health system."

Jeffrey Grossman from the University of Wisconsin Medical Foundation asked if PCORI had a vision for studying the outcomes of its research. Selby replied, "PCORI has a real sense of urgency about evaluating the impact of its research. We have a date with the [Government Accounting Office] in 2018 where we are really going to have to have some of that evidence for Congress to look at. We have an evaluation plan that specifi-

cally looks at very critically [whether] all of this engagement [is] making any difference."

Jonathan Tobin of the Clinical Directors Network and the Rockefeller University Center for Clinical and Translational Science asked if there was an opportunity to use PCORnet to phenotype organizations in the same way that patients are phenotyped. In other words, would it be possible to look at different delivery care models, different types of clinician groups, and other system variables and look at the associations between those different models and the participants in the system and answer questions about uptake, implementation, effectiveness, and outcome? Selby answered that that type of question was something that PCORnet could address.

Petra Kaufmann from NIH said that the National Center of Advancing Translational Sciences, where she works, recently received an IOM report reviewing the Clinical and Translational Science Awards program, and one of its recommendations was to strengthen the capacity of the program to function as a network and, in particular, to leverage existing information technology systems. A key to doing that, she said, will be to ensure that the data systems of its grantees are interoperable with those of the PCORnet members. Toward that end, she said, her center will work closely with PCORI to make sure that there is synergy between the two.

Robert Kaplan from AHRQ asked if PCORnet is giving any thought to how to recognize scholars that are now going to be working as part of large networks and to how that recognition might impact career choices. Selby said that younger researchers are excited about the opportunities that come from working within a large network and about the access to large amounts of data that provides. Young researchers, he said, want to be part of an effort in which their research can be embedded in the care environment, and he predicted that "we will see M.D. and Ph.D. trained researchers working from bases within systems to conduct research that shows up in the *New England Journal of Medicine*." McGinnis added that there is a need for a different type of researcher, one who is comfortable talking to leadership and to researchers from outside of their disciplines.

Continuing on that theme, John Gallin of the NIH Clinical Center asked if as much thought has gone into the training of tomorrow's physicians to interact with this type of system as has gone into what information should be recorded in a patient's medical record. He also asked how to engage patients so that they not only expect to receive something from the system but contribute to it as well. Selby replied that one of the underlying principles for PCORnet is that there has to be something in it for everybody. "If clinicians are really engaged in using these data to improve care," he said, "I think it's a natural consequence that they will begin to take more responsibility and care in putting the data in. If they can see when bad data lets you down and when good data enlightens you, they will take more

care when they feel that they can use these data ultimately to ask questions on their minds. I think the same thing goes for patients. You can talk to patients about their responsibilities vis-à-vis EHRs and PCORnet once you've given them a seat at the table and once they feel that this is their enterprise as well."

Darrell Kirch of the Association of American Medical Colleges said that the challenge for trainees is that they often have to deal with multiple medical record systems as they move through different rotations during their years of training. He also said that medical education needs to change to reflect the fact that EHRs will have uses far beyond billing. "We have a long way to go to create the infrastructure and the attitudes so that the students and residents, who are very willing to use the electronic record, can shift their focus away from reimbursement to creating the research database," he said.

3

Continuously Learning Health Care: The Value Proposition

KEY SPEAKER POINTS

- Creating the space for learning and the will to change stems from understanding what is important to those affected and from the willingness to honor and integrate their perspectives. According to Sarah Greene, this willingness to integrate a variety of viewpoints is also the cornerstone of the continuously learning health system.
- "What we want to do is fail forward fast," Thomas Graf said. "The concept is if you are not failing, you are not doing enough." Graf added that what is important is to learn something from failure, to fail forward, and then keep iterating to the best design possible.
- To be useful, knowledge must be accessible to people who need it, it must be relevant to a specific market, and it must be of high quality and available at a reasonable cost, Trent Haywood said. He added that the health care system needs to consider how to structure itself in a way that does not lead to knowledge hoarding.
- Haywood said that there is no good model yet that addresses how systems get compensated for making investments to generate knowledge. "If people are making investments, and then we want people somehow to be altruistic and forgo their return

on this investment for the greater good, we need to some type of model that rewards that sacrifice that they are making," he said.

- John Steiner said that the value proposition of integrating research with operational and clinical care is much broader than just what can be learned. Tools developed for research that eventually become part of operations also contribute to the value equation.

The goals of this session were to discuss a vision for a continuously learning health care system, to begin to articulate the value proposition for such a system, and to contemplate what it will take to create such a system. Session moderator Sarah Greene, senior program officer at PCORI, began this discussion with a proposal for how to create a value proposition for a continuously learning health care system. Three panelists—Thomas Graf, chief medical officer for population health and longitudinal care service lines at the Geisinger Health System; Rita Redberg, professor of medicine and director of women's cardiovascular services at the University of California, San Francisco (UCSF); and Trent Haywood, chief medical officer for the Blue Cross Blue Shield Association—responded to Greene's presentation with case examples to illustrate the opportunities to make a learning health care system the norm.

IS THE TIME RIGHT FOR CONTINUOUSLY LEARNING HEALTH CARE?

Greene began her presentation by pointing out that creating the space for learning and the will to change stems from understanding what is important to all who are affected by that change and from the willingness to honor and integrate the different perspectives of all those who are affected by that change. This willingness to integrate a variety of viewpoints is also the cornerstone of the continuously learning health system. Greene added that those health care systems that have demonstrated a great deal of success in creating a continuously learning health system have individuals in leadership roles who have a foot in both the research and system administration worlds and who can act as a bridge between different perspectives.

Referring to the "virtuous cycle" of a learning health care system (see Figure 3-1), Greene said that this cycle is based on the bidirectional flow of information between practice and research, and she characterized this process as "messy." Proponents of the learning health care system, she said, need to be able to convince their colleagues that this virtuous but messy

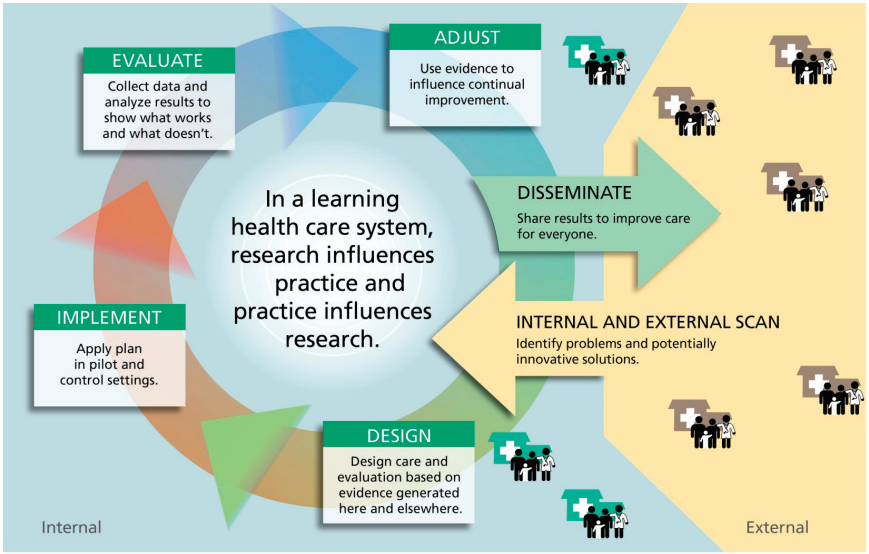

FIGURE 3-1 The virtuous cycle of a learning health system.
SOURCE: Reprinted with permission from the *Annals of Internal Medicine*.

process of continuous learning is the model that can help achieve the triple aim of better care, lower costs, and improved health and to address other goals that are important to health system leaders.

The important elements of a value proposition, Greene explained, are focused on the needs of the customer; they include a promise of value to be delivered and a belief by the customer that value will be experienced, according to factors that are important to the customer. Putting the customer at the center of the value proposition means that a deep knowledge of the potential and current customer base is invaluable. "I would offer to you that we are not yet completely clear on who all of the customers of a learning health system are and what it is they want from this health system," Greene said. This uncertainty may make it challenging to articulate a value proposition, she told the workshop attendees, but it would be a win for everybody if their work can increase clarity for decision makers and reduce the decision makers' anxiety about the changes that are buffeting health care systems.

Greene then laid out a set of four questions to consider when creating a roadmap of customer and stakeholder, needs:

- What do stakeholders value intrinsically?
- What will they need to invest to create a learning system?

- What will they get in return for their investment?
- What are the potential risks and challenges in adopting an organization orientation to a learning health system?

To think about these questions, Greene offered a grid mapping these four questions against the needs of eight different stakeholders: employers/purchasers, health insurers/payers, health care system leaders, providers, researchers, patients, policy/government officials, and industry (see Figure 3-2). Employers, for example, are concerned about total cost of care and productive employees, whereas providers care about professional autonomy and their relationship with their patients. The patient, in turn, values a relationship with the provider and being able to live a life without the burden of illness. In short, defining the value proposition may require tailoring it to the specific stakeholders.

One question that Greene said she hoped the workshop would address was how to go from a compelling value proposition to conditions that support learning. "If we do get to a compelling value proposition out of the course of this meeting and the next meeting in June," she asked, "how are we going to be sure that we can go home and have the conditions that support learning? It is not automatic. There need to be some sustaining features." Some of those sustaining features can be found in three organization conditions that support learning: time allocated to exploration, discovery, and learning; a physical and social environment that enables one to be a "student"; and core values that appreciate learning in its own right and encourage curiosity, knowledge, and discovery. She also listed individual attributes that support learning, including humility, curiosity, self-awareness, a tolerance for ambiguity, openness, and vulnerability. This

Group / Key Question	Employer/ Purchaser	Health Insurer/ Payer	Health Care System Leader	Provider	Researcher	Patient	Policy/ Gov't	Industry
What they value inherently								
What they'd need to invest								
What they'd get in return								
Potential Risks/ Challenges								

FIGURE 3-2 An example of mapping stakeholder needs to create a value proposition.
SOURCE: Reprinted with permission from Sarah Greene.

last feature is perhaps the most difficult to create because so much of the ethos of the health care profession involves knowing exactly what needs to be done. "Learning requires vulnerability," she said, but in health care "we don't ever want to look weak in front of our colleagues." She added that her research at Group Health proved the value of being vulnerable and being willing to fail in an environment that supports and is primed to learn from failure.

Greene also said that it is important to think about the many external market conditions that are putting pressure on health system leaders. These external factors include the Affordable Care Act, the increasing importance of big data and predictive analytics, the data release requirements of the Centers for Medicare & Medicaid Services (CMS), meaningful use and other new regulations, and payment reform. Meanwhile, efforts such as the Data for Good campaign being conducted by PatientsLikeMe are aimed at helping patients understand the value proposition for research. Although this may be the beginning of an inflection point for patient engagement in research, the receptivity to research demonstrated by health systems and clinicians may be affected by these other external variables.

In the end, Greene said, watchful waiting is not an option, and she ended her comments with a quote from Paul Keckley, the former executive director of Deloitte Health Solutions: "This environment rewards leaders and their organizations not paralyzed by its uncertainties, uninformed about its fast changing, nor fearful of the spotlight. Leaders . . . face unparalleled challenges and opportunities, but with them, pressures. Monitor closely the pulse of the industry . . . the stakes have never been higher." Greene predicted that PCORnet is going to trigger such a change and said, "What I have seen already is that PCORnet is creating this climate of trust and humility from the outset and that it is purposely uniting the perspectives of CEOs, researchers, and patients to develop a compelling value proposition."

INCREASING EFFICIENCY AND ELIMINATING WASTE

To provide context for his comments, Thomas Graf began by explaining that the Geisinger Health System is a 1,000-physician medical group that owns 6 hospitals and a 400,000-member health plan. "The culture of physicians that drives Geisinger is really integral to a number of the elements of success and lays the groundwork for that success," he said. He also noted that Geisinger is not a closed system, as only about 40 percent of the patients who see Geisinger physicians or who use Geisinger hospitals are members of the health plan, and only about 40 percent of the health plan members see Geisinger physicians or use Geisinger facilities. What these numbers mean in practice, he said, is that Geisinger has a special environment that allows it to try new approaches in the 40 percent of pa-

tients that the system both insures and treats. "We can go fast and take risks that other folks really cannot take, at least on the financial side," Graf said. "But then we have an immediate scaling opportunity to take something that works to the other 60 percent of our patients and the other 60 percent of the providers that care for the members of the health plan."

According to Graf, Geisinger has spent the past 10 to 15 years developing a culture of quality and innovation. "It began with creating the right infrastructure, the right space, and the right thought process, but also the demand for using quality as the lever to move physicians and nurses in a way that they had not been able to do before," he said. Creating the right environment also involved creating positions for a chief innovation officer and a chief transformation officer to speed innovation and transformation. The proven models that Geisinger has become known for resulted from a culture of innovation and quality that diffused through the system's clinical service lines, its community medicine department, and its frontline health professionals. "That is important," Graf said, "because if we want to be successful and we want to maintain that value proposition over the long term, it has to be tied to things that intrinsically create value for the folks who are delivering that care."

Geisinger's ProvenHealth Navigator, its medical home transformation program, is one example of its success in creating a continuously learning health system. This program, which has now been put in place for 100 percent of the system's patients and clinical practices, started as a series of pilots that were encouraged to fail. "I am not sure if failing often is necessarily the goal," Graf said. "What we want to do is fail forward fast. The concept is if you are not failing, you are not doing enough." What is important, he said, is to learn something from failure, to fail forward, and then keep iterating to the best design possible. In this case, Geisinger deployed its medical home pilots in 2006 and then rolled out the final system across 45 Geisinger sites and 45 sites that contract with its health plan but are not owned by the Geisinger system. The result was a dramatic improvement in quality across all the sites, including a 500 percent improvement in comprehensive diabetes care over a 5-year period and a 350 percent improvement in comprehensive preventive care for adults and children over a 3-year period (Maeng et al., 2012a) as well as a 7.5 percent reduction in costs over the first 3 years (Maeng et al., 2012b). Graf added that the results improved with the length of exposure to the innovation.

The bottom line, Graf said, "is that we have created a compelling model that creates better care for patients, which is a value proposition that we need to adhere to, and easier care for medical professionals." He added that his one complaint about the triple aim is that it omits any mention of health professionals. "If we reduce total cost of care, we improve quality, and we improve patient experience, but we do it on the backs of the health

care professionals, it is not going to be sustainable," Graf said. Instead, the goal should be to achieve what Geisinger calls the "triple aim plus," which also includes improving the experience of medical professionals.

Achieving the triple aim plus requires taking an unreliable chaotic practice and reducing the variability of care by eliminating the 30 to 40 percent of what patients experience that adds no value to the patients. Automation plays a role, and so does better delegation across all members of the health care team, including doctors, nurses, front desk staff, and even patients. "If we can check ourselves into am airport post-9/11," Graf said, "we can get patients engaged in their care, and guess what? They want to be participants."

The final component for success is building evaluation into the organization's culture so that continuous learning can take place. "That is what allowed both the rapid expansion and the ability to scale and generalize the program to organizations outside of Geisinger," Graf said in closing. "That culture of quality embedded in daily life, providing value to patients that is patient-centered and that patients truly value, I think is what has allowed us to succeed."

IMPROVING OUR ABILITY TO CHOOSE WISELY

Rita Redberg began her comments by discussing the "Less Is More" feature that she launched with Deborah Grady at *JAMA Internal Medicine* (Grady and Redberg, 2010). The two editors were prompted to start "Less Is More" by the release in 2009 of the U.S. Preventive Services Task Force recommendation on mammography that suggested that there were more harms than benefits associated with mammograms for women ages 40 to 50. This report received a negative reception that Redberg attributed in part on the fact that the report did not emphasize the harms message and people assumed the recommendations were motivated by costs. "I am not sure that patients talk about or care about cost very much in our current system, but certainly, everyone cares about harms," she said. "If you understood that you were going to have a much higher chance of being harmed than benefited from a test of any kind, I think you would think differently certainly about the test."

The result was the launch of the "Less Is More" collection that highlights areas of health care that have no known benefit and potential harms, of which Redberg said there are quite a few. "If there is no benefit, we feel that a harm, no matter how small, is still going to tip the equation," she said. She added that discussing harms, as well as whether there is a benefit or not associated with a particular intervention, is one approach to improve people's ability to choose wisely, and she recommended that the importance of discussing with patients risks in the context of benefits be emphasized

in medical school and residency training. "Right now, we have a culture that embraces new things but without considering if it is an improvement and if the benefits outweigh the risks," she said, adding that the medical profession needs to do a better job of informing itself about risks and then discussing those risks with patients.

Journals and continuing medical education are two avenues for helping providers learn to choose wisely. Quality measures are another, Redberg said, but she cautioned that using too many quality measures can overload physicians and interfere with their ability to care for patients. She said she believes that the use of "report cards" that provide feedback data on the usage of common testing has the potential to help physicians choose wisely without adding significant burden. Switzerland, she noted, now issues report cards that show doctors how they compare with other physicians on a variety of measures. Swiss officials, she said, believe this is an effective approach to improve care.

The American Board of Internal Medicine (ABIM) Foundation has launched the Choosing Wisely campaign which includes "top-five lists" for different medical specialties (Good Stewardship Working Group, 2011). The reason for creating these lists was to get physicians to start thinking about some of the things they do routinely that they should be doing less of going forward. The ABIM Foundation also partnered with *Consumer Reports* to get the word out to patients. The top-five list for internal medicine included such recommendations as "Use only generic statins when initiating lipid-lowering drug therapy." The accompanying explanation said that statins are all equally effective in decreasing mortality, heart attacks, and strokes when the dose is titrated appropriately to reduce low-density lipoproteins (LDLs, or the "bad cholesterol"), and it suggested that switching to more expensive brand-name statins such as Lipitor (atorvastatin) or Crestor (rosuvastatin) should be done only if generic statins caused clinical reactions or did not achieve LDL cholesterol goals.

Redberg said that there are many reasons for overuse of medical care. One reason is a general enthusiasm for new technology, while another is defensive medicine. Misaligned incentives are an important factor as well, as is demand from patients. Redberg argued that many diagnostic tests are ordered just because it is easy to do. "You get more information," she said, "but it is not always necessary, and even with what seems like the most innocent imaging test, things can go wrong." What providers should do, she said, is to consider before ordering every test or treatment, no matter how mundane, what a test will tell them, what they would do differently given the results of a test, whether it will lead to a change in outcomes, and if the information from that test is needed to make that change. She argued that instead of ordering a test for "reassurance," physicians can reassure their patients amply by talking to them (Redberg et al., 2011).

In her closing remarks, Redberg briefly described the Caring Wisely initiative being carried out by the recently created Center for Healthcare Value at UCSF. The premise for this initiative is that academic health centers have expertise and a tradition of innovation while at the same time having the credibility and integrity to participate in shaping controversial policies. Under the initiative, the center's goal is to work with stakeholders at the state and national level to create a health care system that fosters high-value health care. The initiative, backed by departmental and hospital funds, tests staff-generated ideas that have the potential to provide better care while saving money. For example, when a literature review of the evidence suggested that nebulizers were not helping patients when used beyond 24 hours, pictures went up all over the UCSF hospital reminding physicians not to use nebulizers after 24 hours. "That has been a successful campaign," Redberg said.

ESTABLISHING THE INFRASTRUCTURE TO PAY FOR VALUE

Knowledge is the critical component for creating a learning health care system, Trent Haywood said in his brief remarks, but to be useful knowledge must be accessible to people who need that knowledge, it must be relevant to a specific market, and it must be of high quality and available at reasonable cost. It is also important to consider whether particular knowledge is a public good and available to everyone or whether it is a commodity that can improve competitiveness. "I don't think we are necessarily clear about when we are talking about this knowledge as being a public good and when we are talking about this knowledge as a private commodity where people are actually setting up infrastructure in place for financial incentives for people to actually compete in that particular setting," he said. He added that the health care system as a whole needs to consider how to structure itself in a way that does not lead to knowledge hoarding.

Another question that needs thought is how individual health systems should invest in research whose purpose is to meet the triple aim. Haywood noted that this question has proven difficult to answer because "we know we are not satisfied with some of the research that we get." Concerning value-based payments, Haywood said that his organization is supportive of using them to drive improvement across the board. The challenge is to disseminate the knowledge needed to determine value in the most effective manner. The Blue Cross Blue Shield Association's Center for Clinical Practice spends time working with all of the 37 Blue Cross Blue Shield plans to identify leading practices with some measure of validation and to disseminate it quickly. Haywood concluded his comments by saying that this approach works in a closed system but that he is not sure this would be the case in an open competitive environment.

DISCUSSION

Greene, in her role as session moderator, took Haywood's comments about knowledge and competitiveness and asked the panelists how they go about balancing the tension between transparency and competitiveness. Graf responded that it is important to understand the difference between transparency of knowledge and the ability to execute using knowledge. Geisinger, for example, generates little new groundbreaking research. Instead, it takes knowledge available in the literature and determines how to put it together and deliver it in a reliable way. Although Geisinger freely publishes the findings that result from this effort, it does expect to get paid if it helps other systems with implementation. "We are very free about the knowledge, but less so about the execution," he said.

Transparency is important, Redberg said, because it enables others to replicate and validate findings and to avoid instances where incomplete data availability might lead to patients being harmed rather than helped. "We need to have more transparency and public availability so that people understand risks and benefits," she said. "That can only be done in an open, data-transparent environment." Haywood agreed with Redberg and commented that part of the tension reflects the fact that there is no good model yet that addresses how systems get compensated for making the necessary investments to generate knowledge. "If people are making individual investments, whether it be for their own individual institution or for other organizations, and then we want people somehow to be altruistic and forgo their investment for the greater good, then we need to some type of model that rewards that sacrifice that they are making," he said.

Stephan Fihn of the Veterans Health Administration (VHA) asked Haywood if he had any ideas on how to value knowledge that does not have a market value as opposed to knowledge that directly improves the bottom line. An example would be knowledge that results in some process being improved but that does not meet its full potential in the eyes of stakeholders such as patients because it has not become widely disseminated. In that case, the knowledge only has value after it has been widely disseminated and incorporated into medical practice. Haywood suggested that reward does not have to be strictly monetary and that it could be in the form of social capital.

Fihn's question prompted Robin Wittenstein of the Penn State Hershey Health System to ask the panelists if they had any ideas on how to develop knowledge markets so that learning can be disseminated more rapidly to the eclectic mix of people who have to be involved in researching, understanding, and then implementing new ideas. Redberg said that the use of journals has worked well as a way of disseminating knowledge, but Haywood commented that physicians do not have spare time in the current health

system model to go find information in the literature that could improve their practices. What has to happen, he said, is for knowledge transfer to become part of routine practice. Graf agreed with Haywood and said it is important not to place the responsibility for information gathering and dissemination on health care practitioners but rather to have the health care system do that part and instead reward practitioners for participating in the system. "The system is what reliably produces results," Graf said. Geisinger found that feedback on performance is an effective reward. "It is important to make it as easy as possible for every person in the health care system to get the right answer," he said.

Graf also said that enabling providers to get the right answer for 90 percent of their patients enables them to be more creative and customize the approach to take with the 10 percent of patients who need customized care. "Make the 90 percent automatic so that the doctor can focus on the remaining 10 percent," he said.

Jerry Krishnan from the University of Illinois Hospital and Health Sciences System suggested that the value proposition for patients to participate in research still needs to be made clearer. He and his colleagues have been engaging patient groups and have found that they want to be involved in research once they understand what value it has for them. Graf noted in response that patients certainly value organizations that participate in research, in large part because of the reputation it gives that particular health care system. Whether a patient participates in research ultimately comes down to a matter of trust between the patient and the physician, and building that connection on an ongoing basis is critical. Krishnan also commented that as systems become known for their research and improved quality, it should give them a competitive advantage; thus an effort to understand how to place a value on that advantage could help support the infrastructure needed to generate new knowledge, he said.

Lorraine Johnson, a patient representative for PCORI, said that the question of how patients value research is context dependent and depends on balancing risk and reward for each patient. It is important, she said, to make sure that patients see and understand the benefits of the research in which they participate. Greene, playing devil's advocate, wondered if hearing the term "learning health care system" might scare patients away. "I don't want a health system that learns, I want one that knows," she said. "I think we need to be thoughtful about this."

David Grossman suggested that in the case of not-for-profit health systems, generating and disseminating knowledge could be seen as delivering the community benefit that such hospital must satisfy to keep their 501(c)(3) status. The same could be said, he added, for government health systems such as the VHA. In addition, being first to market in terms of publishing results could be an advantage for not-for-profit systems. Haywood

agreed with these comments but said that it will be necessary to develop some kind of metric to account for this type of activity.

John Steiner from Kaiser Permanente Colorado argued that the process of research itself, not just the improvement in practice, is a huge part of the value proposition. "In particular, I think one way in which research is helpful is in framing what I think of as well-formed questions," he said. "When we work with operational leaders, oftentimes they have a general idea of what they want to learn. Our job is to help them get more precise about what exactly it is they want to learn." The tools developed for research that eventually become part of operations also contribute to the value equation, he said, citing interactive voice response as a one-time research tool that is now largely an operational tool. "My general point is that the value proposition of integrating research with operational and clinical care is much broader than just what we learn," he said. "How we learn brings a lot to the table."

Addressing the issue of widespread application of new ideas, Lewis Sandy from UnitedHealth Group asked if there is any leverage in a network focused on evaluating complicated system interventions, with the patient-centered medical home (PCMH) as an example. In particular, he noted that although Geisinger's PCMH intervention produced better results over time, Group Health's PCMH did not produce better results until it was retooled, and a recently published study of PCMHs in Pennsylvania found only modest improvements in quality and no reduction in utilization over a 3-year period (Friedberg et al., 2014). These varied results, Sandy said, raised the question of whether every learning health system has to conduct its own evaluation of the PCMH concept. "If so, there is not a lot of leverage in terms of installing and deploying a better model of primary care," he said.

Redberg replied that interventions such as the Randomized Evaluation of Decolonization versus Universal Clearance to Eliminate MRSA (REDUCE MRSA) trial that Susan Huang discussed in the workshop's opening session are straightforward enough that they should be applicable across health care systems, but for a PCMH it is likely that each health system will have to develop and test its own unique implementation that takes into account local factors, patient mix, institutional culture, and other factors. "I think there can still be a learning experience from sharing," she said, "but you do need more granular data for complicated interventions such as PCMH." Graf agreed, but wondered if it would be possible to look across PCMH models and draw some conclusions about core elements that are critical for successful interventions. He noted, too, that large payers such as UnitedHealth have the opportunity to conduct such studies with large sample sizes. Haywood suggested that by looking at a granular level across systems, it should be possible to identify core elements for success.

In response to a final question from a workshop participant about whether grants that fund research should include an obligation for applying the knowledge gained from that research, Graf said that this was in fact happening, and he cited the recent CMS innovation awards that tie knowledge generation to implementation. "I think this concept of tying generation and dissemination is important," he said. "The ability to do that will be the challenge." Greene added that this would be a good goal but that the incentives for academia would have to change substantially. She put the challenge this way: "When is the Group Health faculty going to be incentivized and given tenure for getting the knowledge into practice versus getting the journal article published? I think we are a little ways away from that."

Summarizing the discussion, Greene listed the many incentives that she heard during the session that could feed into the value proposition. These included social capital, reputation management, ease and speed of information gathering, making it simple and easy, monetary savings, better care, and lower anxiety. She noted that synergy itself is an incentive. "Having that collaborative capability in an organization creates the joy-in-work phenomenon that I think we would all value," Greene said. She also noted that the research tools and analytical methods developed for this type of research can themselves benefit an organization's operations. For patients, she said, aspects of altruism and knowing that they are "paying it forward" by participating in research that will benefit future patients could act as an incentive as well. She commented that one incentive she did not yet hear about was that research will generate better data that can, in turn, support quality improvement and other aspects of improving care.

4

Integrating Clinical Research and Practice: Examples

KEY SPEAKER POINTS

- The keys to a successful research partnership, according to Susan Huang, include a trial design and operational plan that cater to the strengths of each partner, choosing a research question that aligns well with a major health system priority, leveraging existing infrastructure in order to smoothly integrate research into clinical care, and using routinely collected data that already exist in EHRs.
- Uma Kotagal stressed the importance of using data that are collected systematically for research in the EHR in order to place minimal data collection burdens on care providers.
- David Grossman reiterated the importance of selecting research projects that improve care and outcomes as well as supporting the economic health of the system. He noted that a major challenge for researchers is to ensure that disruptive innovation does not negatively affect the stability of the health care system.
- Another important reason for being part of a network dedicated to improving care while reducing costs, even when it uses scarce resources, is that it enables staff to "do the right thing," Edward Havranek said. "I think we forget that one of the most important aspects of quality, value, diffusing research, new

knowledge, and doing things better is that it appeals to that very uniquely moral and idealistic motivation for doing what we do."

- Havranek also noted that there are times when the reimbursement system acts as an impediment to bringing research findings into the clinic, an issue that Kotagal said arises from the fact that revenue streams and incentives are too often dissociated. One solution to this problem, she said, would be for those who pay for health care to start paying for continuous innovation.

To provide the workshop with a vision of what is possible when care and research are integrated effectively, four speakers highlighted examples of organizations that are on the leading edge of these efforts. These four presenters described the effects that integration can have on efficiency, value, and health outcomes and discussed how the resulting value proposition can help organizations embrace the integration of care and research. Susan Huang of the University of California, Irvine, described the multipartner REDUCE MRSA trial; Uma Kotagal of Cincinnati Children's Hospital Medical Center provided details on the Improve Care Now Network; David Grossman of Group Health and the Group Health Research Institute discussed Group Health's approach to integrating care delivery and research; and Edward Havranek of Denver Health spoke about the High Value Healthcare Collaborative. An open discussion, moderated by Harold Luft of the Palo Alto Medical Foundation, followed the presentations.

REDUCE MRSA TRIAL

The REDUCE MRSA trial is an example of a successful partnership between a health system and an academic research group, Susan Huang said in her opening remarks. The rationale for conducting this trial was that health care–associated infections, many of which are caused by MRSA, or methicillin-resistant *Staphylococcus aureus*, are 1 of the top 10 causes of death in the United States and are likely to be the most preventable (National Center for Health Statistics, 2002). Moreover, there has been considerable debate as to whether the best approach for preventing these infections is to target the bacteria directly or to target at-risk populations, such as those in intensive care units (ICUs). This debate, said Huang, has been going on for over a decade. "The need for a definitive trial was quite prominent," she said.

The trial was conducted as a partnership between the Hospital Corporation of America (HCA), the largest private health system in the United States and one that accounts for about 5 percent of all in-patient hospital stays, and a group of academic researchers who were well-versed in health care–associated infection research and experienced at conducting clinical trials. The trial was done using cluster randomization, which in this case meant randomizing hospitals and assigning all adult ICUs in each hospital to the same MRSA prevention strategy (Huang et al., 2013). The three strategies tested were:

- Routine care: This strategy involved screening patients for MRSA when they were admitted to the ICU. Health care providers used gloves and gowns when caring for patients who tested positive for MRSA.
- Bathing and treating patients who tested positive for MRSA: Health care providers used gloves and gowns when caring for patients who tested positive for MRSA, the patients were bathed daily with a 2 percent chlorhexidine-containing cloth, and for 5 days they had mupirocin antibiotic ointment applied twice daily inside their noses, the noses being the body site most commonly colonized with MRSA.
- Universal decolonization: Patients entering the ICU were not screened for MRSA colonization. Instead, all patients were bathed daily with a 2 percent chlorhexidine-containing cloth and received mupirocin ointment twice daily inside their noses for 5 days. Gloves and gowns continued to be used when treating patients who tested positive for MRSA.

A total of 74,256 patients in 74 ICUs at 43 HCA hospitals across 16 states were enrolled in the trial. This scope and depth of participation, which was achieved over a mere 18 months, would have been impossible without the collaborative partnership at the heart of this trial, Huang said. For baseline data, the study used 12 months of retrospective EHR data available in the HCA data warehouse. The results of the study were unequivocal: Universal decolonization resulted in a significantly greater reduction in the rate of all bloodstream infections than either targeted decolonization or screening and isolation.

Huang credited the success of this partnership to several factors. The most important reason, she said, was that the research question aligned well with a major health system priority and with HCA's "strong dedication to quality." As an aside, Huang noted that HCA's administration emphasized the need to conduct the trial rapidly in order to not impede the health system's quality improvement goals, because the trial would prohibit the

implementation of other interventions that could affect the study outcomes. Another factor contributing to the partnership's success was that the trial design and operational plan catered to the strengths of each partner. "It is not conceivable that each entity, whether it is an academic center or the health system, would excel in every part of what it takes to conduct a clinical trial," Huang said. As examples of how the trial design highlighted each partner's strengths, she cited HCA's centralized data systems and its ability to command a large number of hospitals, the experience of the academic partners at running large clinical trials and at conducting the highly specialized tests for bacterial isolates, and the longstanding experience with quality improvement studies of the Harvard Pilgrim Health Care IRB and that board's willingness to serve as a central IRB for 38 of the 43 hospitals. This last factor played a major role in securing all IRB approvals within 6 weeks.

Huang noted that one interesting feature of this trial was that its cost was approximately $40 per patient, compared to $10,000 or more per patient for previously reported intervention trials. Furthermore, the intervention itself is low cost because it involves swapping out bathing soap and adding a nasal ointment while eliminating the cost and effort of screening patients for MRSA colonization. Huang also noted that 42 of the 43 hospitals that participated in the study were community hospitals and these were distributed evenly across the nation, making it likely that the results of this trial should be generalizable across hospital settings.

Huang explained that there were no onsite investigators for this trial. "We did not parachute in people who had special expertise in research," she said. 'We leveraged the existing quality improvement infrastructure and gave [the hospitals] the protocols and computer-based training modules that [the hospitals] needed, and we had coaching calls twice monthly." In addition, the trial used pragmatic outcomes rather than forcing people to do extensive chart reviews. "We used routinely collected data that existed in the electronic health record to determine the outcomes of this trial," Huang said. Also simplifying the trial was the decision for all data to remain in the hands of the HCA hospitals. "We reached behind their firewall, did all of the analyses, and then only moved summary level data into our hands that HCA approved to maximize protection and privacy of patient data," Huang said.

IMPROVE CARE NOW NETWORK

The Improve Care Now Network was created to bring patients, families, and providers together to produce a system that would transform care for children with inflammatory bowel disease, Uma Kotagal told the workshop audience. The primary requirement for this learning health system was that research and health care delivery should continuously inform each

other in order to standardize care and achieve the best possible practice while reducing variation in outcomes. The framework for the network (see Figure 4-1) started with patients and clinicians creating a learning engine at the point of care, which is where data are collected and recorded in EHRs. The data are used to generate reports that support and highlight variations in practice.

A fundamental principle of the Improve Care Now Network, Kotagal said, is that data are collected systematically and at the point of care using an EHR. This minimizes the burden imposed on providers to collect data and allows it to be used for both quality improvement and research. Both patient-reported outcomes and clinical outcomes are recorded, collected, and analyzed, with the results being fed back to clinicians and patients for use in daily care. Outcomes data are analyzed for each center and displayed in graphical form, enabling each center to work individually but also to learn from each other in a collaborative fashion. In practice, this feedback-based system has increased remission rates to over 80 percent among more than 20,000 patients—representing some 35 percent of all children in the United States with inflammatory bowel disease—at 63 care centers.

Kotagal said that this process makes possible several types of research. Research on improvement includes studies on the factors that motivate clinicians, researchers, and patients and families to participate, contribute,

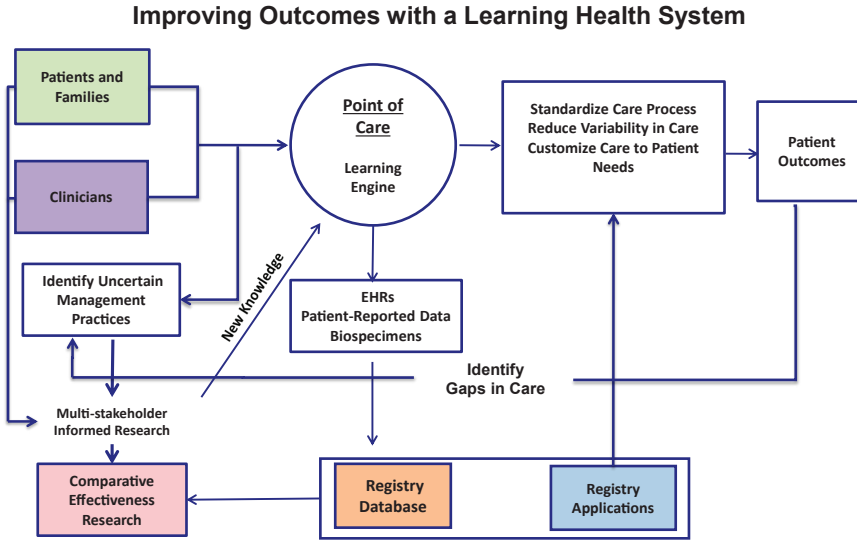

FIGURE 4-1 A schematic representation of the Improve Care Now Network.
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and work to improve their health care system. It also addresses questions regarding who uses the system and their goals and needs. Additionally, the network is used as a high-throughput system for comparative effectiveness research to identify which treatments work best for which patients and to extend the results of studies in adults to those involving children, she said.

An important feature of this system, explained Kotagal, is that it enables the research team to try to discern what is happening with the 20 percent of children with inflammatory bowel disease who are not doing well. Children are taught how to keep track of their own health and to understand the relationship between dietary changes and symptoms in a way that encourages learning. Ongoing studies using both patient-reported data and clinical outcomes data are looking at the potential for telehealth to improve self-adherence among children and to look for biomarkers that would predict remission rates. Kotagal noted in closing that networks such as this are critically important in the pediatric world because childhood diseases are rare. "It is difficult for us to learn at a single site what needs to happen," Kotagal said, adding that "for those health systems that have continued to participate in these networks there is a strategic commitment from their boards, their CEOs, and their clinical chiefs and an understanding that these networks offer us the best chance to rapidly bring new knowledge to the bedside to improve the outcomes for care."

EMBEDDED RESEARCH AT GROUP HEALTH

The process of embedding research into clinical care at Group Health takes a great deal of hard work, said David Grossman, speaking as both a researcher and the operational medical director of Group Health, a nonprofit health system with about 600,000 members in Washington State and $3.8 billion in annual revenue. Grossman said that two-thirds of Group Health's members receive care at 25 Group Health Medical Centers, which have used EHRs since 2005. The Group Health Research Institute (GHRI), established in 1983, has 75 resident and affiliated investigators and an annual revenue stream of about $50 million, more than 95 percent of it from grants and contracts. Core funding for the Institute comes to about 40 cents per member per month. The Institute is a member of several multisite networks, including PCORnet, and it publishes its research in the public literature. "This is a nonproprietary research center," Grossman said. "Institute researchers understand that they must thoroughly consider both the patients' and the business enterprise's interests in a research project before presenting it to the IRB to improve community health and health systems at large."

An important aspect of the research GHRI conducts is that it largely addresses practical problems facing health systems. "Group Health has a

long history of doing practical research," Grossman said, "and all research projects have to be important and salient to Group Health's members."

As an illustration of embedded research, Grossman described a project that originated with the Group Health CEO, who wanted to explore the potential impact of offering Group Health employees a new health plan with value-based benefits. "The questions he asked," Grossman said, "were, why do we have this standard approach to cost sharing that ignores variation in the value of individual services that are delivered to patients? Does it really make sense, for example, to charge the same co-pay for every drug when we know that some drugs have much greater value than others?" To test the impact of value-based benefits, Group Health is offering health plan incentives that encourage employees to engage in health-promoting activities such as exercise. Group Health also reduced co-pays for certain services such as the provision of highly effective medications to control hypertension, heart failure, asthma, and depression, with a goal of improving drug adherence and preventing complications from chronic disease. GHRI is evaluating the impact of the changes on employee health status and workplace productivity as primary outcomes, and on care quality, utilization, and total cost of care as secondary outcomes.

Grossman said that an important factor in the success of implementing this project was close collaboration between researchers and Group Health's human resources and health plan operating divisions to design the evaluation. In addition, early planning enabled the project to secure bridge funding for primary data collection while a grant application to AHRQ was pending. "This seed support from the Institute was absolutely critical for the timely start of the study," Grossman said. Other key factors were the strong collaboration with Kaiser Permanente as partners in the research and their willingness to serve as a control site and use of the existing HMO Research Network virtual data warehouse.

One of the biggest challenges facing the study, Grossman said, is managing leadership expectations, particularly about the timing and speed at which the study will produce meaningful results. Another challenge for researchers is taking into account how the organization might react if study results show that value-based benefits lead to improved health and care quality but at higher cost. "It is important to have frank discussions with organizational leaders about these considerations at the beginning of the process," Grossman said. For embedded research institutions like GHRI, ongoing major challenges include conducting research quickly enough for delivery system expectations and ensuring that research that involves disruptive innovation does not negatively impact the overall stability of the health care system. "We researchers can have fantastic ideas that are really cutting edge, but you can throw a huge wrench in operations by implementing too many changes too quickly," Grossman said. In closing, Grossman

noted that he and his colleagues have come to understand the value of engaging stakeholders, including patients and leaders, early in the design process and sharing interim findings even when they are tentative.

RESEARCH AND PRACTICE IN A SAFETY NET SYSTEM

Denver Health is typical of "safety net" health systems, Edward Havranek said, in that the patients that it serves are mostly poor, with fewer than half having commercial insurance, and as a result it has a very thin operating margin. Denver Health is atypical, though, in three respects: It has gone 22 years without an operating deficit, it has a strong academic affiliation with the University of Colorado that goes back to 1947, and it has an inpatient risk-adjusted mortality for each of the past 5 years that puts it among the top 5 percent of all health systems as well as outpatient blood pressure control rates that rank it in the top quartile. "This finding is robust across subsets within the hospital and over time," Havranek said, adding that the health system is not satisfied with being in the top quartile on measures of blood pressure control and that new data suggest how value-based propositions could improve that metric.

Two questions that a safety net health system faces are whether it should put resources into providing care of higher value and whether it should become a learning health system. "Let me argue here that the answer to both of these is yes when the measure of success is easily monetized and when the time to return is short," Havranek said. "When you don't have much operating margin to play with, you really have to be careful about what you invest in. We really want to invest first and foremost in things where we can carefully and explicitly prove to ourselves that we are not wasting money, and we need to know that quickly. We cannot be 2 or 3 or 4 years into a project before we discover that we are losing money."

An example of a quality improvement project that met these criteria involved testing an evidence-based approach for venous thromboembolic prophylaxis. After the project was initiated in 2008, there was a clear decrease in the amount of money spent on venous thromboembolic prophylaxis, while at the same time the incidence of postoperative deep vein thrombosis and pulmonary embolism went down. "In other words," Havranek said, "saving money improved outcomes by using the best available evidence, organizing and motivating people to work on this together, and giving it a high priority in a system such as ours. You really can do this kind of work."

In this final remarks, Havranek discussed why Denver Health joined the High Value Healthcare Collaborative, a voluntary, largely self-funded network of some 19 health care systems that for the past 4 years has been working on ways of improving the value of health care (see Figure 4-2). "One reason is that safety net providers are isolated," he said. "If you look

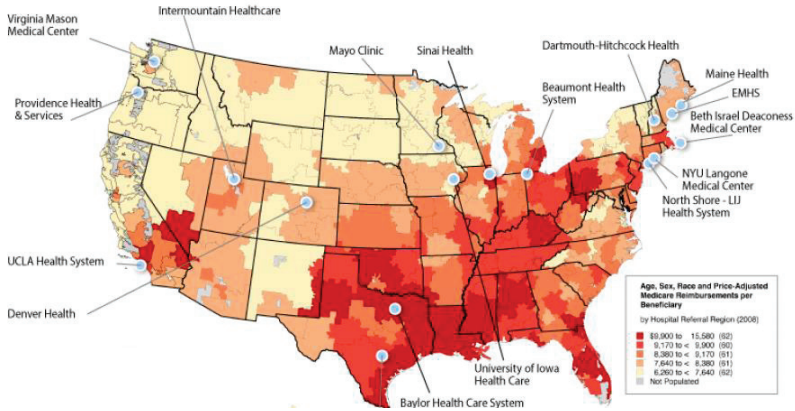

FIGURE 4-2 The High Value Healthcare Collaborative.
SOURCE: Reprinted with permission from the High Value Healthcare Collaborative.

around our communities, we don't have competitors—nobody wants our patients. That lack of competition and local collaboration are both things that we would predict would diminish uptake of innovation. Being able to compare ourselves to the other members of the network creates a context for our efforts that is important."

Another important reason for being part of a network dedicated to improving care while reducing costs, even when it uses scarce resources, is that it enables staff to "do the right thing," Havranek said. "I think we forget that one of the most important aspects of quality, value, diffusing research, new knowledge, and doing things better is that it appeals to that very uniquely moral and idealistic motivation for doing what we do."

Returning to what Havranek considers a failure—the inability to improve its hypertension control outcomes beyond being in the top quartile—he described a study that Denver Health, Kaiser Permanente, and the U.S. Department of Veterans Affairs (VA) conducted, which looked at the effect of home-based blood pressure monitoring. The protocol called for every patient in the study to receive a blood pressure cuff and instructions on how to use it and transmit the data to the health system. Once per week, a pharmacist reviewed the data and called patients to tell them what to do with their medications. The result of this intervention was to reduce systolic blood pressure by an average of 7 millimeters compared to controls. "That was more effective than any single drug that we could give," Havranek said.

The failure came when he went to Denver Health's administration and was told that the cost of this intervention, which Havranek said would raise its quality metric into the top 10 percent, was too high. "So we have

a problem," he said. "We have a research-based solution that we demonstrated within our system and we cannot deploy it. Our partners at Kaiser and the VA have the financial structures where they can justify doing that sort of intervention, and we cannot." The lesson here, he noted in closing, is that "our reimbursement system is fighting against us as we try to bring research findings into the clinical realm."

DISCUSSION

Harold Luft started the discussion by noting that this last example highlights the tension between researchers and the organizations in which they work. "From the researcher's side," he said, "being in an organization makes the research more valuable. But what we are hearing is that speed and the ability to answer important questions quickly is a challenge for the research side, yet it is also the way to provide more value to the organization." James Rohack from Baylor Scott & White Health agreed with this idea and asked if there can be a national solution to the tension between research and operations or if everything has to be done locally in individual communities. Havranek replied that he thinks this tension is not real—that most researchers in health systems understand the need to balance knowledge generation with operational and financial efficiency. Grossman said that if there is a tension it is positive, as it motivates the different constituencies in a health system to work and communicate effectively together, creating a stronger system overall.

Kotagal disagreed, saying there is a tension that has to do with timelines and producing pragmatic results versus developing ideal solutions. She said that another type of tension arises when trying to generalize these small-scale examples. "I do not think there are good designs for how to do end-to-end research," she said. "There are designs, but they have not been replicated to say we know how they work and to scale them. That is where we need to go." Huang also thought that this tension between research and operations exists but that, as the examples presented show, those tensions can be overcome when thought leaders and academics work together with a health system that desires to make quality improvement a priority.

Huang commented on the importance of involving networks of health systems in research because of the large number of patients that such networks can bring into a study. She said that such collaborations provide the speed that health system administrators want as well as the ability to disseminate results more quickly.

In response to a question from Robert Jesse from the VHA about the boundaries between operational and clinical research with regard to the Common Rule, Havranek said that IRB issues are an impediment to doing operational research. "Depending on where you are, it is anywhere from

a minor to a major annoyance," he said. "I think there is some ethical imperative in improving the system and to the extent that we impede the improvement in the system we are doing something that is probably unethical. I think systems need to recognize that when there needs to be a very quick expedited process for demonstrating that things are of no or little risk to individual patients and that the risk in not doing it is substantial, we need to move ahead. There needs to be a real lifting of this cloud over us that is imposed by the IRBs."

Jonathan Tobin from the Clinical Directors Network and Rockefeller University asked if there was a way to look at some of the organizational variables that may facilitate or inhibit uptake by health systems. Huang said that this is where networks of health systems, such as the one that conducted the REDUCE MRSA trial, can play an important role by providing many settings in which to conduct research. She also noted that it is important to ask questions about dissemination and implementation at the outset of a project rather than as an afterthought.

Patrick Conway from CMS continued this line of questioning by asking if the panelists had any ideas on how to accelerate the pace of change beyond these individual great examples of success. Kotagal replied that those that pay for health care have to start paying for innovation. "Currently, our streams of revenue and incentives are dissociated," she said, adding that this is not the case in most other industries. "It would be important for people paying for health care to require continuous innovation," she added. Grossman said that researchers need to be more explicit in laying out the business case along with the clinical case when they design a study and present results to administrators.

5

Creating the Conditions for Sustainability

KEY SPEAKER POINTS

- The first step in blending knowledge into the flow of work, Brent James said, is to identify a high-priority clinical process—one for which research will have a relatively rapid impact on care delivery performance as measured in patient, clinical, and cost outcomes—and build an evidence-based best practice protocol which will admittedly be imperfect but that creates a low-energy state in which the best practice is the default choice that happens automatically unless modified intentionally by the physician.
- Thomas Garthwaite said that the best physicians for his organization are the ones who embrace a dialogue around clinical excellence and that engaging all members of the health care team as active research participants improves retention and boosts morale.
- Being an organization known for research aimed at improving care can help grow market share, Garthwaite said.
- A critical piece of a sustainable research enterprise, Garthwaite added, is the ability to estimate impact, which not only provides feedback to physicians but also offers justification to management.

- What patients want from research, Sally Okun said, is to believe that the health care professionals who participate in research are going to bring the knowledge that they gain from that research to bear on their care. What patients will not tolerate, she added, is being asked to participate in research that does not eventually benefit them or future patients.
- One model of sustainability has a value proposition of what can be called reasonable value at acceptable cost, Lewis Sandy said, while another creates an environment in which research activities pay for themselves through continuous learning and improvement and are positive contributors to a return on investment.

This session, moderated by Lewis Sandy, executive vice president for clinical advancement at UnitedHealth Group, explored the business and financial issues and opportunities presented to organizations by moving toward continuous learning and improvement. Sandy said that there are at least three changes in the context in which health care exists today that could contribute to sustainability: payment reform and the alignment of incentives, the changing role of the consumer, and transparency.

Brent James, executive director of the Institute for Health Care Delivery Research and vice president of medical research and continuing education at Intermountain Healthcare, started the session with a presentation on how to create the conditions for sustainability. Three respondents—Thomas Garthwaite, chief operating officer and vice president of the HCA Clinical Services Group; Sally Okun, vice president for advocacy, policy, and patient safety at PatientsLikeMe; and Karen DeSalvo, National Coordinator for Health Information Technology—then provided their insights on the issue of sustainability. An open discussion followed the panel's presentations and comments.

THE LEARNING HEALTH CARE SYSTEM

Before discussing the topic at hand, Brent James recommended a text called *Realistic Evaluation* that proposes an alternative to the randomized clinical trial that may be useful for evaluating context-specific interventions (Pawson and Tilley, 1997). He also recommended a second text, *Meta-Analysis by the Confidence Profile Method*, that also describes methods that could be used to construct more appropriate designs for testing the complex interventions that this workshop is discussing (Eddy and Shachter, 1992).

In 1991 James and his colleagues conducted a large randomized clinical

trial designed to assess the comparative effectiveness of using an "artificial lung" versus standard ventilator management for acute respiratory distress syndrome. They discovered that there was huge variation in the control arm of the trial with regard to the ventilator settings used by expert pulmonologists, something that had never been noticed or studied. As a result, the researchers created a protocol for ventilator settings in the control arm of the trial. James mentioned this study to illustrate the point that Level 1, 2, or 3 evidence on best practices is available only about 15 to 25 percent of the time, depending on the specific condition, and that percentage can range from close to zero to up to half of the time (see Figure 5-1).

James also noted that the rate of production of new knowledge exceeds the capacity of the unaided expert mind to assimilate all of that knowledge, creating a major source of variation in practice. In 2009, for example, the results from just under 30,000 randomized controlled trials (RCTs) were published in the medical literature, with the results of 75 trials and 11 systematic reviews appearing in the literature every day. As a result, expert consensus is often unreliable. In addition, guidelines rarely if ever guide practice, and even though physicians say they are useful and that guidelines change their practice, they in fact do not change practice, perhaps because no guideline, with rare exception, perfectly fits any individual patient.

An important question that health care faces is how to blend knowledge into the flow of work so that access to knowledge at the point of care does not rely solely on human memory. James said the first step is to identify a high-priority clinical process and build an evidence-based best practice protocol, which will admittedly be imperfect. Intermountain Healthcare then uses what James characterized as 20 different tools for blending that

1. Rapid impact on care delivery performance (best medical result at lowest necessary cost)
   a. internally funded—patient care dollars
   b. publication, external grant funding = "icing on the cake"
2. Investigator-initiated research
   a. traditional academic model
   b. external grant funding
3. Collaborations with external investigators
   a. multicenter trials
   b. local universities
   c. requires an internal "champion"
4. Industry-based groups (pharma, device manufacturers)
5. "Research" done by affiliated medical

FIGURE 5-1 Five levels of clinical research at Intermountain Healthcare.
SOURCE: Reprinted with permission from Brent James.

protocol into the clinical workflow. What this does, he explained, is create a low-energy state in which the best practice is the default choice that happens automatically unless modified intentionally by the physician. The 20 tools include standing orders, clinical flow sheets, patient work sheets, and other action lists. Together, these tools turn evidence-based best care into routine care.

One of these tools is an embedded data system that tracks protocol variations and both short-term and long-term patient results. A critical constraint here is that Intermountain Healthcare demands that clinicians vary the treatment protocol on the basis of each patient's individual needs. The resulting data are used to create a feedback loop that constantly updates and improves the protocol, a process that is transparent to frontline clinicians. These cycles of data collection and analysis also generate the formal knowledge that will go into peer-reviewed publications. Applying this type of learning trial design to acute respiratory distress syndrome patients led to a change in protocol that increased survival from 9.5 percent to 44 percent with a reduction in costs of approximately 25 percent and an increase in physician productivity of almost 50 percent. "This was the first time since this syndrome was defined in the 1960s that anybody had shown an improvement in clinical outcomes," James said. He added that Intermountain Healthcare has used this process with more than 100 different clinical practices to produce dramatically better clinical outcomes and, in most cases, at dramatically lower cost.

There are several lessons from these experiences, James said. First, this knowledge management system saves lives, which is the real measure of success. Second, James observed that in his experience better care is almost always less expensive, and he estimated that the Intermountain system saves $350 million per year thanks to these improvements, a dramatic return on investment.

Because of these outcomes, Intermountain Healthcare has used this knowledge system as a foundation that has enabled it to make clinical quality its core business strategy, James explained. Beginning in 1996, Intermountain conducted a key process analysis of more than 1,400 clinical processes, with each process being a way that a patient experiences care. Of these, 104 processes—42 outpatient and 62 inpatient—were identified as accounting for about 95 percent of all care the system delivered. By 2000 Intermountain had a full rollout of this knowledge system and full administrative integration. One problem that occurred was that, despite having a fully integrated and widely used EHR and full activity-based costing, there were still large pieces of data missing that were essential for clinical management. In fact, these missing data were the reason that Intermountain's first two initiatives for clinical management failed. The remedy was to deploy a methodology for identifying critical data elements for clinical

management and then to build those into clinical workflows, James said. Intermountain also created 58 clinical development teams, each led by a physician who has time allotted for this role, and it hired 17 statisticians to work with these teams.

The clinical processes tracked by these teams account for approximately 80 percent of all care delivered within the Intermountain system. Every patient is followed longitudinally, and the record is stored in a condition-specific patient registry. James noted that the system currently has about two petabytes of data that are used in routine clinical management. All told, these activities and the data storage component cost about $7 million annually, and they enable James and his team to validate every published result in the context of the Intermountain system. "My job," James said, "is to make sure that my physicians and nurses can say to a patient that, in our hands, 'This is what you will get if we pursue this particular clinical course.'"

Another step that Intermountain has taken is to divide its clinical research effort into five levels.

Level 1 research has a relatively rapid impact on care delivery performance as measured in patient, clinical, and cost outcomes. "This is the only area where I can justify spending Intermountain patient care dollars," James said. Priorities for Level 1 research are set by Intermountain's clinical development teams, and no external funding is required, James said, although he added that once this type of data-driven research effort is established, it starts to attract significant amounts of external research funding. James said that the most productive clinical development team at Intermountain, which focuses on women and newborns, published 23 peer-reviewed articles in 2013, while the three cardiovascular teams together published 64 peer-reviewed articles. The point of highlighting this productivity, he said, is that Intermountain's internal research effort is outperforming most academic institutions. His goal, he added, is that Intermountain's clinical development teams publish 1,000 peer-reviewed Level 1 publications in a single year.

Level 2 research is the standard academic model of grant-funded, investigator-initiated research. James said that if someone proposes a major research project that has significant external funding but does not fit with Intermountain's list of internal priorities, he will turn that project down. "It is not the money, but the intellectual capital, the time and attention needed," he said. Level 3 research involves multicenter trials and other forms of collaboration with external investigators and local universities. Each Level 3 project requires an internal champion. Level 4 research is funded by and conducted for industry-based groups, such as pharmaceutical companies and device manufacturers. Level 5 research is done by affiliated medical staff who are independent of Intermountain.

In summary, James offered three ideas for driving sustainability. First, make the business case. "That means you are going to have to explicitly track cost outcomes in every study that you perform," he said. In his case, he benefits from Intermountain's activity-based costing system, which generates patient-level data. His second idea was that data collection should be embedded in the normal workflow, which he said is essential from both an operational and a research standpoint. James's final suggestion was to make the case to senior management that this research is just part of routine operations and that it should be funded as such. He closed his remarks with an old Yiddish proverb: Better has no limit.

EVALUATION AND IMPROVEMENT OF CARE DELIVERY

In his remarks, Thomas Garthwaite spoke about how to conduct and sustain the type of research that James discussed in health systems that are not at Intermountain's level of development, which would include doctors and community hospitals that are not part of a system. HCA, he explained is a large system containing primarily community hospitals, with only 2 of its 165 hospitals being academic medical centers. HCA credentials 65,000 physicians, although only about 30,000 are active at any one time, and about 3,000 of these are employed by the hospital. Garthwaite noted that employed physicians are not necessarily engaged physicians.

HCA's program to partner with physicians to detect and reduce unintended variations in care, both between patients and from the standard of care, is called Clinical Excellence. When this initiative began, HCA executives were worried that suggesting that the quality of their care could be improved might prompt physicians to take their patients to other hospitals. The challenge, then, was to create a data-driven quality-improvement program in a way that engaged physicians rather than driving them away. A pilot study in Nashville, Tennessee, showed that physicians responded positively to accurate, data-driven feedback on how they were doing, coupled with dialog based on the evidence in the medical literature. In fact, Garthwaite said, HCA found that when physicians were engaged in this manner and the changes they suggested were implemented, they became leaders in creating and leading system improvement.

The Clinical Excellence initiative that Garthwaite and his colleagues are creating at HCA starts with metrics generated by its substantial data systems that are focused on where variation occurs. From these metrics, teams at each facility decide which areas they want to target and then work to support preparation, implementation, and tracking. When teams in the field have a question, HCA staff members conduct a review of the literature about the specific topic in question, and the teams then set a targeted performance level using the literature to set what is a realistic goal regarding

clinical performance. A critical part of this process is structuring a plan and supporting it with members of a project management group that is dedicated to this purpose. Data that measure the progress are then displayed in near real-time on a dashboard (see Figure 5-2) that measures, tracks, and guides the management of clinical performance and provides continuous feedback, to both the physicians and management.

Garthwaite said that partnerships with government agencies, academic institutions, professional organizations, and patient-centered nonprofit organizations play an important role in developing and sustaining a learning health care system for community hospitals. As an example, he discussed a project conducted in partnership with the March of Dimes that looked at the elective induction of deliveries before 39 weeks of gestation. This study, using HCA system data, showed that babies born at 37 and 38 weeks had a significantly higher risk of requiring admission to the neonatal intensive care unit. HCA published the results of this study (Clark et al., 2011), and guidelines based on the study have been adopted by The Joint Commission and most insurers.

Concerning business imperatives, Garthwaite said there are a number of factors that can contribute to sustainability. Reiterating something that had already been stated by other speakers, Garthwaite said that good quality care is the most effective and efficient care, with reduced variable cost. HCA's work has led to the increased use of high-value medications, reduced complications, and shorter lengths of stay. Another benefit from a business perspective is that nurses who become active participants in this research feel more valued and proud of their efforts, which improves both retention and morale. Reputation enhancement is another benefit that can help grow market share.

Garthwaite said that he believes it is important to create an accountability structure that reviews progress on a regular basis. "It is critical that the improvement in outcomes is measured, shared, and celebrated," he said. Quantifiable quality and economic impacts provide feedback to physicians and management.

Concluding his remarks, Garthwaite said that a key challenge for the future will be developing real-time decision support that is valued by physicians and other providers because any investment in their time is offset by an improvement in the quality of care. He said that creating decision-support tools that can meet those requirements will be important for driving evidence to the bedside and identifying the most effective treatments.

IMPROVING CARE FOR ME AND PATIENTS LIKE ME

The focus of Sally Okun's talk was an equation that she believes leads to a new way of thinking about how patients and patients' perspectives can

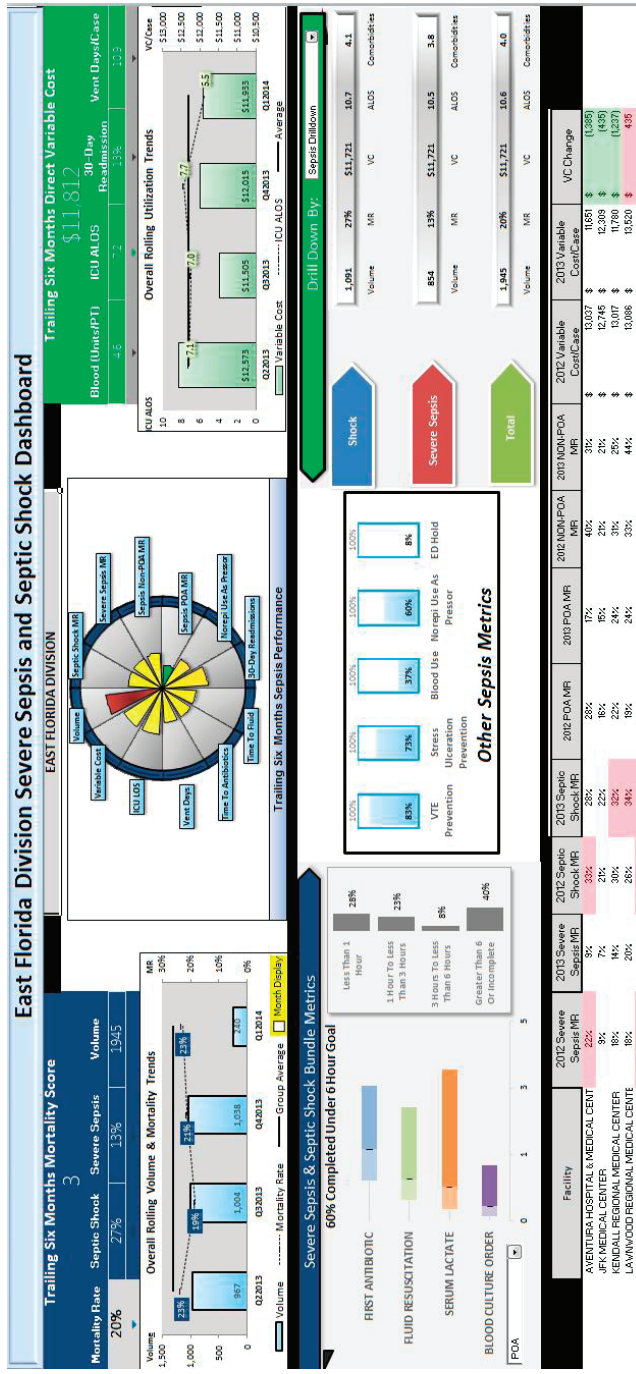

FIGURE 5-2 HCA's dashboard links performance and outcome.
SOURCE: Reprinted with permission from Thomas Garthwaite.

have the most significant impact on a sustainable learning health system. This patient-centric value equation states that shared data plus shared decision making equals shared accountability, and it can be applied to every level of the health care system, from the patient level to the institutional level to the community. "Without patients, you will not have a continuous learning health system, and if we don't embrace that notion right from the start, we are probably not going to get very far," Okun said.

Okun's company, PatientsLikeMe, has been in business since 2004 and currently has more than 250,000 patients with some 2,000 conditions reporting to the site. PatientsLikeMe is research oriented and research based, and Okun said that what patients want from research is to believe that the health care professionals who participate in research are going to bring the knowledge that they gain from that research to bear on their care. She added that surveys have shown that most individuals would share their medical information if it was going to be used to improve their health or someone else's health. However, when Americans are asked if they believe that this is actually happening, most say they do not know. "I think we have a long way to go to help patients and families in our communities to begin to understand that research actually is something that they should be engaging in," Okun said, "but we should also give them the opportunity to engage in it seamlessly." She suggested that research should be part of the routine of care and that patients should take it for granted that they are participating in a learning health system on a regular basis.

Sarah Greene had mentioned earlier that patients do not like the idea that the health system is still learning. What would help alleviate that concern, Okun said, would be to convey the message that the health system is learning from each patient so that health care professionals can do their job to the highest degree of excellence. The fundamental question that PatientsLikeMe tries to answer for patients pertains to this issue: Given my status and data, what is the best I can hope to achieve, and how am I going to get there?

Okun explained that basing decisions on the patient-centric value equation does not imply that clinical data should be shared with patients so that they can make informed decisions and get some outcome. What it does imply is that the patient and physician should each share data in a way that enables them to come together to understand potential benefits and burdens of a particular course of action and how those will impact the ability to achieve the desired outcome.

Most health care systems, Okun said, do not have a mechanism for systematically collecting patient-generated data. "We all collect data about what patients say, but not in a way that helps us learn much about the next patient that might come along who maybe had the same subjective experience of that same chief complaint," she said. "My charge here is to suggest that we can quantify patient-generated data in ways that let us aggregate

FIGURE 5-3 PatientsLikeMe's InstantMe history tool for a patient with bipolar disorder.
SOURCE: Reprinted with permission from PatientsLikeMe, Inc.

it, collect it, learn from it, and then ultimately we have measured it in such a way that we can then apply it broadly." Okun suggested that it would be powerful indeed if it was possible to bring together patient-generated data and clinical data in a systematic way that would inform decision making for individual patients.

Referring to the last part of the equation—shared accountability—Okun said that too often the expectation is that patients cannot rise to the occasion when it comes to accountability. "I'm going to challenge you to accept that they definitely can," Okun said, adding that she had drawn that conclusion from what she and her colleagues see every day on PatientsLikeMe, where patients provide data on what it is like to live with a wide range of conditions. She added that the shared-accountability piece is important because medical care is not about the clinician getting a good outcome—it is about the patient getting a good outcome in the specific context of each patient's life.

PatientsLikeMe spends a good amount of time looking at reported outcomes from patients to see if there are clinical endpoints and surrogate endpoints in order to learn if particular types of patients report side effects and outcomes. One of the simplest tools it uses with every patient is the InstantMe tool, which asks one simple question: "How are you doing?" Patients record the answer to that question one or more times a day and bring this information into their clinical encounters (see Figure 5-3). Patients report that this format brings their information to life in a way that their health care professionals can easily assimilate and use.

As a final message, Okun said that patients want to see their data coming to life in a way that is useful to their clinicians. What she would like to have happen is for the health care community to come to PatientsLikeMe and work with it to design tools that will help it better understand what patients are experiencing in their lives away from the clinic. "If you begin to embrace that notion," she said, "you will find that patients are ready, willing, and able to participate in a variety of questions and research studies that you might have in mind and that actually could bring insights that you will just never get in any other way."

LEVERAGING DATA FOR IMPROVEMENT

Karen DeSalvo started her talk by saying that Okun is right about patients knowing quite well what is going on with them and that asking them one simple question—How would you rate your health?—can help predict how that patient will do going forward. "Of all the things that we can capture and know," she said, "please don't forget what patients are trying to tell us because it is as powerful as what we can capture."

DeSalvo then described the Office of the National Coordinator for Health Information Technology (ONC), an agency formed in 2004 as a way to develop a national strategic plan and approach to health information technology. There was an infusion of capital associated with the economic stimulus and passage of the Health Information Technology for Economic and Clinical Health, or HITECH, Act, which charged the agency to work with the private sector on building an infrastructure that would allow for standard data capture across the health care environment for certain eligible providers. Money was also made available to build the workforce that would manage this system and help utilize the resulting accumulated data. DeSalvo noted that 9 out of 10 hospitals have had the opportunity to participate in the meaningful use program, with the result that there is now rapid uptake of certified, standardized EHRs in the United States. This, she said, is a dramatic increase compared to other nations that have not made this type of investment.

DeSalvo said that it is increasingly clear that some parts of the health care continuum do not have the opportunity to contribute to the grand amount of data in the nation's learning health systems. "Importantly, that is where some of the most vulnerable and some of the most expensive patients are in our community," she said. Reaching those places, which include long-term post-acute care facilities, behavioral health, dialysis, the emergency medical services sector, and some of the smaller health systems that are not capturing data on the scale of an Intermountain Healthcare or HCA, is a national imperative because without the entire picture, it will be a major challenge to achieve the triple aim of having better care at a

better price and improving the health of the population as a whole. It has also become clear, she said, that there are opportunities to improve the usability of EHRs in ways that will increase safety and enable clinicians to do their jobs better.

Interoperability is a priority for ONC, DeSalvo said. "We must create an infrastructure that is open enough that if you collect information in your database, in your health care environment, whatever that might be, that it can be free and flow to the benefit of that patient across the care continuum," she said. This is challenging work because it requires defining the right standards and building the right systems so that they are sustainable over time and not just experiments in closed systems. It requires defining privacy and security in a way that is palatable to everyone, that protects people and their data, and yet that allows the data to be put to good use. It also requires creating the right governance infrastructure, which involves coming to some agreement about who gets into the system and who does not and what happens to those who do not follow the rules.

DeSalvo ended her remarks with some words of caution concerning big data. "Big data is really tempting," she said. "It is tempting to anyone in the private sector to begin to play with, but you need to walk into this with some a priori hypothesis that is testable. Let's be careful with how we are using this data." She also said it is important to be thoughtful as the PCORnet infrastructure is being developed about not over-burdening the frontline health care professionals because, at the end of the day, it is a health care system and its foremost responsibility is to care for patients. "We certainly want to make sure that we are not over standardizing and structuring data in such a way that we lose context and narrative or prevent that care environment from being the rich place that patients and providers so enjoy," DeSalvo said. Returning to her initial comments, she again stressed how important it is to capture the rich and valuable information that patients have to contribute.

DISCUSSION

To start the discussion, session moderator Sandy said that the message he heard from the presentations was that there are two models for sustainability. The first had as its value proposition what he called "acceptable cost, reasonable value." With this model, the activities of a learning health system are not too costly, and they produce some value. Some of that value is easy to measure, some not, and some could tie into an organization's nonprofit status. The key is that these activities are not a big strain on the budget, and that makes them sustainable. The second model of sustainability, Sandy said, is one in which the continuous learning and improvement system should pay for itself and be a contributor to return on investment.

James and Garthwaite both agreed with Sandy's assessment. James went on to say that that Intermountain Healthcare's efforts are based on the second model. He said that the system's chief financial officer set a goal that its learning activities should produce enough return on investment so as to limit the health plan's rate increases to no more than 1 percent above the consumer price index by 2016. Intermountain nearly met that goal in 2013 and has likely surpassed it in 2014. He noted that in 2013, six projects alone accounted for $39 million in savings. Where this type of activity will not work well is in a fee-for-service system, which actually punishes these kinds of improvements because they reduce utilization. "That is why Intermountain is shifting to a capitation model as rapidly as we reasonably can," James said. He also said that there is now an opportunity to apply this model to the entire health care system and noted that it would have a tremendous financial impact if it avoided even half of the estimated $1 trillion in wasted expenses the nation spends annually on inefficient and ineffective procedures.

Jeremy Boal of the Mount Sinai Health System said that he is impressed by the handful of health systems that seem to have operationalized this second model and that have built return on investment into the core of their operations, but he wondered why so few health systems are following in these pioneers' footsteps. "What is holding us back," he asked the panelists, "in being able to make the kinds of transformations that you and a few other key organizations have been successful in making?" James replied that he believes that the key is to spend the time and effort to build an infrastructure, which includes data systems, that makes it easier to accomplish an organization's goals and that provides transparency to both patient and clinician. "If you build the right infrastructure, it makes it easy to do it right," James said.

James Rohack of Baylor Scott & White Health commented on the difficulty in getting different EHR systems to talk to one another, which even extends to the U.S. Department of Defense and VA systems not being able to communicate with one another. The question he had for DeSalvo was that, given that ONC is coming out with rules and regulations that the federal government cannot seem to implement itself, "What is the solution, and when will we see that these electronic systems will be able to talk to each other?" DeSalvo, who had been at ONC for only 3 months at the time of the workshop, replied that she understood his frustration from her own experiences as a physician dealing with different EHRs but said that the success story so far is that there are now data that are available to be shared, thanks to the standards that ONC has developed. The goal for ONC now, she said, is to work with the private sector to decrease the technical optionality that makes interoperability so difficult and to develop an open architecture for data exchange. DeSalvo also said that the govern-

ment has not given up on getting the U.S. Department of Defense and VA systems to be interoperable and that she is intent on making that happen.

DeSalvo went on to say that ONC's efforts now are focused on identifying a core set of information that matters for patients and clinicians in much the same way that physicians do when they prepare index cards for each of their patients that they carry with them. "We have to get focused and serious and parsimonious about what it is that matters," she said. "What are the measures that matter? What are the core pieces of information that matter for the clinical environment that we need to share? That begins to simplify the conversation about interoperability."

In response to a question about why more work is not being done to reduce fixed costs, given that they account for 70 to 80 percent of a health system's budget, Garthwaite said that one reason is that variable costs are more easily calculated for specific interventions. Having said that, he added that there are opportunities to reduce fixed costs, perhaps by limiting the "technical arms race," where each hospital feels it needs robotic surgery capabilities to remain competitive in attracting the best surgeons. James said that Intermountain does track fixed costs, and he estimated that over half of the savings his group has realized are from fixed costs. For example, Intermountain's initiative to reduce elective labor inductions saved approximately 45,000 minutes in labor and delivery time, enabling the system to deliver some 1,500 more babies each year without adding any capacity.

Bray Patrick-Lake, the patient representative on the PCORnet coordinating center executive leadership committee, asked James if Intermountain involves patients in setting the priorities that determine which research projects are approved and which are rejected. James replied that each of the clinical development teams, which set the research agenda, involve patients directly. Patient input is also an important part of Intermountain's clinical operations, he added. Patrick-Lake also asked James how Intermountain balances the speed of implementation against the time it takes for research to be published in the peer-reviewed literature. James said that Intermountain is not very good at publishing because it is not an organizational priority—implementation is. "As soon as we get the answer, it's on to the next question," he said.

After some discussion that reiterated the message that patients have a great deal to contribute to a learning health care system, Okun said that it is important for the research community to understand that patients will be intolerant of research that does not go anywhere. "They want to see some outcomes that are going to benefit them," she said. James agreed strongly. "Any organization that does not put the patient outcomes first should not be allowed to treat patients," he said. "If your research comes before your patient outcomes, you should not be allowed to treat patients."

6

Addressing Issues of Regulatory Oversight

KEY SPEAKER POINTS

- A new paradigm for regulatory oversight assumes, according to Nancy Kass, that it is desirable to increase the quality, value, fairness, and efficiency of health care, health care systems, and institutions and that any learning that does take place must proceed in an ethical way.
- Quality-improvement studies need to take advantage of better experimental designs, Susan Huang said, and they need to be done in multiple settings. Quality-improvement researchers, she added, need to "stop being afraid of randomization" because they fear that a randomization trial design inevitably leads to the need for a protracted institutional review board approval process.
- Well-designed studies can be turned into rigorous academic publications quickly, said Rainu Kaushal, and researchers can translate their findings into actionable information for policy makers and health care stakeholders without jeopardizing publications.

This session took on the challenges and opportunities related to the legal and ethical oversight of integrating care and research efforts. Nancy Kass, the Phoebe R. Berman Professor of Bioethics and Public Health at the

Johns Hopkins Bloomberg School of Public Health and Berman Institute of Bioethics, opened the session with a discussion of an ethical framework for learning health systems. Susan Huang of the University of California, Irvine; James Weinstein, CEO and president of the Dartmouth–Hitchcock Health System; and Peter Margolis, a professor of pediatrics and the director of research at the James M. Anderson Center for Health System Excellence at Cincinnati Children's Hospital Medical Center then provided some examples of approaches to dealing with oversight challenges. An open discussion, moderated by Barbara Bierer, the senior vice president for research at Brigham and Women's Hospital and a professor of medicine at Harvard Medical School, followed the presentations.

Before the first presentation, Bierer commented that as the discussion moves along the continuum of research to practice or practice to research, it is important to remember that the regulatory guidelines of the Office for Human Research Protections (OHRP) define research as a systematic investigation including research, development, testing, and evaluation design to develop or contribute to generalizable knowledge. This definition, she said, means that quality improvement projects conducted internally still fall under the provisions of the Common Rule if the intention is to publish the results and make them generalizable.

AN ETHICAL FRAMEWORK FOR LEARNING HEALTH SYSTEMS

Nancy Kass proposed a new way of thinking about ethics and human research, one that moves away from the current "distinctions paradigm," which is based on the premise that ethics and oversight should be based on whether an activity meets the regulatory definition of research. Instead, Kass proposed a "learning health care system paradigm" in which research and care are integrated and for which ethics and oversight decisions are based on whether there are moral concerns that would be deduced through a variety of considerations.

The ethics and oversight of research came to the public's attention in the 1960s and 1970s as a result of research ethics problems that gained prominent attention in the media, mostly notably the Tuskegee Syphilis Study. Given the context out of which they emerged, the regulations that were developed strongly emphasize protections. For example, IRB review and informed consent are now required for any kind of human research that meets the criteria that Bierer mentioned in her introductory remarks. These regulations rely on being able to define and identify the activities to which those regulations apply, Kass said. "Anything that met the regulatory definition of research needed oversight," she explained. "Anything that didn't, such as clinical care, did not."

Kass then listed five criteria that have been used for distinguishing re-

search from clinical care (see Figure 6-1). Two of these criteria are defined by regulations, and the other three reflect common themes found in the scientific literature concerning morally relevant criteria that distinguished research from clinical care. Kass said that the three claims from the literature all make sense logically, but in practice those distinctions turn out to not be true in many cases. For example, one claim in the literature is that research has more risks and uncertainties than clinical care, but in fact, Kass said, "when you start to look at the data, there is a remarkable amount of uncertainty and risk in clinical delivery as well."

Based on the work that Kass and her colleagues have done, she believes that the distinction paradigm does not work. "We challenge the view that using distinction for policy about what needs ethical oversight should be sustained," Kass said, "There are practical, conceptual, and moral problems in relying on distinction." From a practical perspective, too often IRBs look at regulatory definitions, but still do not know how to handle specific research proposals, and there can be disagreements between an IRB and OHRP that delay important research. Conceptually, the distinction is problematic because the definitions do not consistently put the same types of activities into the same categories, and from a moral perspective, the distinction paradigm leads to overprotection of low-risk research and underprotection from unsafe or unproven care.

To argue for a new paradigm, Kass described her team making two assumptions. The first is that integrating learning into health care is an ethi-

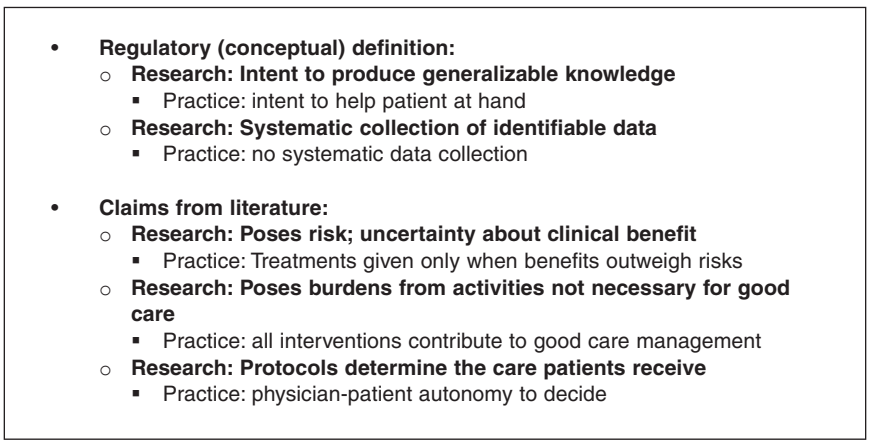

FIGURE 6-1 "Distinction paradigm" approach to distinguish research from clinical care.
SOURCE: Reprinted with permission from Nancy Kass.

cal good. "It is a good thing to increase the quality, value, fairness, and efficiency of health care, health care systems, and institutions," she said. The second assumption is that any learning that does take place must proceed in an ethical way. "We must always be thoughtful about what kinds of activities are compromising patients' rights and interests and what kinds aren't and what kinds of safeguards we can build in, in addition to informed consent, that help make an impact on patients' rights and interests," Kass said.

From these assumptions, Kass and her colleagues developed an ethical framework for the learning health care system that has seven obligations:

1. Respect the rights and dignity of patients/families.
2. Respect the judgment of clinicians.
3. Provide each patient optimal clinical care.
4. Avoid imposing nonclinical risks and burdens.
5. Address unjust health inequalities.
6. Clinicians and health care institutions should conduct continuous learning activities
7. Patients and families should contribute to the common purpose of improving the quality. and value of clinical care.

The first obligation is obvious, Kass said, and it is a central consideration for all IRB deliberations and for clinical care. She emphasized, however, that not every decision is of equal moral relevance to patients and that the duties of respect go well beyond autonomous decision making by patients. For example, it is of great moral importance for a patient to be involved in a decision about whether to have back surgery or physical therapy to alleviate back pain, but it is of little importance as to what kind of hand sanitizer the hospital uses. Kass added that one issue concerning autonomous decision making is that all considerations here get lumped into informed consent. "I don't mean to minimize the importance of informed consent," she said, "but there are so many additional ways in which we can demonstrate respect to patients."

The second obligation—to respect clinical judgment—gets to the point that the goal of quality improvement research should not be to take all decision making out of the hands of physicians. This obligation requires asking whether an activity affects a clinician's ability to use his or her own judgment when it advances the medical and autonomy interests of the patient. There is, however, a tension that exists between honoring this obligation and taking into account the evidence that clinicians' judgments can be biased, conflicted, or less than fully informed, Kass said.

The obligation to provide patients with optimal clinical care, Kass said, raises the question of how a learning activity will affect the net clinical benefit to patients when compared to the benefit of the "ordinary care"

that they would receive in the absence of learning. Similarly, the obligation to avoid imposing nonclinical risks and burdens on patients is judged by examining the kinds of burdens that patients are being asked to undergo in a learning activity or research project versus the burdens that patients undergo when receiving "ordinary care."

Kass said that the obligation to address unjust inequities might be "a little bit more out there," but she noted that as an organization identifies an agenda that it wants to take on, it needs to be mindful of a duty to think about the injustices that happen in health care. The questions to ask, she explained, are whether a learning activity will exacerbate or reduce unjust inequalities and if an activity can be structured to advance the goal of reducing unjust inequalities in health care.

The sixth obligation says that health care professionals, health care institutions, and payers all have an ethical responsibility to conduct and contribute to learning activities that advance the quality, fairness, and economic viability of the health care system. Health care professionals, health care institutions, and payers are uniquely situated to contribute such data, and they have the expertise to make use of such data. Kass said that this obligation is relevant to their responsibilities to provide high-quality care.

The most controversial of the obligations, based on feedback she and her colleagues have received since publishing this framework (Kass et al., 2013), and the one that is most frequently misunderstood holds that patients have an obligation to participate in the enterprise of learning. "I do think there are certain kinds of activities where patients ought not be given a choice," Kass said. "That doesn't mean they ought not to be informed, but there are certain activities that in no way change the risk, the care, or the burden for patients where we could learn things that could make a difference in improving care." Akin to much current, ongoing quality improvement, what needs to happen, she said, is that there needs to be a better way of explaining that this type of research is part of a cycle that helps provide patients with high-quality care. This obligation, she explained, derives from the moral norm of common purpose—that all patients have a common interest in having a high-quality, just, and economically viable health care system. She stressed that this obligation does not mean that patients must participate in all learning activities, but when a learning activity has little or no impact on the first four obligations, patients should have an obligation to participate.

In her final comments, Kass turned to the subject of implementation and discussed two steps that need to be taken to put this framework to use in the real world. The first step is to put in place ethics-relevant policies, which are transparent to patients, that deal with ongoing learning activities, that engage patients to help decide which studies need consent and further protection, and that provide accountability. The second step is to evaluate

the types of learning activities to determine what needs review and consent, and Kass listed three categories of learning activities that can help guide this triage step. Category 1 research creates no additional risk or burden and would require no consent or prospective oversight, though there would be random audits to ensure that these criteria are being met. Examples of this type of research would be chart reviews, some systems level interventions, and prospective observational studies that do not change care.

Category 2 research presents a low level of risk or burden and includes those studies for which there would be no reason to think that patients would object or prefer one approach over another. An example would be a study comparing the efficacy of two very similar blood pressure medications. There would be prospective oversight of Category 2 research, and consent would be streamlined. Category 3 research, which includes traditional intervention research, carries more risk and/or burden, and the different approaches being studied present meaningful differences to patients. Category 3 research would require prospective oversight and prospective patient consent.

APPROACHES TO DEALING WITH OVERSIGHT CHALLENGES

Susan Huang, University of California, Irvine

Susan Huang discussed three clinical trials that she said illustrate some of the issues that she and her colleagues have been struggling to solve. The first trial was the REDUCE MRSA trial that she discussed in the first workshop's opening session. This trial benefited greatly, Huang said, from the fact that the chair of the Harvard Pilgrim Healthcare IRB, which served as the lead IRB for all sites enrolled in the trial, had years of experience in health care quality improvement. The IRB chair knew that in the context of this trial, the protocols met the national criteria for minimal risk and a waiver of informed consent set by OHRP, she explained. Given that the three strategies were already adopted by hospitals as quality improvement strategies and none was known to be more effective than the others, the IRB also ruled that randomizing by hospital did not increase the risk to the patients regardless of which of the three protocols they would receive. This enabled Huang and her colleagues to do a head-to-head comparison of these quality improvement programs. "If we had to obtain individualized consent," she said, "we would not have been able to understand the effect of these quality improvement strategies in the way they are usually implemented by hospitals." She noted that this trial was unusual in that it was studying interventions to prevent contagious pathogens for which the individual risk of infection is affected by the infection status of other patients in the same ICU. "Applying a unit-wide intervention to reduce bacteria has

indirect benefits that could be equal to or greater than the intervention a patient directly receives," she said.

The second trial Huang described involved seven academic medical centers, each of which was testing the efficacy of antiseptic bathing in adult ICUs in a study that was similar to the REDUCE MRSA trial except that the patients were randomized according to when they received the intervention, not whether they received it. Six of the academic medical center IRBs waived consent, but the seventh required individual consent of their ICU patients. The seventh medical center had such poor uptake of the intervention that its ICUs dropped from the study, which in turn meant that the necessary prospective data that was critical to the study could not be collected, and the data could not be analyzed as a randomized clinical trial. Thus, a variation in IRB rulings regarding patient consent within a randomized clinical trial can have a significant bearing on the success and standardization of a trial, including cluster randomized trials where the intent is to apply the intervention throughout the cluster in a uniform and representative way.

The third example was of a cluster randomized trial of the same antiseptic soap used in the REDUCE trial in 10 pediatric ICUs. The IRBs at the five academic medical centers involved decided that individual consent was required despite the intent for this intervention to be a unit-based intervention. Although children do represent a vulnerable population, Huang noted, the types of quality-improvement strategies being studied in these trials are being employed by children's hospitals in the United States as part of routine care. Although the investigators "did an absolutely heroic job of getting consent," Huang said, they were still unable, for various reasons, to get consent for 35 percent of ICU patients who had been assigned to the intervention. As a result, the trial did not achieve the power that the investigators needed in order to analyze the trial as planned, so the as-randomized analysis failed to find a significant difference although the as-treated analysis for the 65 percent who participated did find a substantial effect size and a significant difference. The research was published in *Lancet* (Milstone et al., 2013).

Huang said she picked these three examples as a means of pointing out gaps in the way that IRBs make their decisions. She noted that NIH has examined some of these ethical dilemmas and that the NIH Collaboratory has tried to move some of these issues to the forefront by engaging OHRP, FDA, and PCORI. One gap is the lack of understanding about why there is such variation in the way IRBs rule on studies. "We cannot be dependent on whether or not we were lucky enough to have someone who was familiar with health systems, who understood quality improvement processes, and who knew that there were hospitals doing this all the time," Huang said. In particular, it is imperative to address the idea of consent for quality-

improvement studies with minimal risk. "How do we get more uniformity in approaching things that are minimal risk so that we have more answers for the things that we are already doing?" Huang asked.

There are also gaps in the way quality-improvement studies are designed and conducted. Huang said that statisticians are rarely, if ever, involved in the design of a quality-improvement study. She said that quality-improvement studies need to take advantage of better experimental designs and they need to be done in multiple settings for generalizability and also because target outcomes are often infrequent. Furthermore, she said, quality-improvement researchers need to "stop being afraid of randomization" because they fear that a randomization trial design inevitably leads to a protracted IRB approval process. Improving this process and increasing the standardization of rulings across IRB committees, especially in the case of minimal risk studies, will be necessary to take advantage of one of the greatest strengths in study design. One place to start would be to better understand if and when randomization actually increases risk. In addition, from the patient's point of view, there is still work to be done in explaining concepts such as randomization and keeping the randomization process transparent.

IRBs also need more consistency when dealing with vulnerable populations such as prisoners and children, particularly for low-risk quality improvement studies, Huang said. "We need to be able to study the things that drive quality improvement that we do every day and be able to reasonably test them in important populations such as children," she said. "Otherwise, we may never get the right answer for what you want to know."

The field must also figure out a way of working with industry on quality-improvement trials, Huang said, given that these pragmatic trials may often request contributed products and that pharmaceutical companies may have an interest in using the mounting data from well-conducted quality-improvement studies that support product use. This area is not well developed, particularly the use of cluster randomized trials for FDA indications.

James Weinstein, Dartmouth–Hitchcock Health System

In his comments, James Weinstein first described an 11-state trial that he ran—the Spine Outcomes Research Trial—that involved enrolling patients in a randomized or observational cohort to determine if the less expensive observational trial could replace RCTs for quality-improvement studies. This trial ran into all of the IRB issues that had been noted by previous speakers, he said, but, nonetheless, he and his colleagues were able to run the trial and publish the results in the *New England Journal of Medicine* (Weinstein et al., 2007) and the *Journal of the American Medical*

Association (Weinstein et al., 2006a,b). What Weinstein and his colleagues found was that the RCT was not much better than the observational trial. "There were some differences," he said, "but the differences were not significant in many of the diagnostic groups."

At end of the day, Weinstein said, patients have a great deal of decisional regret if they were not involved in the decision-making process. He noted that laws have been changed in California and Washington State to mandate that clinicians and patients together make shared decisions. He said that rather than have the process be one of informed consent, it should be one of informed choice, with the patient actively involved in the decision-making process.

In his final remarks, Weinstein discussed the High Value Healthcare Collaborative, previously discussed in Chapter 4, which he started with colleagues at the Mayo Clinic and Intermountain Healthcare and which has grown to include safety net systems such as Denver Health and Sinai Health in Chicago. These safety net hospitals do not pay to belong to the collaborative, whereas the other members pay about $200,000 per year to participate. The collaborative developed a master collaborative agreement that allows for the collection of data from EHRs and claims data from all payers and all patients and for that data to be shared among all the members. Weinstein noted that many of the nation's 5,000 hospitals are struggling to survive, and he said he hopes that the nation creates more collaboratives to help share the burden of working to build a better health care system that reaches everyone equitably across the nation.

Peter Margolis, Cincinnati Children's Hospital

Peter Margolis addressed the challenges of using data collected in EHRs from 66 institutions and transferred into a registry that is used to support clinical functionality as part of the Improve Care Now network. The registry is updated daily from data provided in real time. The registry includes personal health information that is held separately from the data. Margolis explained that when a patient's data are pushed back out to care centers, the personal identifiers are reattached. The registry also uses a consent management tool that identifies which patients have consented for research and which have not.

Five years ago, he said, nine centers using a single protocol started the network. As the network grew, Margolis and his colleague decided it was important to put in place a more standardized approach for getting IRB approval, and they did so using a federated model in which the centers could choose to rely on Cincinnati Children's as a central IRB with a single consent form. This consent form informs patients that their data are being used for clinical care and quality improvement, and it asks them to consent

to having their data used for research purposes. "We have quite a sense of urgency about making this process run smoothly," Margolis said, "because we know that patients who participate in the system do better." Of the 66 centers, 43 percent have chosen to rely on Cincinnati Children's IRB.

What he and his colleagues have noticed is that there is significant variation among the IRBs regarding how they deal with the complexities of this type of data sharing, where some data is used for clinical care and some for research. "There are also differences of opinion about the kinds of risks that are involved for patients," Weinstein said. Furthermore, there is a great deal of confusion among physicians and care teams about Health Insurance Portability and Accountability Act (HIPAA) regulations and IRB oversight. For example, he said, physicians and care teams have little appreciation for how much data sharing takes place under HIPPA authorization. He noted that the IRB process is time consuming, taking an average of 22 hours and 82 e-mail transmissions per care center to work through the IRB and legal approval process. "Meanwhile, the patients are not exposed to the benefits of the system," Margolis said.

Two of the 66 care centers have now decided that they are not willing to share personal health information outside of their institutions. Those two centers created a separate encryption program to identify and re-identify patients, a process that has taken too long to accomplish, Margolis said. One of these two centers is not seeing the kinds of improvements in outcomes that the rest of the network sites are realizing.

Margolis ended his remarks by noting that there are huge opportunities for improvement using this type of data collection system but that health care systems first have to think about how to do more to inform patients and make them aware of just how a network such as the one he discussed can be a benefit to them. Most patients, he said, are used to interacting with their own clinicians and do not think about being part of a network. Health care systems also need to understand how to do this type of information collating and dissemination without overburdening physicians. Finally, he commented that it is important to educate clinicians, IRBs, and health systems that there are different ways of managing IRB approval and patient consent.

DISCUSSION

Session moderator Bierer started the discussion by asking Kass to explain how she thinks about informational risk, privacy, and the continuum of risk that she outlined. Kass replied that information risk is important and that it is something that is getting attention. "What I think is critical," she said, "is to not separate our thinking in terms of what kinds of protections we want for research from the kinds of protections we want for clinical care

and, particularly, for electronic records." Regardless of which realm is being considered, protecting patient privacy is critical, and it will be achieved through a combination of technology, rules, and firewalls.

After commending Kass for her work reconceptualizing the notion of risk with regard to the need for IRB approval, Harold Luft of the Palo Alto Medical Foundation said he was surprised by Brent James's comment that only a small percentage of findings are eventually published. From his perspective as an economist, Luft wondered if there might be a way of incentivizing organizations that do quality improvement work to move their work into the public domain, perhaps by making a small percentage of Medicare and Medicaid dollars available for that purpose. Kass said that that was a great idea and that it should be extended to cover not only publication but implementation as well. "This is not to suggest that every project when it's done is ready for widespread implementation," Kass said, "but there is some number that are ready."

Weinstein said that part of belonging to the High Value Healthcare Collaborative is a requirement to publish. He said that the Collaborative will soon have publications out that identify institutions and provide cost variations, outcomes, and other measures. He said that he hopes these publications begin the process of uncovering some of the variables that affect care. The collaborative will also be publishing case study reports of the type that are informative but do not get the attention of full papers in major journals. Rainu Kaushal, from Weill Cornell Medical College, said that well-designed studies can be turned into rigorous academic publications quickly and researchers can translate their findings into actionable information for policy makers and health care stakeholders without jeopardizing publications.

Commenting on the trouble of getting studies other than RCTs published in major journals, Richard Brilli from Nationwide Children's Hospital said that journal editors need to be educated about newer statistical methods. "The traditional research community needs to be less afraid of statistical process control and interrupted time series with upper and lower control limits," he said. Brilli added that statistical process control is just as valid a way to show improvement over time as are the more traditional randomization methodologies. Huang agreed that this can be a valid approach and said she believes it is a failure of our educational system that the randomized clinical trial, even when poorly conducted, has become the be-all and end-all for research. However, she added that too many quality-improvement studies use other approaches that are not statistically well designed and are not long enough to show meaningful improvements. Brilli replied that the Standards for Quality Improvement Reporting Excellence, or SQUIRE, guidelines do provide advice on how to publish quality-improvement work using statistical process control.

Steve Fihn from the VA also commended Kass's work and said that the VA has now adopted many of the principles that she and her colleague developed and, furthermore, that it has published them in a handbook that governs operational evaluations by the VA's leadership. He added, though, that the VA's ethicists commented that many of the activities that Kass was talking about are indistinguishable from some of the activities that administrators are already doing. "It begs the question as to whether those things ought to be under some sort of evaluation and created pushback," Fihn said. In reply, Kass recounted an anecdote about one system that, in order to stay out of trouble with the system's IRB, created a "quality office" distinct from a research office and made sure to use words such as "survey" and "project" instead of "questionnaire" and "study" because "questionnaire" and "study" sound too much like research.

Lucila Ohno-Machado from University of California, San Diego, said she liked the notion of no additional risk and highlighted the challenge of quantifying risk at baseline in order to know whether there is additional risk. Margolis replied that there is no good vocabulary for describing how much risk exists concerning the loss of privacy but that making physicians and leaders more aware of the actual quantitative risk could be helpful.

John Steiner of Kaiser Permanente Colorado asked the panelists to comment on the role of empirically measuring items such as time to IRB completion in order to further the process of reform. As an example, he said that Kaiser has seven research departments and seven IRBs and that looking at the natural history of the studies that pass through each of the IRBs provides information on pain points and barriers and helps identify potential solutions to improve the process. Kass said that there have been some studies of variation in IRB approval that have been published but that there is room for many more studies of this type. "Metrics can be helpful for quality improvement, and IRBs are no exception," Kass said, adding that the IRBs at Johns Hopkins have in fact used metrics to implement a few changes that made a big difference in time to IRB approval.

Bierer remarked that the Harvard-affiliated institutions have all signed on to one master agreement that allows any institution to rely on any other IRB for any clinical research. In the 7 years since the agreement was developed, she said, more than 1,000 protocols have been approved, and the culture of the entire Harvard system has changed to be more collaborative and trusting. Steiner added that one aspect of sustainability is for networks to be able to demonstrate to those who fund quality improvement studies that they can get IRB reviews done rapidly and efficiently.

In response to a question from Kenneth Mandl of Boston's Children's Hospital about how to get the public more engaged in quality-improvement research, Kass said that her sense is that the public has no idea how much is left to be learned in clinical medicine. "People know there isn't a cure

for cancer, but for everyday medical care, I think people are shocked," she said. She and her colleagues have a PCORI pilot grant to conduct engagement sessions with patients, educate them about the learning health care system, and find out what kinds of protections they would like to have in place. She also said people who have health problems are eager, in general, to have their data used. It is healthy people who seem to be more concerned about privacy.

7

Governance That Accelerates Progress and Sustainability

KEY SPEAKER POINTS

- There is a business imperative to conduct research related to institutional goals for health care delivery, James Rohack said, but governance and related operational mechanisms need to be in place to shorten the cycle time from research evidence generation to related health care organization management decisions.
- Grant funding cycle times make it difficult for grant sources to have major roles in research related to a health care delivery organization's operational goals, Rohack said, and so sustainability should depend primarily on operational funds.
- One way to send the message that health service delivery research is important is to give it the same weight as basic science research in an organization's reward system, Rohack said.
- "From my standpoint as a leader of an organization," Mary Brainerd said, "I want you to bring your 'patientness' with you to everything that we do, everything we design, every way we think about what we are going to do in research."
- The time frame for most research is too long, and too much knowledge is not put to use in a productive manner, Brainerd added.

- Transformation of a research enterprise to conduct studies that are larger, of higher quality, faster, less expensive, and more engaged requires transformation of governance, John Steiner said.
- One possible operational definition of network sustainability, Steiner said, relies on the development of shared research assets to facilitate a sequence of research studies in a specific content area or multiple areas and developing a community of researchers and other stakeholders who reuse and develop those assets, both technical and human/cultural.
- Steiner said that the governance of interorganizational research "requires us to develop precision tools on the one hand but also to permit the creativity to use those tools in new ways." The culture of leadership and decision making in research networks can be characterized as one of leadership without control.

Institutional governance of continuous learning activities that can accelerate progress and sustainability was the focus of a panel of brief presentations by James Rohack, Chief Health Policy Officer for Baylor Scott & White Health, who discussed how his organization aligns research with institutional goals; Mary Brainerd, President and CEO of HealthPartners, who spoke about data sharing in a competitive environment; and John Steiner, Senior Director of the Institute for Health Research at Kaiser Permanente Colorado, who addressed various issues involved in governing interinstitutional research. An open discussion followed the presentations. Session moderator Paul Wallace, the chief medical officer and senior vice president for clinical translation at Optum Labs, started the session by saying that most of the governance that has been created has been for intrainstitutional issues. "We figured out how to check the boxes and get things done within our own shop," he said, "but what is changing is that we have a national context now, and we have to work across institutions." He cited PCORnet as the most robust effort at developing interinstitutional governance, and he mentioned other examples, including the NIH Collaboratory and AcademyHealth's Electronic Data Method's Forum and its Generating Evidence and Methods (eGEMs) to improve patient outcomes project. He noted that one challenge is to design durable governance structures that are sustainable but not static.

ALIGNING RESEARCH WITH INSTITUTIONAL GOALS

Baylor Scott & White Health, as James Rohack explained, was formed in October 2013 when 117-year-old Scott & White Health Care in central Texas merged with 107-year-old Baylor Healthcare System in the Dallas, Texas, area. The combined organization has a unified approach to governance, which includes education because, Rohack said, education has to be part of the goal of aligning health care with research if "we are going to have the new cadre of people delivering care who understand how culture and quality is part of a driver to improve care all the time." Rohack described the STEEEP (Safe, Timely, Effective, Efficient, Equitable, and Patient-Centered) Quality Institute that works with system researchers as well as with outside clients to identify opportunities for making health care more safe, timely, effective, efficient, equitable, and patient-centered.

Baylor Scott & White Health is committed to what Rohack called "lean thinking." Lean thinking, he explained, is not about "more is better" but rather focuses on providing the right care at the right time to the right person. "The mission embeds that personalized care," he said, "but it also looks at research and improvement as a part of that culture," and an important piece of realizing that mission is innovation in how to scale things across the entire combined organization. He said that Scott & White had had its own health plan for 35 years, is part of the HMO Research Network, and has been dealing with population health in the capitated payment model, and it now has to push that model through the integrated system (see Figure 7-1).

Having circles of care and innovation and creating strategy maps to align these models is all for the good, Rohack said, but the key is operationalizing these things. That requires, he said, engaging the board of trustees on a regular basis and informing them of progress toward meeting specific metrics for success as well as creating a leadership council composed of the people who are on the ground leading the specific research programs designed to reduce mortality and morbidity, improve patient experience, manage health at a population level, and improve financial operating margins.

Rohack offered four lessons that the northern division of Baylor Scott & White has learned in its efforts to create a learning health care system based on these models. Clearly, he said, there is a business imperative to conduct research related to institutional goals for health care delivery, but governance and related operational mechanisms need to be in place to shorten the cycle time from research evidence generation to related health care organization management decisions. Another lesson was that, although federal funding can be helpful for this type of research, typical federal peer review funding cycle times make it difficult for these sources to play major roles in research related to a health care delivery organization's operational

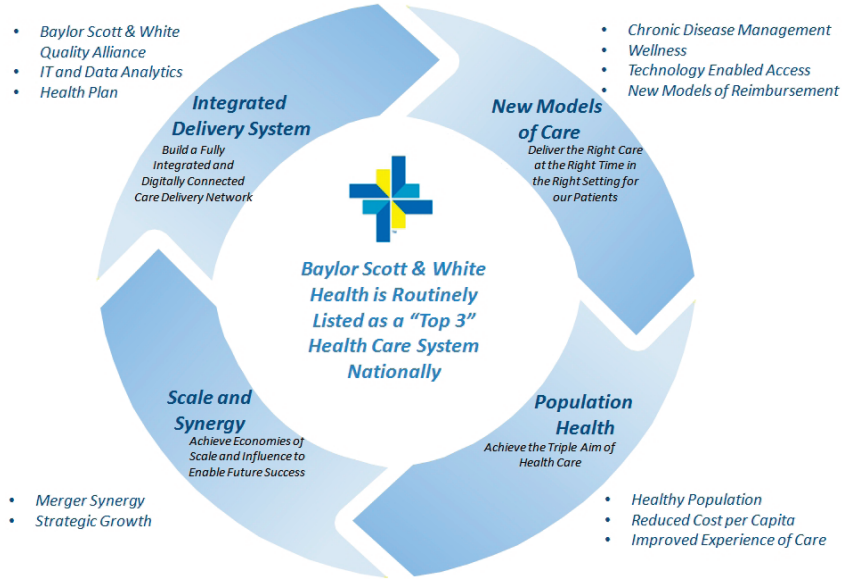

FIGURE 7-1 The Baylor Scott & White circle of innovation.
SOURCE: Reprinted with permission from James Rohack.

goals, and so sustainability should depend on operational funds, not grants. Finally, successful delivery organizations will have a robust infrastructure in place to support these aligned research efforts as a core component of day-to-day operations.

One issue that Baylor Scott & White has addressed is the need for a workforce that understands in a deep way the role for and the value of quality-improvement research. Its approach in its central division has been to embed its research projects as a core function and engage its medical residents in the design, planning, and execution stages. "Every resident receives didactic training on how to conduct such projects and how to integrate the learning that results into their day-to-day practice," Rohack said. To emphasize the importance of this training, Baylor Scott & White gives health service delivery research the same weight as basic science research in its reward system. "This is an important message," Rohack said.

As an example, he briefly discussed a traumatic brain injury research project that connects basic scientists exploring the blood brain barrier with clinical scientists exploring biomarkers for traumatic brain injury, clinicians studying how the symptoms manifest, and quality investigators exploring how data can be used to improve quality of care and quality of life. Together, these teams are aligned in a way that will allow them to

address questions regarding how to best deliver care to patients who have traumatic brain injuries.

One lesson learned from the central division's experiences, Rohack said, is that partnerships are hard because they rely on the personalities of those in charge. He said that the High Value Healthcare Collaborative, of which Baylor Scott & White is a member, has been successful because of the personalities of the leaders and the researchers, who are willing to share with others. Rohack added that as part of the recent merger of the Baylor Scott & White systems, they have encountered a number of challenges associated with bridging academic and clinical service organizations. He highlighted issues with faculty titles and tenure—tenured versus nontenured, professor versus clinical professor—as a major stumbling block. He cited a lack of understanding across partner organizations, for example, when the academic center does not run a clinical enterprise but expects the clinical enterprise to teach the medical students and residents. Who controls the indirect dollars from outside grants can be a difficult issue to resolve, he said, particularly in instances where the money flows through the academic center, which takes its cut for overhead and leaves the clinical enterprise to use more of its own funds to support the work; "Trust is the key here," he said. Rohack concluded his remarks by highlighting what he considered an underappreciated crisis, saying that it is important in all of these efforts to remember the incredible pressure that health care providers are under these days. "There is a crisis in caregiving that nobody seems to be talking about—caregiver satisfaction," he said.

DATA SHARING IN A COMPETITIVE ENVIRONMENT

The origins of HealthPartners as a not-for-profit, consumer-governed organization that grew out of the credit union cooperative movement have a great deal to do with how governance is organized at this health system, Mary Brainerd told the workshop. HealthPartners was formed when credit union leaders looked at why their members were in debt and found that the main reason was health care. The result was the first prepaid health plan coupled with a consumer-led delivery system. "I think no set of roots could be more closely aligned with the Triple Aim than people wanting affordable health care and wanting it for themselves and their families and the quality and delivery system approach that worked for them," Brainerd said.

Today, she explained, HealthPartners resembles the Geisinger system in the sense that only about 35 percent of its members use the HealthPartners delivery system and only about 35 percent of its delivery system patients are HealthPartners members. Brainerd said that HealthPartners has about 1 million patients, 7 hospitals, and 22,000 employees. She added that HealthPartners is somewhat unusual in that it conducts dental research to

inform its 60 dentists at 22 locations, making it one of the few health care organizations working on dental issues.

As part of its mission to improve health and well-being in partnership with its members, patients, and community, HealthPartners has come to realize that it "needs to do a better job of caring for and treating whole people, not just medical issues but mind, body, and spirit," Brainerd said. "We know there is a whole world of opportunity for us to be more effective." The organization has come to stress partnerships with its patients and members. "From my standpoint as a leader of an organization," Brainerd said, "I want you to bring your patientness with you to everything that we do, everything we design, every way we think about what we are going to do in research." For example, she said, one of her goals is to eradicate words such as "comply" and "adhere" and to eliminate thought processes that involve "doing" something to patients; instead, the mind-set should be to think about what caregivers can do together with the people served. "This redefinition of partnership should be and is at the core of the work of PCORI," she said. In that type of partnership the only measures that count are the ones that matter to patients: Do you feel better? Can you do what you need to do every day? Can you accomplish the goals you have for your life?

Partnerships with outside organizations are also important, Brainerd said. HealthPartners, for example, has partnerships with the HMO Research Network and the Institute for Clinical System Improvement. One important feature of the latter partnership is that it requires sharing its data publicly and transparently. HealthPartners has also been the sponsor and creator of the Minnesota Community Measurement Community, which delivers performance metrics directly to consumers in Minnesota. One outcome of being part of the Measurement Community was that HealthPartners' orthopedic department, which scored below average on quality metrics, began an effort to improve its standings on future assessments. "Sooner or later," Brainerd said, "results are going to be known everywhere, so we thought it was an advantage to get out in front of them and focus on improving performance, not challenging the appropriateness of measurement."

She noted that when she looks at where her organization is spending its money, she preferentially funds those projects that lead to performance enhancement. "Why?" she asked. "Because the time frame is too long for most research, and too much of the knowledge that we have already created isn't being put to use. We need performance change on time horizons that are much more rapid than those created by a traditional research structure. That's not to say that we have decided that research is not important. It is just not as important to the performance gains that I need to see as we look to deliver on the triple aim."

Brainerd said she is now working to better align the organization's performance improvement initiatives with its research initiatives. She said she hopes that HealthPartners' current work with Partners for Better Health Goals 2020 to create long-range stretch goals for meeting the triple aim will help her organization's educational, research, and operational focus. She is also emphasizing creating systems that make it easy to do the right thing. "I am concerned that when we get research results, we don't have an effective way to implement them quickly to become reliably delivered and sustained," she said. One approach that Minnesota is taking is to work through Minnesota Community Measurement and the Institute for Clinical Systems Improvement (ICSI) to drive change in all of its members by helping them implement improvements identified by individual members. It is a highly collaborative approach to improve results everywhere across the region.

HealthPartners, Brainerd went on to describe, has developed a ClickReduction program as part of its commitment to its physicians to reduce the amount of time it takes to do the things effectively using EHRs and to make the right thing easier to do. She noted that from her perspective there is not a problem of knowledge hoarding, as was discussed previously, but rather a failure to implement the knowledge that already exists about what works in a way that can realize real improvement in quality and outcomes.

In her closing remarks, Brainerd said that she is optimistic that early efforts to learn how to partner with patients will yield important improvements. A key to this effort will be to learn how to communicate better with patients and not leave them confused by the often conflicting information that so often appears in the popular media. "We have, through all of the knowledge that we have created, confused our patients and consumers to the extent that even care that would be beneficial is sometimes not being sought," she said. "I think the opportunities are there to connect in new and different ways with our patients, to remember they come to us with their own knowledge and beliefs." Patient councils can be one avenue for connecting, and Brainerd noted that a patient council that was created to help redesign a physical space for mental illness care not only accomplished that but also ended up catalyzing a new care model for patients with mental illness. She also expressed concern that there is not enough research on the intersection of health care and behavior change. For example, it would be valuable to learn more about how to connect better with patients to encourage healthy behaviors or how to increase the likelihood of effective medication use because currently medications are used effectively only about 50 percent of the time.

GOVERNING INTERINSTITUTIONAL RESEARCH

Speaking from his perspective as a scientist running an 11-site diabetes network with EHR data from more than 1.3 million individuals with diabetes as well as the chair of both the Kaiser Permanente National Research Council and the HMO Research Network governing board, John Steiner said he tries to make sense of the relationship between sustainability and governance. His first message in that regard was that "transformation of a research enterprise, which we all agree needs to happen, really requires a transformation of governance."

Research studies, he said, need to be larger, which means they must include more sites and subjects. Research needs to be of higher quality, which means it needs to use trustworthy, high-quality data and better analytic methods while achieving or maintaining regulatory and fiscal compliance. Research needs to be faster, in terms of initiating studies, organizing the contractual relationship between collaborators, and getting studies approved by IRBs. Research need to be less expensive, which means relying not only on data collected primarily in the course of large, randomized trials but also on data collected during the course of routine care. Research needs to be more engaged, which means integrating patient and organizational/clinical perspectives as well as the members of interinstitutional research teams. The connection among all of these needs is that they all require skillful governance, Steiner said.

Steiner offered one possible operational definition of network sustainability that consisted of two parts. First, sustainability involves the development of shared research assets in order to facilitate a sequence of research studies in a specific content area or multiple areas. Second, sustainability has to do with developing a community of researchers and other stakeholders who reuse and develop those assets, both technical and human/cultural. Governance of shared institutional technical assets requires a great deal of attention to detail. The governance of a community requires broad principles and a light touch. Summarizing these ideas, Steiner said, "Governance of interorganizational research requires us to develop precision tools on the one hand, but also to permit the creativity to use those tools in new ways."

Concerning research assets—that is, the precision tools—the organization and governance of a network needs to be well defined, and the relationships among institutions need to be clear. "This is not limited to what we often focus on in governance," Steiner said, "which is governance of the data. That aspect has to do with discussions about the data model you use, how you ask questions of that data and of the sites that hold it, as well as a whole long list of issues around assuring the quality and validity of that data." Although it is important to have mechanisms in place to ensure

that data are trustworthy and that there is a data governance structure, the other elements of sustainability—including shared knowledge about tools and research methods, administrative efficiency, physical infrastructure such as biobanks, and predictable infrastructure funding—have to be done effectively for this kind of research to work.

Next, there needs to be governance that helps foster a shared sense of mission, vision, and values and that protects human subjects, who are also stakeholders. Governance structures need to create a strong relationship with the delivery system, which is another stakeholder. Finally, Steiner said, governance should encourage the development of a culture of leadership and collaboration based on fair and transparent decision making. Each of these general items, he said, generates a long list of specific governance issues that require consideration if one is to create sustainable networks.

One of the lessons about interinstitutional research collaborations that Steiner said he has learned is that single-investigator-driven projects rarely add substantially to infrastructure. "To achieve stable governance of a research network, you need to be able to adapt to different principal investigators, different lead institutions, different scientific priorities, and a whole range of varying pressures and incentives," Steiner said. "Governance structures need to be flexible enough to adapt to the legitimate needs of those projects while also being inclusive enough to gather the learnings from each of these independent scientific networks and studies and to collate them into some organized whole so that you develop common models of analyzing data and the like." The second lesson is that even with substantial infrastructure investments, research networks are unlikely to become independent from institutional support.

Turning to the subject of leadership, Steiner said that the culture of leadership and decision making in research networks can be characterized as one of leadership without control. "These organizations are decentralized, and it is impossible to enforce top-down mandates," he said. Instead, the emphasis has to be on decision making based on trusting the capacity of researchers to self-organize and innovate. Drawing on chemistry for an analogy, Steiner said the organizations and investigators in a network are linked by hydrogen bonds rather than covalent bonds.

As an example of how such an interinstitutional research network can form, Steiner discussed how the seven regional and independent research departments in Kaiser Permanente came together under the umbrella of a strategic research plan. This plan, Steiner explained, led to the creation of the Kaiser Center for Effectiveness and Safety Research in 2009, which in turn made the conversations between researchers and organizational leaders across the Kaiser system more systematic. This center has invested heavily in building a data coordinating center, which has enhanced Kaiser's data model and data quality. Kaiser is now having conversations about the use of

metrics to judge how its seven IRBs are functioning and to start the process of coordinating IRB activity throughout the Kaiser system.

One of the best decisions that Kaiser made, Steiner said, was to develop a national research administrators council whose members tackle the thorny problems associated with contracting, pre-award work, and post-award work, which all bog down research in an environment that needs to be more nimble in order to execute on task orders and contracts within a 12- to 24-month time horizon. These actions have facilitated several new initiatives at Kaiser, including the creation of a Kaiser Permanente national biobank whose goal is to link rich clinical information with biological samples.

In conclusion, Steiner reiterated what other speakers had said over the course of the day: Make the right thing to do the easy thing to do. He also quoted a Taoist precept that says, "Ruling a big country is like cooking a small fish. Too much handling will spoil it."

DISCUSSION

To start the discussion, moderator Wallace asked the panelists if they had any thoughts about whether there were features of a network that could be specified so as to not duplicate efforts and that would provide the capacity to be adaptive with other features. Brainerd thought that one good area for collaborative work would be measurement, where work under way could be coordinated so as to not produce too many of the competing measurements that often stand in the way of progress. Steiner cautioned against overgoverning, and, along those lines, Rohack wondered if the meaningful use criteria are a distraction. "Are they taking people away from what we want to do, which is to incentivize people's intrinsic motivation to do this kind of research, with mastery, purpose, and autonomy built into it?"

Harold Luft of the Palo Alto Medical Foundation asked how governance structures can help increase data transparency among collaborators without putting institutions at risk when data are made public. Brainerd said that in Minnesota, there was a history of shared measurement development among health systems in the state that forced organizations to be transparent with one another and to give up control of what was being measured. In addition, the collaborating organizations committed to a year of collecting data on a measure before publishing any specific measure. Wallace added that the opportunity exists to develop governance structures that encourage data sharing within the constraints of boundaries that have yet to be established. It was noted by several participants that sharing and publishing data are risky.

During the course of the discussion, Steiner reiterated the importance of governance structures that enable research to occur without interrupt-

ing clinical workflows. "The less the disruption, the more likely it is to get top-level buy-in," he said. Sometimes, however, it is the workflow itself that needs to be studied, Steinder added, and this is where codesigning interventions with the people who have to carry them out and the people who have to live with the consequences is of critical importance. Susan Huang noted that in the REDUCE MRSA trial, every thread of every protocol that was developed considered whether a particular action would be feasible in common practice. Involving both patients and those on the front lines of clinical practice has to be a critical part of any discussions and planning activities, and that must be part of any governance structure, she said.

8

Fostering the Well-Prepared Stakeholder Culture

KEY SPEAKER POINTS

- Creating value is good, Peter Knox said, but the real goal should be to create value at speed.
- Two drivers of engagement, according to Peter Margolis, are (1) effective leadership, which builds shared responsibility for improving outcomes, making transparent measurements, and sharing data in a way that engages all participants in the system in collaboration to produce continuous learning, and (2) effective resources, such as tools, training, and financial support that enable all of the different constituencies to participate with reduced transactional barriers.
- Clinicians, Margolis said, have an intrinsic motivation of common purpose, a sense of mastery, a commitment to continuous improvement, and a sense of trust and solidarity, that can engage them in creating a culture of learning.
- When the clinical community fails to provide patients with the information they need, Bray Patrick-Lake said, patients go and create their own opportunities, particularly by using social media. "We need to figure out how to integrate people and help them get what they need out of the system," he said.
- Patients need to be made aware of the benefits of belonging to a health care system that engages in research and that belongs to PCORnet, Patrick-Lake said.

The goal of this session was to discuss challenges and opportunities in the engagement of clinicians, patients, families, and the public in integrating care and research efforts. Integrating learning into the delivery of care is a cooperative activity involving the patients who receive care, the people who lead the systems in which research takes place, and the clinicians who provide care. It is an activity that is "not for the faint of heart and that takes ongoing, continuous work," said session moderator Jean Slutsky, the director of the Communication and Dissemination Research Program at PCORI. In this session, Peter Knox, the executive vice president and chief learning and innovation officer at Bellin Health, spoke about his organization's efforts to create a culture of learning that can also execute quickly on the basis of new knowledge. Peter Margolis, codirector of the Center for Health Care Quality at Cincinnati Children's Hospital Medical Center, addressed the topic of physician engagement, and Bray Patrick-Lake, director of stakeholder engagement for the Clinical Trials Transformation Initiative and a member of the PCORnet Executive Leadership Committee, talked about the importance of patient engagement in a learning health system. A discussion moderated by Slutsky followed the three presentations.

CREATING A CULTURE OF LEARNING

Creating value is good, Peter Knox said, but the real goal should be to create value at speed. According to a recent evaluation, Knox said, his company, Bellin Health, was the best performing of the 32 pioneer accountable care organizations (ACOs) (L&M Policy Research et al., 2013). Based on the fact that Bellin Health had the lowest cost per member of the pioneer ACOs and also scored the highest on quality of care and patient experience, Knox argued that his organization created value for the government. Bellin accomplished this feat, Knox said, by learning how to overcome the odds that it, like most organizations regardless of what industry they are part of, would fail to execute its strategy successfully. What, he asked, does it require to succeed? "We believe an organization that can deliver value at speed requires intentionality, discipline, focus, and rhythm," he said, explaining that the last factor, rhythm, is about managing energy, which is in limited supply in most organizations.

In 2000 Knox created a framework that has served as the template for his team's efforts to produce value at speed at Bellin (see Figure 8-1). This framework holds that for an organization to execute effectively it must think about six dimensions. The first dimension is strategic position, which involves listening to and understanding the market, understanding the value proposition, and preparing the organization to focus on patients' important priorities. The second dimension is the production system or organizational structure that delivers on the specifications developed according to the

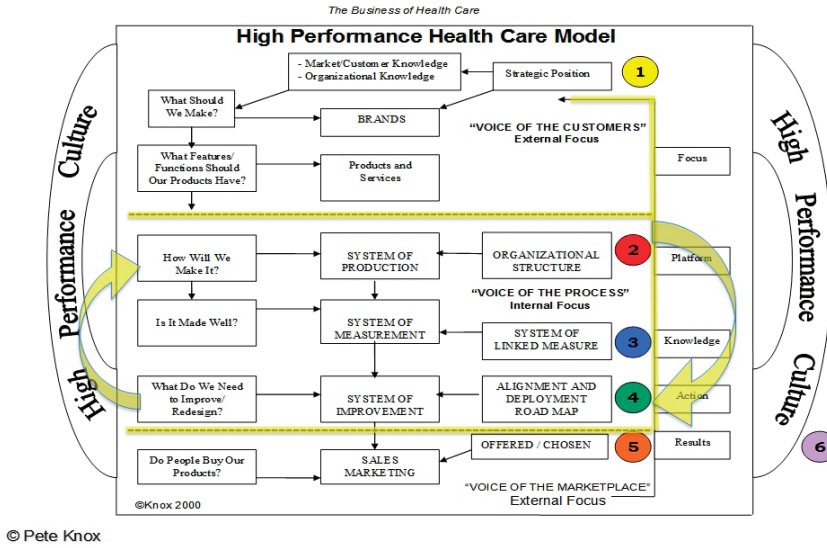

FIGURE 8-1 Bellin Health's high-performance health care model.
SOURCE: Reprinted with permission from Peter Knox.

strategic position. The third dimension is a system of measurement that can be overlaid on the production system to provide insights into how the system is performing.

Once those first three dimensions are in place, only then is it time to create a system of improvement, which is the fourth dimension. "When I'm called in to work with health systems," Knox said, "this is usually the problem that I see immediately—they've jumped in at dimension four. First you have to understand the market, understand how you're producing your products and services, know where your gaps are, and be very focused on where you spend your time and energy. This is where I think we have to align research if it's going to be relevant in the value equation."

Marketing the product is the fifth dimension, and, again, this is a place where health systems often fail to execute. As an example, Knox recounted an advertisement he heard for a health system that bragged that its cancer survival rates were above average. Bellin's approach was to use what its customers had said was most important to them—understanding their options when told they had cancer. Bellin worked with its physicians to improve its production system so that it could make a guarantee in the market that it would give individual patients diagnosis-to-treatment options within 3 days. The first five dimensions, Knox said, are all wrapped up in the final dimension, which is a high-performance culture that supports creating value at speed.

To strategically align their organization for success, Knox and his colleagues have defined three breakthrough initiatives: eliminating cost, waste, and variation; managing populations beyond its Medicare population covered by the pioneer ACO for triple aim outcomes; and new business development and growth. "These are the things we have to hit out of the park," Knox said, and every quality improvement project that Bellin conducts has to fit within these three initiatives. As an example, Knox discussed Bellin's new business development process. When looking at a possible improvement, if it is an incremental increase the organization sets a goal of defining, implementing, and disseminating the improvement across the organization within 60 days. New products, by contrast, are put into an incubator and nurtured so that they have a chance to succeed.

Knox explained that Bellin's production system incorporates research at four levels. Population research is at the first level, and Knox said that the system is in the midst of a 10-year agreement with the Green Bay Packers to improve the health of their community. Second-level research is breakthrough research which, in particular, focuses on how to conduct research on best practices in primary care from around the world and implement those best practices in the Bellin system. Microsystem research, the third level, covers clinical trials aimed at improving care, and fourth-level research includes the studies that clinicians and researchers at Bellin are running to improve their ability to care for patients more efficiently and with better outcomes. As an example of this fourth level of research, Knox cited a study that aimed to understand why patients were missing appointments; the results of that study led to changes that caused no-show rates to drop from 12 percent to 4 percent.

Addressing the concept of managing energy, Knox said that the entire organization runs on a rhythm of 120-day cycles, with the leaders in the organization getting together every 120 days to redefine and recalibrate the organization's priorities. In addition, a select group of executives, including the CEO, chief information officer, the chief medical officer, and the chief financial officer, get together weekly to talk about how they are managing organizational energy and the breakthrough and operational priorities as well as how to continuously foster the development of a culture to support the organization's goals. Bellin has also built a competency model around the breakthrough initiatives that prepares the organization's staff develop the competencies needed to operate in a world in which health care is being managed differently as it moves from a fee-for-service model to one that manages health.

Knox explained that Bellin has a delivery structure built around the patient and a project delivery structure designed to help the organization adopt breakthrough initiatives and operational priorities. The first structure integrates patients in nearly every aspect of quality improvement, and the

second integrates people from all over the organization. "These two distinct structures are designed to deliver service every day reliably and predictably to our customers, but also to achieve better and greater value each and every day," Knox said in closing.

CLINICIAN ENGAGEMENT

Engagement in a learning health system, according to Peter Margolis, means producing information, knowledge, and know-how to improve both personal health and the health care system. "This means participating in all phases of knowledge development and research, from forming questions, doing work, getting learning to happen, and applying the results," he said. Based on lessons learned from scores of projects involving large numbers of clinicians and care teams, Margolis and his colleagues have identified several key drivers for engagement. These include effective leadership to build shared responsibility for improving outcomes and transparent measurements and data sharing that engages all participants in the system in collaboration to produce continuous learning. Also required are effective resources, such as tools, training, and financial support that enable all of the different constituencies to participate, and also tools that reduce transactional barriers.

As an example of a standardized process for engaging clinicians, Margolis discussed a project involving a network of about 75 endocrinology practices—50 pediatric and 25 adult—that focus on research for patients with Type 1 diabetes. Despite the widely accepted findings of a 1993 study (Diabetes Control and Complications Trial Research Group, 1993) showing that intensive therapy delays the onset and slows the progression of diabetic retinopathy, nephropathy, and neuropathy in patients with diabetes and that clinicians can help patients prevent the development of these complications by helping patients maintain glycemic control, the Type 1 Diabetes Exchange showed that there is a wide variation in the degree of glycemic control that patients are achieving today.

When physicians are shown these data, Margolis said, their first response is to provide a variety of excuses, none having to do with the fact that some clinics have developed more effective processes for helping their diabetic patients achieve glycemic control. However, it turns out that within a short period of time after starting the discussion, clinicians start engaging in meaningful conversations about how to learn and apply lessons from the best performing clinics. "We talk about the things that motivate clinicians to make improvements," Margolis said, "but the important intrinsic motivations that our model is meant to tap into are the common purpose, the sense of mastery, the commitment to continuous improvement in learn-

ing, and the sense of trust and friendship and solidarity that builds up in a network."

Margolis said that when this process works—when clinicians get engaged in solving a problem—there are processes available that can help focus that engagement on outcomes and learning from data. What is important, he said, is engaging in a discussion that creates a sense of urgency and a culture of learning while at the same time reducing the fear and anxiety that any professional feels when his or her performance is not where it needs to be. When this works, it produces a culture where everyone is working together and where, as Margolis put it, "our networks steal and share shamelessly."

PATIENT ENGAGEMENT

In the session's final presentation, Bray Patrick-Lake said that patients dream of a high-quality health care system that is patient-centered and efficient and that enables reliable and timely access to evidence-based prevention and treatment options that are responsive to individual patient needs. Moreover, she said, while the current health care system is not operating optimally for anyone, she believes that it is possible to create just such a system if everyone can come together to work on the issues that this workshop has identified: inefficient use of resources, siloed data that could be used to improve care on a daily basis, research that never filters back to patients, and lack of transparency when it comes to value and outcomes. She noted, too, the lack of any kind of useful information or data for many conditions and the fact that many guidelines are not based on evidence that patients might find to be reasonable.

Patrick-Lake said that the field needs to get smarter about the data it collects and how it explains those data to patients. "Can we identify elements that actually make a difference to patients and help physicians improve care?" she asked. "We have got to get smarter about making data work for us." When the clinical community fails to provide patients with the information they need, patients go and create their own opportunities, particularly by using social media such as Facebook. "There are now 7,000 patient groups in this country, and I'm not sure we need any more," she said. "But every time a patient steps forward and they don't get what they need, they're still going to try to get answers for themselves and for their children. And so we really need to figure out how we integrate people and help them get what they need out of the system, so we can stop going off and creating all of these different siloed activities."

Another thing that is happening, she said, is that patients are getting more involved in the research endeavor and are experiencing many of the same frustrations that clinicians and researchers face in dealing with IRBs

and contracting offices. Patients, she continued, are becoming results-oriented, demanding more from the system, and in some cases taking control of the system. In her role with the Clinical Trials Transformation Initiative, an FDA-driven public–private partnership to improve the quality and speed of clinical trials, she harnesses the energy of patients to work with all of the stakeholders to produce systemic change.

Patrick-Lake noted that one way in which patients are driving this change is through the PPRNs that have been forming. These networks include people who have backgrounds in statistics and information technology and who are taking data and making it work for patients. These networks are creating benchmarks for patients so that they can see how they are doing compared to other patients. They are creating forums for real-world populations of patients to compare medication regimens and exchange other relevant information that they feel they are not getting from the clinical community. "Patients are coming together to create these user-designed systems that actually meet the triple aim and that have been shown to reduce spending," Patrick-Lake said, adding that these networks need to think more about metrics and that she hoped that the PCORnet community would help with that task.

Her hope, she said, is that in another year or two all patients in the United States will know whether they are in a learning health care system and if the system they get their care from is part of PCORnet. Being part of PCORnet is a benefit, she said, and the community needs to communicate that to patients so that the patients realize that if they are not part of a research effort, research results will not be applicable to patients like them. "We need to be raising awareness every day," she said. From her perspective as a patient with cardiac and vascular conditions, she said she hopes that nobody else has to go through what she has experienced and that others can benefit from the knowledge that her clinicians have gained in treating her.

One point that Patrick-Lake stressed is that PCORnet is a living laboratory that is working hard to engage patients and to develop new approaches for better engaging patients. But in the meantime, it is time for the community to start engaging patients in whatever way it can, using the many innovative methods that are available. "If you don't know how to do it," she said, "ask around because there are others that do, and hopefully we will have more evidence of what works in the future. Everything about patient engagement is not completely solved, but that doesn't mean we shouldn't do it now. We need to dig our feet in the ground and say that together we're going to address these issues."

DISCUSSION

To start the discussion, session moderator Slutsky said that one of the take-home messages that she heard from these and other presentations is that if you are not part of a learning health system as a clinician, a health system, or a patient, you should be angry. She thought that all of the workshop attendees would agree that it should be an aspirational goal for everyone to be part of a learning health care system. She also noted that the situation with the health care system is somewhat analogous to what happened at General Motors with its ignition system problems: There was a simple fix, the data were available, yet because of an organizational failure, the problem was not corrected, and people died as a result. "The analogy with health care," she said, "is that we often know about harms or have an inkling of a harm but as providers or a health care system we do not know how to change and fix the problem." She added that a learning health care system represents the best way to address that sort of problem and to identify and fix problems before they become serious.

Jon White from AHRQ asked Knox to comment on the resources that a system needs to invest in, in an information system. Knox replied that he and his colleagues are building what they are calling a knowledge brain that has to operate at three levels: a strategic level that can look at populations, understand populations at a macro-level, and help devise strategies to improve population health; the mezzanine or registry level that operates outside of the boundaries of the Bellin Health system to help accomplish the triple aim; and a point-of-care level that helps clinicians when they are in front of patients. The base platform for this triple-level brain is an Epic EHR in which Bellin has invested about $30 million, and White said that he is working with a partner, Cryptic, to build out the strategic and mezzanine levels of the brain. He said that Bellin is investing in the development of the Cryptic system. "Our investment is significant for an organization of our size, but we're very intentional about what we're trying to build," he said. "At every level we've defined clear specifications on what we need that level to do, and we're working with partners to help us deliver on those specifications." He added that each of the levels is imbedded in the Epic EHR so that information can move to and from the point-of-care level.

In a question posed to Patrick-Lake and Knox, James Rohack asked if they had ideas on how to balance the need to create an efficient organization with the need to invest in technology for competitive reasons. Patrick-Lake said that this is a challenge that has been amplified by patient distrust of the new ethos that less care is usually better care for the patient even though that is what the learning health care experience is finding to be true. Overcoming this distrust requires building strong relationships with the patient community that can help educate them about evidence-

based medicine. Knox added that it will be critical to work with partners to continue to develop evidence-based best practices and then put in the time and effort to prove to the patient community that this less-is-more approach to medicine creates value for more than just the health care system itself. He also noted that value is the key concept, and as an example he said that Bellin has invested heavily in robotic technology because it adds value, while at the same time it has been working with partners to provide access to technologies that would not provide value to Bellin alone. "For us, it keeps coming back to that value equation," Knox said in summary.

Rachel Hess from the PaTH CDRN wondered how to balance the speed of implementation with the need to ensure that any new process will not harm patients. As an example, she cited the case of epogen, which initial data had suggested was beneficial to patients with breast cancer but which later data showed actually increased mortality. Patrick-Lake said that this is an issue that patients deal with every day as new information is published or appears in the media. One suggestion she made was to involve the relevant patient organizations and to ask them to review recommendations before disseminating them. Margolis added that one of the benefits of being in a learning health care system involving large groups of people engaged in standardized processes is that when there are competing views of what to do, it is possible to be intentional about mounting the studies needed to address conflicting data.

Patrick-Lake added that PCORnet offers the same opportunity on an even larger scale. "I think that's the paradigm shift that we can see where we can partner and study things in a much broader capacity," she said. This remark prompted Richard Platt of the Harvard Pilgrim Health Care Institute and director of the PCORnet Coordinating Center to note that he would be meeting with the various NIH institute directors to discuss how they might engage with PCORnet to take advantage of the opportunities created by working at the scale that PCORnet will create when it is fully implemented.

Jonathan Tobin said that another opportunity that PCORnet creates is to look at the organizational and clinician level measures that are embedded and interlinked with the delivery of services that may be important causal variables for understanding variation in outcomes, which are probably as much related or more related to those variables than they are to individual patient-level factors. "So if we think about the cascade of dissemination and implementation from the standpoint of understanding and explaining that variation," he said, "one very prominent role that PCORnet can play is to monitor the downstream implementation of the innovations from clinical trials and to begin to understand the interaction of those patient and organizational and clinician level variables and understand how they can be

modified in a way to produce better results and at the same time advance the generalizable knowledge about dissemination and implementation."

Physicians sometimes talk about empiric practice—using knowledge, instinct, and experience to treat a patient in the absence of hard evidence—and Harold Luft wondered if it might be possible to produce faster advances by returning to empiric practice but in a way that collects data for each patient to more quickly build an evidence base. Knox thought that such N-of-1 studies can provide a basis for an initial advance in knowledge that can then be tested on a larger scale. He noted that Bellin Health is working with its women's services group to redesign the care experience for women and that it is testing some changes in as few as five patients, recording the results, adjusting the process, and then scaling from there.

At one point, the discussion turned to the issue of dissemination and scale, with several workshop attendees asking how it would be possible to take the lessons learned from exemplar systems and disseminate them nationally. Margolis said that one contributor to this problem is the unwillingness of systems to share their learnings, something that PCORnet is addressing directly. Knox added that there needs to be a nationwide assessment to identify gaps in knowledge transfer and to then apply a value equation in order to better understand and address those gaps. Patrick-Lake stressed that best practices cannot be considered proprietary.

Sally Okun recounted a project that she ran with the American Academy of Neurology that involved deploying its epilepsy care guidelines into the epilepsy patient population and surveying the patients to see if the care they were receiving met these guidelines. The results showed that care being delivered by neurologists varied significantly across the country, with the greatest departure from best practices seen in patients treated by neurologists who were not epilepsy specialists. There were two particularly disturbing findings: Neurologists did not discuss contraceptive control with patients on antiseizure drugs or the potential for surgical intervention. Okun wondered if patient education and activism could be a route to achieve better compliance with best practices at a scale extending beyond the exemplar learning health care systems.

Katherine Newton from GHRI said that one factor that slows the speed of dissemination is that many dissemination plans are based on prestige rather than patient needs. By that she was referring to the academic reward system that leads researchers to try to publish their research in top-tier journals that may not accept their papers, at which point they then submit to another journal, a process that can add months to the dissemination process. "Peer review can take a long time," Newton said, "and even then, results are embargoed because we want the big press release, which again is about prestige. It seems to me that in this age there are some trials that are important enough that there will be a very fast dissemination plan that

will get out to our patients and practitioners as soon as they need it." The problem, she said, is that such a process could negatively affect chances for promotion.

John Steiner said that one of the issues that underlie this problem is the need for control, explaining that the system that exists now is one in which researchers have perfected the art of controlling the agenda by limiting access to information until such time as they think it is ready to be released. "What this panel has done is point out that other groups have legitimate interests in that information far earlier in the process," Steiner said. He added that this is a place where governance of research has to change in such a way that gets patients at the table early in the process. Referring to patient advocates such as Patrick-Lake, Steiner said, "I can't imagine you standing for me saying I can't release findings until I get to present it at a national meeting. Getting you at the table early, I think, creates the circumstances under which the traditional control of researchers is unlikely to endure, and that's a really good thing."

David Ballard from Baylor Scott & White Health wondered why more institutions are not using the entrepreneurial model that some health care delivery organizations have been using to get their best practice models to the market. As examples, he cited the Cleveland Clinic's effort to market its cardiac surgery model to states and Geisinger's partnering with XG Health Solutions, a venture capital firm in which it is a minority owner, to get its solutions to the market. Knox noted that Bellin is the fourth-largest vendor of retail clinics through its FastCare brand and that it is about to launch a franchise licensing model. Bellin has a dedicated group of people in its organization who actively seek out such opportunities and market voids that it could fill with its best practices. It then has a structured process for launching the appropriate solutions into those markets. "We're trying to build a system that searches, identifies, and then launches," Knox said.

Margolis said that Cincinnati Children's Hospital Medical Center, as a not-for-profit organization, takes a different approach based on what is known as lead user innovation, which recognizes that in a community of people participating around a common purpose, some 15 to 30 percent will start product innovations that anticipate the needs of the rest of the community. Margolis said that the large network that he works with generates at least one new idea a week that someone thinks has the opportunity to produce value. Like Bellin Health, Cincinnati Children's uses a formal design and prototyping process that takes advantage of the diversity that exists within its networks to test these ideas under a wide range of conditions. This process, he said, has the benefit of also producing champions in the system who, once the innovation is working, can advocate for its adoption once it gets distributed into the entire system. "We're starting to be approached by industry and a variety of different disease-specific groups

that are interested in learning how to do this," he said, "and it's causing us to think a lot about how to scale that kind of system up and make it more widely available." When asked by Ballard if this is being done in the context of a single 501(c)(3) organization, Margolis replied, "We do it in the context of a network that includes multiple medical centers and a 501(c)(3) working together, but with very complicated money flows."

9

Multiuse Infrastructure for Continuous Learning

KEY SPEAKER POINTS

- Sustainability requires that learning become part of the fabric of care and that health care organizations embrace infrastructure support as essential to their survival, Patrick Conway said. Furthermore, he noted, that infrastructure needs to become part of the financial model in a way that enables investments in the research infrastructure that will drive continuous learning to improve population health and the efficiency of care delivery.
- Research works best, Brent James said, when it is integrated into routine care delivery at the level of data systems and organizational structure.
- An organization can foster a culture in which its leadership team and medical professionals work together consistently to create a virtuous cycle between research and operations to create value at speed, according to Scott Armstrong.
- Being a part of PCORnet is allowing institutions to pick up the pace of learning and improvement by catalyzing efforts to extract information and create synergy among the many data systems that exist at most large institutions, John Warner said. He added that PCORnet represents an opportunity to build the infrastructure needed to maximize return on the huge investment that health systems have made in EHRs.

- PCORnet should consider collecting cost data, Warner said. "You simply can't measure clinical effectiveness without it," he said. "If we are going to make the types of investment that are going to be required from our health systems into these types of research, we have to measure cost in a way that we can transparently provide the information to our patients and their families."
- Armstrong said that cost data will be critical to determining which investments are providing the expected rate of return and which should be discontinued.

This session of the workshop included brief, prepared comments by panel members followed by moderated roundtable discussion among the panel and the workshop participants on the challenges and opportunities to establish and maintain the infrastructure for continuous learning, including but not exclusive to PCORnet. Members of the panel included Patrick Conway, the chief medical officer and deputy administrator for innovation and quality at CMS; Brent James, the chief quality officer and executive director of Intermountain Healthcare's Institute for Health Care Delivery Research; Scott Armstrong, the president and CEO of Group Health; and John Warner, the vice president and chief executive officer of the University of Texas Southwestern Medical Center. Sarah Greene, a senior program officer with PCORI's CER Methods and Infrastructure Program, moderated the discussion that followed the panel presentations.

PANEL DISCUSSION

Patrick Conway, Centers for Medicare & Medicaid Services

In a recent paper, Conway and two colleagues described four categories of payment (Rajkumar et al., 2014):

- Category 1: fee-for-service payments with no link to quality or cost
- Category 2: fee-for-service linked to quality and value
- Category 3: alternative payment such as ACOs, bundled payments arrangements, and advanced primary care models
- Category 4: population-based payments

CMS is trying to drive Category 1 payments to as close to zero and as fast as possible. Category 2 payments are the majority of the Medicare spend, Category 3 payments now account for approximately 15 percent and growing of CMS's outlays, and population-based Category 4 is also

growing, said Conway. He noted that shifting more of the payments to higher-level categories in as short a time as possible will require the efforts of PCORnet and others. CMS is currently working on the goals for these four payment categories for the next 2 years, Conway said, and rapidly implementing change based on evidence will be critical to meeting these goals.

Doing population-based management of health care is challenging, Conway acknowledged, and although some systems do it better than others, even the good ones will admit that they are still learning how to implement change faster and more efficiently. CMS is currently working on developing performance metrics that states and communities can use to assess their progress in moving toward population-based health management. Noting the importance of linking a patient's perspective with clinical data, Conway said he was excited to see that this is happening in the systems represented at the workshops.

The greatest challenge, Conway said, is creating a sustainable system starting with the infrastructure that PCORI is seeding with its funds. Sustainability, he said, requires that learning becomes part of the fabric of care and that health care organizations embrace infrastructure support as essential to their survival. For a pioneer ACO, for example, the infrastructure needs to become part of the financial model in a way that enables investments in research infrastructure that drives continuous learning to improve population health and the efficiency of care delivery.

Conway concluded his remarks by saying that he was fairly confident that the nation's health care system is heading in the right direction, both in terms of quality and cost. The pace of change, however, worries him. "If we don't get the pace right, I worry that we are going to end up with those blunt cuts that actually harm Americans," he said. "The question is, can we accelerate change through PCORnet and other innovations? Can we accelerate that pace of improvement so that we really get those population health outcomes at lower cost at scale across the nation?"

Brent James, Intermountain Healthcare

A couple of years ago, James said, he and Intermountain Healthcare's vice president for strategic planning conducted an internal analysis that showed that some 70 percent of the care the company provides is "quasi-capitated," and as a result, Intermountain Healthcare launched a series of major initiatives that are now integrated with inpatient and outpatient care. The fruit of these initiatives is a reduction in hospital volumes that exceeded projections and a few years of the best financial performance the system has ever experienced. "The models do work, and they work well," James said. He noted that trying to predict when the transition from fee-for-service to fee-for-performance will occur is like trying to time

the stock market, so the best approach is to assume the risk and start managing care today.

Intermountain Healthcare started this process in 1996, James said, and the health system currently has some 60 longitudinal, disease-specific registries running in its enterprise data warehouse, with data pulled from many sources, including the EHR. Those 60 registries account for approximately 80 percent of the care that Intermountain Healthcare provides, thereby enabling the health system to truly manage care on a large scale. He explained that determining what data to collect in the EHR is a critical factor in developing a system that can lead to learning and improvement. Once the data systems are running, it is important to develop an organizational structure that promotes champions for specific projects who are paid to own projects and oversee them as their full-time job.

At Intermountain Healthcare, Level 1 research is aimed at answering questions that will have a relatively immediate impact on the company's care delivery performance. This covers what James characterized as a tremendously broad and interesting set of research questions, often around competing treatments for the same condition, and answering these questions has proven to be a fruitful area of research that generates more peer-reviewed publications than most academic medical centers generate. "The reason it works is that it is integrated into routine care delivery at the level of data systems and organizational structure," James said. He added that Intermountain Healthcare has a master data agreement that took 15 months to develop and cost approximately $500,000 but which, once in place, enabled studies to start within days of the study being conceived. He concluded his comments by saying that the process to select topics for research should depend on organizational priorities.

Scott Armstrong, Group Health

Group Health, Armstrong said, is a 1,200-physician group practice with employed physicians and a series of medical centers across Washington State and northern Idaho that covers about 600,000 insured patients. Unlike Intermountain Healthcare, Group Health is 100 percent capitated and about 95 percent of the system's revenues come from premiums, with the rest coming from co-pays. Because of this structure, Armstrong said, Group Health, with input from the Group Health Research Institute, is a laboratory for aligning the entire organization, from health plan to care delivery, around population health and total outcomes for all of the system's patients. Armstrong also noted that Group Health has a cohort of patients who have been members since 1947, offering what may be an unprecedented longitudinal health record.

Group Health operates as a 501(c)(3) not-for-profit HMO with a board elected from among the organization's members. This organizational structure results in a high level of accountability to patients, but it also creates an expectation among members that they themselves play a critical role in achieving desired outcomes. Armstrong credits this two-way accountability for Group Health's early adoption of EHRs and almost immediate access to those records by patients through any computer. He also said that the organization's culture is such that its leadership team and medical group consistently work together on advancing the virtuous cycle between research and operations to create value at speed. Group Health's culture of continuous learning has created value in the marketplace through lower costs, confidence in the care delivery experience, and quality as measured in a number of ways. As an example, he cited the way in which patients, clinicians, and accountants worked together to build a primary care medical home model in one of the organization's 50 medical centers. "To me, the value of this was that we could get it up and running," Armstrong said. "We could check how it was working and make refinements. At some point, I had confidence that I would not have had otherwise to very quickly expand that model to our other 50 medical centers at a pace that we would never have moved, if it weren't for this kind of relationship."

John Warner, University of Texas Southwestern Medical Center

The University of Texas Southwestern Medical Center (UT Southwestern) is a large, complex university health system that not only operates the university hospitals and clinics, Warner said, but also provides faculty who account for more than 90 percent of the physicians at the Parkland Health and Hospital System. UT Southwestern Medical Center also provides faculty physicians who staff both Children's Medical Center in Dallas and the Dallas Veterans Administration Hospital. Furthermore, UT Southwestern delivers some component of the medical training of more than 50 percent of the health care providers in Dallas as well as offering training to the lay community. As a result, Warner said, his organization has the opportunity and obligation to provide a learning environment not just for its campus, but for a city and a region.

UT Southwestern, Warner told the workshop, has had a very positive experience thus far working with PCORnet as a participant in the Greater Plains Collaborative CDRN. According to an informal poll that he conducted just prior to the workshop, staff who have worked with the network reported that their experience has been that being a part of PCORnet allows the organization to pick up the pace of learning and improvement. One reason for this, he said, is that being part of PCORnet has catalyzed an effort to create synergy among more than 70 internal and external data registries,

including its EHR, used at UT Southwestern. "Being part of PCORnet has allowed us to more effectively submit and extract data in both internal and external registries," Warner said. He noted that no one medical center or hospital has enough information technology staff to do this alone. "Having partners in this 10-hospital system collaborative network," he said, "has helped us move the needle more quickly, allowing us to build the infrastructure needed for us to extract data; to take our existing data, compare it with other research databases; and to answer new questions so we can begin to look at value and care improvements in a very different way."

Concerning the opportunities that PCORnet creates, Warner said that he would like to see cost added to the data being collected. "You simply can't measure clinical effectiveness without it," he said. "If we are going to make the kind of investment into the types of research that will be required from our health systems, we have to measure cost in a way that allows us to transparently provide the information to our patients and their families."

DISCUSSION

To start the discussion, Greene asked the panel members how each of them can put research at the top of their priority list, given all of the other demands for time and resources that they face in serving the good of the entire organization. James replied that the entire purpose of the research institute that he runs at Intermountain Healthcare is to answer questions for the system's administration that will allow the administration to make good decisions, and it is why the institute is 100 percent internally funded. As an example, he said that the administration was trying to decide whether it should put psychologists in its primary care clinics based on the argument that doing so would reduce utilization enough to pay for extra nurses. A prospective cluster randomized trial showed that argument to be true, enabling administration to make an evidence-based decision. James then seconded Warner's call to track cost as part of the learning health system, something that Intermountain Healthcare has been doing for years.

Warner, James, and Armstrong all commented that they appreciate the value that research creates because of what they hear from the clinical service lines, from the nurses and physicians who are providing care, and from patients. What is critical, James said, is that research lead to deployment. "If you have got the structure in place with the data and the organizational structure, a natural consequence of doing the investigation is you have got a deployed system," he said. Armstrong added that the question that he wants to answer now, with all of the data systems in place, is which investments are not providing the expected return. "Quite frankly," he said, "I think we are carrying enormous costs that aren't giving us the return that we used to get."

Conway added the perspective of a policy maker who has compiled data on the percentage of decisions that he makes with the help of data. He said that when he first started at CMS, that figure was about 2 percent, and while it has now risen to somewhere between 40 and 50 percent, it has been stuck there for 2 years. He said that he has come to realize that the problem is not that he and others are not looking hard for the evidence but that the data and evidence just do not exist.

Steven Lipstein of BJC Healthcare asked if the panelists were concerned that the desire to generate value with speed would lead to unintended consequences that would actually harm certain segments of the provider and patient communities. Armstrong replied that there is a balance that needs to be struck but that, overall, the health care industry is grossly conservative and far too slow to change. The key is to protect patients in terms of safety and quality, Armstrong said, and the industry should be proud that it does that well, but it needs to accelerate the pace of change. Conway agreed that there is a balance between risk and benefits, and while he said that he does not know the right answer, he said the pace of change today is not too quick, and he worries more that the opposite is true. He added that focusing on things that have no unintended consequences will not enable the system to transform itself at the pace that the nation needs it to occur.

Robert Kaplan from AHRQ asked the panelists if they had questions that they would not try to answer with PCORnet and for which they would demand data from an RCT before enacting change. James said that there is a set of principles that can determine which trial method is appropriate and that he and his colleagues use a full range of designs, the choice of which is determined by the question that needs answering. He did note that there is technical body of work using a formal empirical evaluation of internal validity within a study, known as the confidence profile methods, with which James said he can design a good quasi-experimental study that will produce higher internal validity than most RCTs. He estimated that Intermountain Healthcare does use RCTs for about 1 of every 20 studies it runs. "We tend to use as rigorous a design as we can do in a reasonable length of time that matches the need and the circumstances of the data," he said.

Selby agreed with James that observational data in PCORnet can complement RCTs, which are costly and thus limited in the number that any health system can afford to run. But aside from that, PCORnet can facilitate more efficient RCTs when such trials are indicated. Selby pointed to the REDUCE MRSA trial as a good example of how the two types of trials are complementary, noting that there was a randomized trial followed by observational studies to watch the impact of the interventions. He said that the PCORI methodology committee is spending time on this very topic.

Jonathan Tobin from the Rockefeller University Center for Clinical and Translational Science asked if it would be possible to systematically

design a series of RCTs that had parallel registry studies conducted, either in the same settings or in similar settings, in such a way that it would be possible to generate answers and effect sizes from the randomized trials and effect sizes from the observational studies. The results could provide some insights into when it is necessary to invest in an RCT and when questions can be answered with registries. Warner said that in cardiology, his area of practice, this type of comparison has been used often to look at practice variation, and it has proven to be a good approach.

Sean Tunis from the Center for Medical Technology Policy said that the sustainability challenge for PCORnet is to enable and demonstrate the value of observational studies that are conducted with greater rigor and higher-quality data than is the case with the typical quality-improvement study. He wondered if there is a business case to be made for investing in a system that does raise the quality and reliability of observational studies. James said that there is a business case to be made, but that it is necessary to match the method to the problem. Warner acknowledged Tunis's point and said that it is still an open question whether UT Southwestern has realized the full potential of its decade-long investments in its EHR. He said that health care systems need to expect more from their EHRs and that PCORnet represents an opportunity to build the infrastructure to extract more meaningful data from EHRs. Greene added that creating a sustainable public good is also going to require broad patient engagement.

Joel Allison of the Baylor Health Care System said that there is a general lack of individual accountability with respect to health decisions and asked how the health care system can change patients' behavior to become more engaged in personal accountability. He also expressed concern about the role of health literacy in changing behaviors and asked if there is ongoing research that addresses issues involving health literacy. Warner agreed that it is important to understand the impact of health literacy on the decisions that patients make and said he believes that the requirement for PCORnet members to pay attention to public engagement is a positive step toward gaining that understanding. Armstrong agreed that health care systems need to do a better job of using their patient-centered relationship to explore how patients understand the information they are given and the consequences of the choices they make outside of the exam room. He added that Group Health is involving patients in system change in a way that asks them if processes are designed in a way that increases the likelihood that they will pay attention.

Armstrong also said that Group Health is taking advantage of the fact that some 15,000 employees and their families are also covered by Group Health's insurance plan. These employees are given the opportunity to receive up to $750 in premium discounts based on the beneficiary's improvement in body mass index, blood pressure, and other health screening tests.

Group Health has partnered with Kaiser Permanente Colorado to serve as a control to enable a true assessment of the impact of financial incentives to advance this kind of engagement on the part of the beneficiaries. "I don't know how that translates into an agenda for PCORnet, but I think it is an area that we need to be investing much more time and attention in," Armstrong said. Conway added that CMS's Innovation Center is considering broadening its research portfolio to look at ways of engaging consumers and patients in a real way with the decision-making process.

Rachel Hess from the University of Pittsburgh commented that she was impressed with how operational motivations have been embedded within a research infrastructure. James said that this has been an intentional development to achieve both performance improvement and learning at the same time. He noted that any time he and his colleagues launch an investigation—even a rapid-cycle quality-improvement project—they always add a little bit of data to the system, which lowers the overhead for the system and eventually speeds the pace of change.

Kenneth Mandl from Boston Children's Hospital asked for the panel's input on the part of the virtuous cycle that is involved with returning evidence back to the point of care, particularly with respect to criticisms of the rigidity of EHRs. James said that there are a number of applications designed to work on top of the EHR and that are organized around the continuum of care. He noted that when systems are developed to capture data in an EHR that are concerned with creating an effective care management system, those data turn out to be the data that are needed to run trials effectively. What disappoints him, he said, is that very few people think about this in advance when building their systems. Conway said that what is important is to think concurrently about both the questions that need answering and the deployment of the results, and Armstrong added that systems have to be bidirectional in that they have to be pushing information out while they are receiving information.

10

Continuous Learning as an Executive Agenda Priority

KEY SPEAKER POINTS

- Belonging to a research network should be an executive agenda priority, Jonathan Perlin said, because it enables an organization to contribute to addressing the big questions that concern the nation regarding health care while also improving the care of individual patients and improving the sustainability of the health care system.
- There is a strong business case for health care systems that have already made significant investments in information technologies to support research networks, Perlin said. These networks allow the systems to leverage their investments in information technology by investigating questions that can be best addressed using data from multiple organizations.
- CEOs can create a forum and the mechanisms by which clinicians and patients can pose questions and where researchers and analysts can work out approaches for answering those questions, Raymond Baxter said.
- Organizations have a limited supply of intellectual capital, and it should be spent on research that produces change for patients, Baxter said; the barometer for success, he added, is the speed at which research results produce changes in care and outcome.

- What appeals to CEOs, David Labby said, is not the development of new interventions but rather answering questions that will help them manage a global budget and integrate mental and physical health in a way that benefits patients and cuts costs.
- The health care system would be further along in its transformation if it could mobilize what it already knows in an efficient and an effective way as opposed to continuing to invest in creating new knowledge that the health care system does not know how to apply, Labby said.
- Language differences between those who manage health care systems and those who conduct research to improve those systems has created a significant barrier to progress, Patricia Smith said.
- Measures to judge progress should include, Russ Waitman said, reduced practice variation, improvements in the lives of patients and those in the community, reduced disparities and variability in underserved populations, reductions in resource consumption, increases in quality of life and longevity, and increased patient satisfaction.
- Making these measurements of progress, Waitman said, requires data, and data require infrastructure that captures data efficiently, at low cost, and in ways that it can be integrated with other data sources, which is where the initial focus of PCORnet lies.
- There is a concern among CEOs, Glenn Steele said, that many of their questions are not amenable to RCTs, but they are nervous about the biases inherent in using observational data; in addition, there is also concern about the generalizability and scalability of results.
- Taking cost out of the system will not happen without moving toward population health and providing value, and both of those steps require knowledge of the sort that a learning health system can produce, Steven Corwin said.
- In the absence of knowledge to refine the blunt measurement of cost and utilization, Corwin commented that he fears that the health care system will bifurcate into one that has hospitals that treat the "haves" and hospitals that treat the "have nots," which would be problematic for the country as a whole.
- Privacy and security issues need to be addressed in a way that balances the need for transparency with the concerns of liability in an area where legal requirements are evolving, Corwin noted.

One of the goals of the workshop series was to explore the challenges and opportunities that health system leaders see with respect to creating a continuous learning environment within their institutions. Over the course of the workshops there were several sessions that dealt with the issue of continuous learning as a priority for health system executives. Jonathan Perlin, the president of clinical services and chief medical officer at HCA, described an example of an effort that was successful in integrating research and practice and that resulted in cost savings. A panel discussion, moderated by Michael McGinnis of the IOM, sought to identify and prioritize the key issues for health systems leadership in moving toward a system that more tightly integrates care and knowledge-generating activities. This panel, which also discussed whether a shared value proposition is the key to sustainability, consisted of Raymond Baxter, the senior vice president for community benefit research and health policy at Kaiser Permanente; David Labby, the chief medical officer at Health Share of Oregon; Patricia Smith, the president and CEO of the Alliance of Community Health Plans; Janice Nevin, the chief medical officer for the Christiana Care Health System; and Russ Waitman, an associate professor of internal medicine at the University of Kansas Medical Center.

A second panel discussion, moderated by Lewis Sandy, the executive vice president for clinical advancement at UnitedHealth Group, featured short comments by four health system leaders: Glenn Steele, Jr., the president and chief executive officer of Geisinger Health System; Ronald DePinho, the president of the MD Anderson Cancer Center; Rodney Hochman, the president and CEO of Providence Health and Services; and Steven Corwin, CEO of New York-Presbyterian Hospital. That panel, which continued the explorations of the first panel, identified further opportunities for making learning activities an executive-level priority. Both panel discussions were followed by an open discussion among the panel members and workshop participants.

BEYOND THE REDUCE MRSA TRIAL

To provide an object lesson in how system executives' activities can address issues that are relevant not only to the national agenda but also to the success of their institutions, Jonathan Perlin discussed his perspective on the REDUCE MRSA trial that Susan Huang had previously described. He also used this example of a successful data-enabled trial to illustrate some of the organizational challenges to the conduct of pragmatic research within a health care organization and to highlight some potential solutions to those challenges.

From his perspective, Perlin said, the REDUCE MRSA trial aimed to tackle a major problem for health systems—the hospital-acquired infections

that affect about 4.5 percent of all hospitalized patients and that result in some 80,000 deaths annually. Approximately one-quarter of the patients infected and about one-quarter of the patients who succumb are infected with either MRSA or some other form of *Staphylococcus* infection. Prior to the conception of the REDUCE MRSA trial, HCA had already been using a procedure, modeled on what is done in European hospitals, that screened patients for MRSA and then isolated them if they were positive. With support from the CDC, and together with other academic partners, HCA tested the effectiveness of this approach against two other promising strategies: decolonizing MRSA-positive patients with a chlorhexidine antiseptic sponge bath and 5 days of antibiotic therapy delivered via nasal ointment versus universal decolonization of everyone prior to their entry into the intensive care unit.

Over 18 months the REDUCE MRSA team tested the three procedures in 74 ICUs at 43 hospitals using a cluster randomization design. Ultimately, some 75,000 patients received one of the three interventions, Perlin said, and the clear winner was universal decolonization, which not only reduced MRSA infections but reduced all bloodstream infections by all pathogens by 44 percent. Putting these numbers into terms that are germane to health services researchers, Perlin said that for every 99 patients who are treated, one bloodstream infection was avoided. "This occurred on top of every other best practice, and so it really set a new standard for reducing bloodstream infections," he said. Addressing the bottom line, Perlin estimated that for every 1,000 patients admitted to the ICU, HCA saves $170,000, or a total of $19,720,000 per year in institutional enterprise benefit.

Perlin said noted that although this was obviously an important outcome, an equally important benefit of the REDUCE MRSA trial was that it took a mere 18 months to complete because it drew upon archived data for baseline results and involved 43 hospitals, each contributing data. Perlin estimated that had this study been done at one hospital, it would have taken 64 years to treat enough patients and accumulate enough data to gain the power needed to answer the research question. "So it didn't take 1 hospital 64 years, it took 43 hospitals 18 months," he said. Moreover, this study was not conducted in an academic unit but rather in standard hospital settings using routine health workers. "What we think is particularly powerful about this is that it answered real-world questions in real-world environments that we believe generalized to real-world situations," Perlin said, adding that the total cost for the study was only $3 million. In contrast, the slightly smaller Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial cost $80 million. The REDUCE MRSA study was so effective, he added, because of the federal and academic partners that participated in the study and that enabled HCA to leverage its internal expertise in infection prevention. Those partnerships were important for

supporting the business case for this study, which in the end provided a powerful return on the investment that HCA made to support the study.

Perlin acknowledged that he and his fellow health care executives often worry more about costs than about the promise of benefits, and he counseled the workshop attendees to pick questions to study that provide both operational and financial opportunities. He also said that this type of research activity, when aligned with organization priorities, can amplify and accelerate ongoing quality-improvement activities. It is time, he said, for health system administrators to challenge their information technology infrastructure and to look for opportunities to collaborate to address deficiencies in organizational capabilities. For example, HCA selected its academic partner for the REDUCE MRSA trial for its expertise in administering large clinical trials and in patient consent issues. It may also be necessary to challenge a health system's clinicians to embrace research that has the purpose of improving performance, which if successful will generate pride that is self-reinforcing.

Why participate in such studies? Perlin said that the fundamental reason is to contribute to addressing the big questions that concern the nation regarding health care. Another important reason is to improve the care of individual patients while improving the sustainability of the health care system. "You can answer meaningful questions and support quality improvement by fostering evidence-based research that is oriented to performance improvement," Perlin said. Participating in such research also provides a "first adopter advantage for improvement innovations," he said, and there is also a strong business case to make for supporting this type of research. Health care systems have already made significant investments in information technologies to meet the meaningful use criteria, and participating in research networks creates the opportunity to leverage that investment with those of other organizations and answer questions that can be best addressed using data from multiple organizations. This type of research, Perlin said, provides the opportunity to bridge the translation gap that separates knowledge and practice. "Here is the opportunity to create knowledge out of practice itself and create a learning health system."

HCA is now designing a study to determine best practices for preventing and reducing surgical site infections associated with cardiac and orthopedic procedures. This study will involve 50 hospitals and 400,000 patients and be conducted in 1 year. Another study will aim to identify best practices for detecting and treating sepsis more effectively. "With 20 million patient encounters, with hundreds of thousands of ICU encounters, and with physiologic data, we believe that we can find early markers, create a standard definition, and perhaps look serendipitously for processes or treatment interventions that work more favorably," Perlin said. "We also want to look at the relationship to improve antimicrobial stewardship." A

third study, with partner Vanderbilt University, will look at how transitions of care should be optimized for safety.

Ultimately, the main reason that HCA participates in this kind of research is that "we believe we can improve health care, we can improve value, we can improve the sustainability, and we can improve the health system," Perlin said. "We think it's fun and enjoyable to be part of a learning health system."

In response to a question from Steele about whether HCA is "monogamous with randomized controlled trials," Perlin said that the answer was no and that the organization is open to other validated methods of conducting CER. Commenting on the methodological aspects of the trials, Richard Platt of the Harvard Pilgrim Health Care Institute, which was the main academic partner on the REDUCE MRSA trial, noted that the reason it was possible to do this study so effectively was that it relied solely on information that was collected as part of routine care and on data that was available in HCA's clinical data warehouse. "The reason that the randomized trial gave such a solid answer," Platt said, "is that it was built on the basis of 12 months of historical data that was exactly analogous to the data from the 18 months of the study. Had we not had that baseline data, the study in fact would have been substantially underpowered, even at 75,000 patients."

Platt also mentioned that the NIH Collaboratory is working at a conceptual level to identify the problems associated with embedding pragmatic trials in clinical settings and to identify ways to deal with them, an effort that is complementary to PCORnet's role in building the infrastructure to conduct such trials and use what the Collaboratory is developing. Eric Larsen, the workshop planning committee chair, added that one observation that the Collaboratory made is that there is a great deal of standardization and training needed before trials of this sort can be run effectively, a comment with which Perlin agreed.

PRIORITY OPPORTUNITIES FOR CEO LEADERSHIP TO MAKE A DIFFERENCE

The final session of the first workshop drew on the previous day and a half of presentations and discussions to identify and prioritize the key issues for health systems leadership in moving toward a system that more tightly integrates care and knowledge-generating activities. The panelists each delivered brief, prepared remarks on this topic and then entered into a period of discussion among all workshop attendees. As a prompt for the panelists' remarks, session moderator Michael McGinnis of the IOM listed several questions for them to consider in a strategic effort to achieve a closer, sustained alignment of research and practice:

- What might be the core benefits that would appeal to a CEO?
- What key infrastructure elements are needed?
- What obstacles need to be addressed?
- How can patients and families be enlisted as active allies?
- What is the most important step that a CEO can take to make that happen?
- What perspective will be the most attractive to board support?
- What policy signals or actions are important for engaging purchasers and research funders in this effort?
- What might be some measures of progress by the year 2020?

Raymond Baxter, Kaiser Permanente

In his remarks, Baxter commented that researchers working alone will not be able to address the needs of the health care system and that finding solutions will require a central role for operational leaders, clinical leaders, and patients. He noted that Kaiser Permanente refreshed its research strategy some 4 years ago so that the organization could answer clinically meaningful questions more quickly and efficiently. This reorganization included creating the Center for Effectiveness in Safety Research (which is charged with building the infrastructure needed to integrate research and care), expanding the company's biobanking operations to a national level, and most recently, setting up its data portal and joining PCORnet.

At the same time, a team of Kaiser Permanente researchers, acting at the instigation of Kaiser's National Research Council, queried Kaiser's chiefs of staff and other clinical leaders in the organization to find out what questions they thought most needed answering in order to meet the triple aim. In response to this request, Baxter received 342 questions, which he realized could be an operational agenda for relevant research in a learning health care organization. To his surprise, between 25 and 30 percent of the questions already had answers, though the evidence was not known or available to those who proposed those questions. "That's disturbing in its own light," he said, "but in retrospect not too surprising." Some questions were not posed in a way that made them easy to answer, and in the case of others there was nobody with an interest in finding an answer. Eventually, Baxter and his colleagues settled on five questions that they thought would provide "quick hits," but 18 months later, none of those quick hits had produced answers. "They did eventually," Baxter said, "but it is not clear that any care transformation happened from the ability to answer those questions."

What Kaiser has done since is to examine the full range of analytic capabilities in the organization, from business intelligence to care analytics, and it is now trying to array them in a continuum that can triage questions

so that the questions go to the right analytic unit—the unit that has the right tools, measures, data, and approaches and that can deliver the necessary degree of rigor and precision so that the person who asked the question can take action at the end of the day. "That's a much more complex process," Baxter said.

Turning to the questions that McGinnis had posed, Baxter said that CEOs do not want research—they want performance improvement, and they want it at speed. "CEOs are impatient with what we do and what we have done traditionally," Baxter said. What CEOs can do with regard to infrastructure is to create the forum and the mechanisms by which clinicians and patients can pose questions and where researchers and analysts can work out approaches for answering those questions. "Creating that forum of people working together on that is essential," Baxter said, "because the researchers cannot guess at what are the questions that operators and patients have in their minds. And operators and patients can't always pose the question in a way that's readily translated by researchers." He added that "a CEO can create not only the mechanism but the culture that says that that's important." He noted that while CEOs are sometimes credited with more power than they have, the one thing they absolutely can do is change organizational culture so that everyone is encouraged to participate in research to answer questions that are important for the organization. "That goes against the tradition of investigator-initiated research," Baxter said, "but I believe that paradigm is going to have to change significantly."

As far as what CEOs can do to enlist patients and families as active allies, Baxter said that they can insist on greater engagement and model it in their own behavior. "The CEO who talks to individual patients, who reads the complaints of members and patients who are not well served, that's the kind of CEO that can drive this kind of change in research as well," Baxter said. Concerning what a board needs to hear, he said that the message that research can affect costs is persuasive, but the message that research can change and improve care is probably more so. "Unless we can organize our research and analytic capabilities in a way that has a demonstrated impact on improving care and improving health," he said, "I'm not confident that the cost arguments will be effective." The reason, he said, is that organizations have only a limited supply of intellectual capital that should not be spent on research that is not producing change for patients and members. The barometer for success, Baxter said in concluding his remarks, is the speed at which research results produce changes in care and outcome.

David Labby, HealthShare Oregon

Labby began his comments by noting that, 2 years earlier, Oregon had adopted the concept of using coordinated care organizations for its

Medicaid population. These coordinated care organizations act as a regional health authority that oversees all spending on physical, mental, and dental health for all of the Medicaid patients in a given region. Labby noted that the state cajoled competitive organizations to participate by threatening them with a 30 percent rate cut if they did not join. The carrot was that the state gave these coordinated care organizations the freedom to transform care in ways that best served their interests and the interests of patients at lower cost. The sense of urgency to avoid draconian budget cuts, Labby said, changed CEO behavior so that suddenly competitors were working together to create the structures needed to cooperate on a large scale.

The main obstacle to success, these CEOs said, was the lack of data needed to assess operations and effectiveness. However, within 1 year, Labby and his colleagues had produced a data system that could aggregate information from different health systems. That success created a second problem—how to use the aggregated data in a productive and appropriate manner. Oregon is looking now to hire a person who can help solve this latest problem, Labby said. He added that he thinks that CEOs do not know exactly what questions to ask other than that they know they want to know how to increase system efficiency. What appeals to CEOs, Labby said, is not the development of new interventions but rather answering questions that will help them manage a global budget and integrate mental and physical health in a way that benefits patients and cuts costs.

Reflecting on the workshop's discussions, Labby said that it is clear that there is a great deal of knowledge that is not being used. "Do we need to generate more knowledge that we don't use," Labby asked, "or do we need to figure out how to use the knowledge we already have? I think, from a health system point of view, if we could mobilize what we know in an efficient and an effective way, we would be way further down the pike than if we keep investing in and creating new knowledge that we don't know how to deploy."

Labby commended the work that Intermountain Healthcare has done in building infrastructure and the extreme amount of intentionality shown by the Bellin system in the way it approaches research that benefits the organization. What CEOs need, Labby said, is help creating those same structures and organizing their operations with the same intentionality. He noted the pressure that CEOs are facing, given the huge changes that are occurring in health care's current transitional state between the older volume-driven, fee-for-service models and the newer value-based, capitated fee-for-performance payment models. The old organizational and operational structures will not work in the new model, Labby said, and CEOs need help developing those new structures.

Turning to the subject of patients and families, Labby spoke from the perspective of the Medicaid population with a focus on the so-called high

utilizers. In reality, he said, these individuals are not high utilizers, but rather they are people who have been marginalized and traumatized for generations. "What they need is a trauma recovery program," he said, "and so our medical home for that population serves as a trauma recovery program." Because this population needs help connecting with peers in their community, Oregon created a certification program for peer wellness specialists who, once they have been certified, become part of the health care workforce.

Boards of directors are interested in costs and meeting contracting budgets, Labby said. Concerning policies, he suggested that PCORI can seize the current opportunity to develop a new research agenda that helps with health care transformation. Regarding measures of success, he proposed that health care spending being less than 16 percent of gross domestic product (GDP) would be a positive sign that transformation is occurring.

Patricia Smith, Alliance of Community Health Plans

Smith began her comments with the observation that the people attending the workshop speak a different language from those she talks to on a daily basis in her job as a lobbyist—something that she characterized as a major barrier. "If we can't cross the communication bridge, I think we will have lost a big part of the battle," she said, noting how important it is to be able to convey the importance of research to learning. She explained that her board is made up of the CEOs of health plans and that, as a result, she has given a great deal of thought to what matters most to them. "Learning clearly matters, but learning in an environment that delivers for the public, for communities, and for the nation, is what really matters," she said.

One of the facts of life for the CEOs that she works with, Smith said, is that all of their operating funds come from premiums, and premiums are what purchasers care most about. They pay less attention to value. What that means for researchers, Smith said, is that the research community needs to show that their work has relevance to consumers, whether it is in better health, price, credibility, trust, or a combination. Smith reiterated the earlier message that what CEOs value is to fail forward fast, to create value at speed, and to do so in a way that meets the priorities of their organizations.

Regarding how CEOs can engage patients, Smith said that the issue of trust truly matters to patients. Those in the executive suite must translate the need for public trust into a strong governance model that respects learning. Smith concluded her remarks by saying that population health is improving communities and that communities are healthier when the health care systems that operate within those communities are healthier.

Janice Nevin, Christiana Care Health System

To provide some context for her remarks, Nevin said that Christiana Care Health Systems is a large regional, community-based academic health center with three campuses, two acute care hospitals, a rehabilitation hospital, a Visiting Nurse Association operation, multiple outpatient sites, and revenues approaching $2 billion. Christiana serves Delaware, where it is the dominant provider in Wilmington and the surrounding New Castle County with an 85 percent market share, as well as south New Jersey, southeastern Pennsylvania, and Cecil County, Maryland. Because of its market dominance in the Wilmington area, Christiana's leadership sees itself as a public utility upon which the community depends and which the community expects to be sustainable. For that reason, Christiana sees research and education as critical factors in its ability to serve its community, Nevin said.

In 2011 Christiana created an entity called the Value Institute whose express purpose is to bring together quality improvement and operational excellence and marry them to health care delivery research. "The perspective of our CEO is that the Value Institute is a way for us to focus on value as our fundamental strategy for service," Nevin said. "This is about more than just quality and cost, but about value grounded in the needs of our neighbors as they perceive them." Among the institute's initiatives are studies to identify reliable tools in the setting of oversedation and its role in sepsis and also refining anticoagulation algorithms for patients undergoing surgery. In addition, the Value Institute also has a $10 million Center for Medicare & Medicaid Innovation grant to study how to use new technology to collect and organize data in a way that allows clinicians to use the data to improve the care of patients with ischemic heart disease.

Turning to the questions that McGinnis posed, Nevin said that the core appeal to a CEO of closely aligning practice and research is what is embodied in the Value Institute. "If we can align practice and research," she said, "there is potential for us to do better in delivering our core mission, and we're going to invest in that work." She added that engaging patients and families is a "must do" as part of this alignment and added that a message for CEOs should be to first define how their organizations define "patient-centered." CEOs, she said, need to embrace the message that several panelists throughout the day had stated, which is to look at partnerships with patients and families as a core business strategy. "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. "To me, that's job one."

McGinnis asked what such an infrastructure looks like, and Nevin replied that it starts with patient and family advisory councils but goes beyond that. Christiana, for example, is embedding patient advisors in every patient care unit and including them in the system's operational committees.

These patient advisors have become active and important contributors to the successful operations of the entire system, she said. The next step is to bring payers on board as partners and to do a better job of helping patients and families understand outcomes in a way that enables them to make good decisions for their health.

Russ Waitman, University of Kansas Medical Center

Speaking from his perspective as the principal investigator for the Greater Plains Cooperative CDRN, Waitman said that two ways to appeal to a health care system CEO could be to present patient-centeredness as an altruistic goal and to sell it as a way to drive costs down. He said that his CDRN is not seeking funds from the CEOs of the institutions that belong to this CDRN and that this is a plus because, as he put it, "I don't know that we have formulated a good value proposition yet." He also thought that patient-centeredness would be a strong appeal to a health system board, particularly for those of nonprofit institutions.

Waitman's suggestions for how CEOs can engage with patients and families and recruit them as active allies focused on forming a team with Clinical Science Translation Award community engagement groups. Such an alliance could bring community and research perspectives together with the health system perspective and create the potential for generating new ideas. Concerning measures of progress by 2020, Waitman said that PCORI has metrics that it is supposed to meet by 2017 and that these metrics—reduced practice variation, improving the life of patients and those in the community, reducing disparities and variability in underserved populations, and others—can serve as a starting point. Other measures to judge progress should include reductions in resource consumption, increases in the quality of life and longevity, and increased patient satisfaction. Performing these measurements requires data, and data require an infrastructure that captures data efficiently, at low cost, and in ways so that the data can be integrated with other data sources. This last issue—making sure that data can be integrated—is where much of the initial focus of PCORnet lies, Waitman noted. "Making the CEOs aware of what steps are happening in terms of data integration and data structures is going to be important," he said.

Waitman noted that one of the biggest signs of success would be if barriers for data exchange were lowered. As an example, he cited the difficulty in getting data from the Social Security Administration regarding which patients included in a large database have died. He suggested that policies need to be developed with an eye on how data can be repurposed back to the health system. Thinking about barriers brought Waitman to his final point. Health care, he said, is fundamentally a reactionary business today, and part of the mind-set of this business sector is to be cautious when roll-

ing out new programs that may or may not work in a particular health care system. As a result, one good approach is to iterate rapidly while taking off small pieces of risk, rather than engaging in projects that would require a total reworking of a system. At the same time, he said, systems need to be able to incorporate "blockbuster" developments, such as the development of endoscopic surgery. Balancing these three things in an organization will be a major challenge for PCORnet going forward, he said, particularly with regard to whether to introduce the data analytics that PCORnet will enable slowly or in a way that is more intertwined with a health care system that is fundamentally a reactionary one.

CHALLENGES AND OPPORTUNITIES FOR ENABLING CONTINUOUS LEARNING IN HEALTH CARE ORGANIZATIONS

In order to stimulate discussion about the challenges and opportunities faced by organizations in enabling continuous learning, moderator Lewis Sandy posed four questions for the panelists, each of whom was a leader of a health system, to answer. Panelists each delivered brief, prepared comments on the topic and then engaged in a discussion with all workshop attendees on those questions:

- How does knowledge generation fit on your agenda?
- How does this idea of integration of research and practice fit the rapidly changing environment of policy, practice, and reimbursement?
- How do we speed up knowledge generation and get it installed into a learning health system?
- How do you see this agenda really being advanced in the real world that you live in every day?

Glenn Steele, Geisinger Health System

Geisinger Health System, as Glenn Steele described it, is a "Petri dish for innovation because of our structure and our culture and our demography." Indeed, the organization's most important strategic aim is fundamental innovation in how it provides and pays for care, and continuous innovation based on dynamic data feedback is the means by which the organization goes about realizing that aim. Steele said that the focus of the organization's behavior change over the past 12 years has been both in the provider part of the organization and, for the 50 percent of its patients who are also insured by Geisinger's health plan, in the payer part of the organization. Looking forward, though, Geisinger is now aspiring to create enabling technology beyond the EHR that will change the behavior of its patients and members. "Basically, what we're attempting to do, which

relates to our business model," Steele said, "is create value and either redistribute that value to the people who buy our care or keep some of it for ourselves and redistribute it for more innovation or expansion."

Addressing what his organization needs from PCORnet, Steele said that he and his colleagues worry that much of its observational data and the approaches that it takes to research are not amenable to RCTs and that they are "extremely nervous" about the biases that are built into the results it gets from using observational data. They also worry that the things it discovers at Geisinger will not be applicable anywhere else, given that Geisinger has built scaling and generalizing results as part of its systemic strategy. To address these fears, Steele said that he wants Geisinger to work with PCORnet on studies that may or may not involve RCTs but whose findings would be scalable and generalizable.

Ronald DePinho, MD Anderson Cancer Center

MD Anderson is an unusual cancer center with the responsibility of delivering multidisciplinary research-driven care to a large number of patients from around the nation and the world. It maintains a national network of health care partners and leads a 29-sister-institution program in 23 countries. It has a large research enterprise that is integrated into its care pathway, and it drives a clinical trials enterprise that leads approximately one-third of FDA approvals in cancer treatments. As such, Ronald DePinho said, MD Anderson has a solid perspective on the cancer field that relates to the quality of care throughout the United States and the world. "There are significant knowledge and competency gaps," he said, "as cancer is an extremely complicated disease, requires multidisciplinary care, and is very technology intensive and knowledge intensive with respect to how to apply, for example, genome profiling to the care of patients."

When he arrived at MD Anderson 3 years ago, DePinho said, the institution had a homegrown EHR with 70 different transactional systems, all of which are now being standardized into an Epic-centered EHR. In addition, there were 50 different research databases and a number of independent tissue banks, each of which was useful but not integrated or aggregated in a way that enabled the system to learn as much as it could from what was happening in its clinical operations or its research laboratories. DePinho said that he considers the organization's EHR as merely another transactional system with which to ingest the vast amount of information coming from its clinical care enterprise. The consequence of these different clinical and research systems being so disconnected was that a study aimed at determining the cost of each step in the care of a cancer patient required manual curation of data to understand the outcomes value and economics

of each of several dozen steps involved in caring for patients with head and neck cancer.

Today, MD Anderson is implementing one EHR system and an eResearch platform that are fully integrated with one another. The organization piloted these new systems with leukemia, for which it already had standardized most of the processes involved in diagnosing and treating each patient. In addition, DePinho said, the organization is in the process of including more than 1 million patients and their legacy data into the same big data warehouse to which powerful analytic tools such as IBM Watson can be applied. Such an effort has many challenges, he said, and among the greatest is ensuring data quality upon ingestion. The organization's major focus now that it has created this big data environment is to have the right kind of analytics interface to produce continuous learning that will drive optimal patient management and acquisition of new knowledge.

DePinho commented that most of the workshops' discussions had been provider-centric and that there is a great need and opportunity to create a health/wellness system that is consumer-centric. Toward that end, MD Anderson is developing mobile platforms, decision-support cognitive computing systems, and interchange systems in order to advance the paradigm of care to systems that can reach the individual out in the community. He also said in closing that there is no difference at MD Anderson between clinical care and research. "Two-thirds of patients do quite well with standard of care," he said, "but for a third of cancer patients who fail standard of care treatment, their standard of care is clinical trials." DePinho concluded, "Research-driven, multidisciplinary care of the patient is the standard of care for MD Anderson."

Rodney Hochman, Providence Health and Services

Providence Health and Services, Rodney Hochman told the workshop, is the third or fourth largest nonprofit health care system in the country, with 4,500 physicians and 35 hospitals providing care in Alaska, California, Montana, Oregon, and Washington. Providence Health owns a Catholic High School in Burbank, California, which Hochman says is the best place to go to find out what 15- and 16-years-olds are thinking, and it is a leader in public housing in both Oregon and Washington, enabling it to more closely study the social determinants of health. Providence Health also has the single largest installation of the Epic EHR.

With his headquarters in Seattle, Hochman has been aggressive about hiring former Amazon employees who have a strong background in and appreciation for customer care. Providence's head of innovation strategy, for example, had not worked in health care before joining the organization, yet his customer- and consumer-centric approach is bringing a fresh look

at how Providence tackles innovation and designs its digital platform to enable advances in health care that are patient-centric.

Hochman said that his goal for Providence is to treat a third more patients at a third less cost, and the only way to get there, he said, is to have a robust digital platform to enable the kind of research that these workshops have highlighted and discussed. To get to that goal, he and his colleagues have picked out five areas across the 35 system hospitals for which Providence will first examine best practices every 3 months and then involve relevant clinicians in redesigning care to reflect those practices. "We've taken the approach of putting the clinicians in charge of how we are redesigning care," Hochman said. He added that his belief has gone from one that felt that standardization over scale is the way that health care will change to one that holds that innovation over scale will make a difference in how medicine is practiced. He concluded his comments by saying that the health system could make significant improvements if would take action on those things that existing evidence already shows are effective at improving care and reducing costs.

Steven Corwin, New York-Presbyterian Hospital

Steven Corwin said that he and his colleagues at New York-Presbyterian Hospital regard PCORnet as a strategic imperative because the current framework for taking cost out of the system is, from his perspective, a blunt instrument that uses price and utilization but little knowledge. Taking cost out of the system will not happen without moving toward population health and providing value, and both of those steps require knowledge of the sort that a learning health system can produce. In the absence of knowledge to refine the blunt measurement of cost and utilization, Corwin commented, he fears that the health care system will bifurcate into one that has hospitals that treat the "haves" and hospitals that treat the "have nots," which would be problematic for the country as a whole. In his view, Corwin said, data platforms and EHRs by themselves are insufficient to provide the real-time data needed to improve workflows in a way that will change behaviors. No matter what the incentives are, physicians are not going to create uniformly structured notes from every patient interaction in a way that will record every single detail that needs to be studied. One solution, he said, would be to move toward systems that are able to extract information using natural language processing.

Another problem that Corwin described relates to organizational culture, particularly with regard to the trend to merge systems and getting everyone in an organization to buy into a culture that is dedicated to continuous learning and improvement. Another issue that concerns him involves what is known now versus what will be known in the future. "The

evidence of yesterday is not the evidence of tomorrow," he said, "and to say that we should not be in a continuous learning environment, I think, is problematic. Just think about the way we used to take care of bleeding ulcers." Finally, Corwin said in his concluding comments, privacy and security issues need to be addressed in a way that balances transparency and liability.

DISCUSSION

Cost and Payment

David Posch of the Vanderbilt University Hospital and Clinics started the discussion by offering some general concerns. He noted that for 50 years hospital systems have been living in a period of seemingly unending money that has now, at last, ended. "Money is shrinking now, and that is a fundamentally new phenomenon in health care," he said. "We have not in our generation had to deal with that, and we don't know how to deal with that reality." In his organization, for example, volumes have been higher than ever, but revenues fell by $120 million in a single year, forcing him to make cuts immediately or risk the ire of his board and the system's bondholders. What guides him are three things that he uses as his "true north." "First," he said, "the health system is fragmented from a patient's perspective as they try to manipulate themselves through the system. Second, we fail to apply evidence every time to every patient, and, third, we don't engage our patients and families effectively. Anything we do has to solve those three problems."

Stephen Grossbart of Catholic Health Partners said that one of the big challenges that he sees is that quality departments are not adapted to using financial data and presenting it in a way that finance people understand. "So from a CEO perspective," he said, "placing expectations on finance and quality to work collaboratively would be helpful." He stated that every hospital system chief financial officer should be a quality champion, in contrast to the situation that he sees today, where the finance department does not understand the relationship between quality and savings.

Corwin said that he does not see how the nation can take cost out of the system unless the nation engages in population health more effectively, and accomplishing that task will take a long-term strategy that is currently lacking. "I'm sure that in the short run we can use PCORI and other things to take cost out of the head of hospital care, but unless hospitals think of themselves as beyond the four walls and their systems, ultimately I don't think it will mean anything," he said. He noted that his system and others are taking expensive populations and reducing the cost of caring for those populations by putting in place resources such as community health and

mental health workers. His system has seen admissions and emergency room visits drop by 20 to 30 percent as a result of taking this type of population health approach. Steele added that reductions of that scale should be the norm and that any system not realizing those types of reductions will be in trouble going forward.

Scott Armstrong of Group Health commented that the biggest impediment that he sees in reforming the health system is the speed at which the payment system transforms from the current fee-for-service basis. Steele replied that Medicare is already moving aggressively to a fee-for-performance basis, and even the residual fee-for-service payments are dropping per unit of work performed. "That's a real motivation to look at extracting as much cost as possible," he said, "even for that residual fee-for-service payment." Steele said that Geisinger is already working in an environment in which half of its revenues are capitated, which he says is terrific in that it puts a true focus on the total cost of care. Hochman added that health care system CEOs need to "get over" the ambiguity of where the nation is headed regarding fee-for-service and population health and focus on doing what is best for patients, and costs will take care of themselves. He noted that a contract that Providence recently signed with Boeing included many provisions about quality, which he says gets to the same point—doing the right thing for patients.

Uma Kotagal from Cincinnati Children's Hospital Medical Center asked if there are ways of reducing the transaction costs associated with operating a learning health system, noting that in her view that systems are still "clunky" and that integration across a health system is still not routine or streamlined, which leads to high transaction costs. Hochman replied that the learning network has to become more real-time. "You can't come to a meeting every 6 months and figure out what people are doing," he said. "It really has to be day-to-day." Real-time feedback will both increase the speed of adoption and reduce transaction costs. "The learning that comes out of a network like this has to be in real time and has to be continuous," Hochman said, "and we have to figure out how to do that." Steven Lipstein from BJC Healthcare said that tapping into PCORnet will help reduce transaction costs by increasing the size of the database with which to conduct research and generate knowledge without having to resort to having to build a dataset from the ground up with each research project.

Jeffrey Grossman from the University of Wisconsin Medical Foundation reiterated earlier comments about the challenges of executing and getting desired outcomes on a system-wide basis. "I'm really fascinated by those organizations that have managed to connect their ideas with outcomes," he said. "We're very good, but we're not where we need to be." Grossman also spoke of the challenge from the perspective of a physicians group associated with investing significant funds to develop learning systems when dealing

with a health system that still operates on a fee-for-service mentality and of the need to move research beyond what happens within the confines of the health care system facilities into communities to study and address all of the external determinants of health at the population level. That issue, he said, gets to the question of what the business model is for health care systems. "Is our business really health care delivery," he asked, "or is it the health of the populations for which we're at risk?"

Lipstein also offered a suggestion for his fellow CEOs who are investing in patient-centered outcomes research infrastructure projects. "If you're going to make an investment in patient-centered outcomes research infrastructure this year," he said, "don't budget the return on investment this year. This is not a quick activity no matter how sophisticated or efficient we become." Lipstein also pointed to the need for sustainable investments in patient-centered outcomes research. He said funds for those investments can be carved out of money currently being put into new equipment and instrumentation as well as from marketing and advertising. "Carve a little bit out and put in place a sustainable investment in patient-centered outcomes research and expect it to position you for long-term success," he advised his fellow CEOs, "because then you will be the creators of new knowledge, and that will be an advantage for you in your respective parts of the country."

Randall O'Donnell from Children's Mercy Hospital commented on the confusion between coverage and access to care. "Medicaid coverage does not equal access," he said, "and the farther you happen to live away from a metropolitan center where there is a mission-driven organization that runs primary care centers, the less likely it is that you're going to have access." What is needed, O'Donnell said, is organized access through medical homes, adequate case management, and a global payment system, but what is happening in the real world is that states are growing frustrated with Medicaid and are turning to proprietary plans that will, he said, "stick with fee-for-service until the cows come home because they feel that they can still eke out just that extra penny of profit if they're managing on a fee-for-service basis as opposed to locking in their profit by globally farming out the cost to a willing provider." Selby said that part of the agenda for improving health systems should be to study new models of coverage, including access.

Disparities and the Safety Net

When asked to provide his thoughts on what could be done to make his job as a health system CEO easier, Joel Allison from the Baylor Health Care System said that one of his biggest challenges is figuring out how to allocate resources and capital to create a learning health system and engage in the research needed to improve quality and reduce costs while also hav-

ing to serve the system's community in the role of a safety net provider. "How do you make sure that whatever you are implementing is going to improve the health not only of the individual but that whole population?" Allison asked. Forming better connections between clinical excellence and medical education research is one step, he said, but he said he worries about reimbursement for some of the initiatives his health care system is enacting that do reach out to the larger population. He added that the transition to a pay-for-performance system must happen faster if the goal is to move more quickly to a population health approach. Scott Hamlin from Cincinnati Children's Hospital Medical Center agreed with that comment, while wondering where the next few hundred million dollars will come from to make that happen and to keep current efforts to develop a learning health system going during this transition.

Addressing the issue of whether the business is health care delivery or the health of the populations for which they bear risk, Lipstein said that the issue of how to compare performance between systems that treat predominantly affluent communities and those that treat largely disadvantaged populations is a real one that does affect the business model. "The way CMS has this laid out, you can win easily by avoiding disadvantaged populations," he said, and although CMS believes this is not going to happen, it is in fact taking place. "If you just look at the distribution of readmission rate penalties across the United States, they're not happening in Scottsdale, Arizona, and they are happening in Detroit, Michigan," he said. McGinnis added that CMS is seeking to form a sounding board for issues on this population health dimension that he encouraged the CEOs to join, and Lipstein asked the IOM to join the National Quality Forum in recommending that PCORI put together a special committee on disparities.

Priorities and Challenges for PCORI and PCORnet

Paul Viviano from the University of California, San Diego, Health System said that one of the biggest challenges his organization faces is that its multiyear implementation of its EHR system has been, in his words, a disaster. "There's no way to calculate the expense and the impact this has had on our health system," he said. "Our faculty, they're resentful and they're angry and they don't want to talk about the next phases of this even though they're desperately needed. And so it has been a huge distraction for the organization in every conceivable way." Another challenge, he said, lies in linking the data from more traditional research with the data that are being accumulated within the health care system through the course of proving clinical care. This is as much a problem of academic silos as it is about EHR vendors creating such links, he said.

One issue that Posch identified was how to scale solutions across what

are becoming ever larger health care systems. Instead of introducing a change in a single or even several hospitals, he now has to worry about scaling across 50 hospitals and 4,500 physicians. In terms of PCORI's mission, what he sees as the most pressing issue is how to execute and implement today's knowledge at scale because, as he put it, "I've got to make those cuts now." He urged PCORI to study the science of execution at scale so that all of the discoveries that PCORnet and other initiatives will produce will enable him as a hospital CEO to realize savings and recreate a clinical enterprise intelligently.

Jonathan Tobin from the Rockefeller University Center for Clinical and Translational Research and Robert Dittus of the Vanderbilt University Medical Center both agreed with the suggestion that PCORI needs to fund studies on implementation. Dittus said that, in particular, PCORI could help identify the data that need to be collected to better understand the variables involved in implementation. "The science of implementation is in its infancy, much like clinical epidemiology was in the early 1980s, and we should build on the shoulders of the people who built that science," Dittus said. Joe Selby said that PCORI is well aware of the need for implementation science and believes that it is within its mandate to fund such studies. He added, though, that one of PCORI's critical strategies is to get research started correctly by asking the right questions from the start, which he said should make implementation go more smoothly.

Russell Rothman from the Vanderbilt University Medical Center said that he thinks there are great opportunities for synergy between the tools that the CDRNs are building and the help that health systems are requesting. He cited three specific examples, the first of which was the work aimed at developing methods for extracting clinical data from health systems in a way that can be used for reporting and accountability as well as looking at variations in care, inefficiencies in care, and opportunities for improvement. The second example was the work the CDRNs are doing to expand the capacity to collect novel data, particularly patient-reported data and outcomes, and the third was providing tools for real-time, evidence-based clinical decision support.

Corwin commented that the future of precision medicine based on personalized genomics will depend on complementary data collection and new analytical tools to handle what will eventually be enormous datasets of dissimilar data. "I feel extremely strongly that the EHR that we have today will not be what we're using tomorrow," he said, adding that it will take an enormous investment to develop the capacity to handle and use these big datasets. DePinho agreed completely with that assessment and said that PCORI provides an overarching framework for the community to come together to think about these challenges and opportunities. Regardless of the solution that is developed, the standardization that PCORnet is facilitating

will be key to creating systems that can ingest and process the torrent of information that is coming. Hochman added that he hopes that more effort is made to break down the barriers between all of the different disciplines that will need to work together to find solutions to the big-data problem.

Rita Redberg said that she is enthusiastic about the idea of PCORnet as a way to facilitate practical clinical trials because there are some things that will be impractical or impossible to study using the gold-standard randomized clinical trial. She was not as excited about clinical decision supports because, she said, they are often not as good in execution as they are in theory, often because physicians are already fatigued by all of the information in an EHR and more often than not ignore the messages that decision support systems provide in the EHR. She also questioned whether embedding appropriate-use criteria into the EHR will address issues of overuse and underuse, and she encouraged systems to start including harms as well as benefits in the data collected.

John Gallin from the NIH Clinical Center commented on issues of data ownership and data sharing and wondering if PCORI should develop guidelines and policies regarding data ownership. DePinho replied that projects such as the Human Genome Project and the Cancer Genome Project have already developed guidelines for data ownership and sharing that health care systems considering issues such as academic promotion and tenure decisions can apply. He added that getting academics to buy into those policies takes effort, which should not be underestimated, but that in the end the researchers involved in those two projects realized that they gained far more from being part of a network and sharing data than they would have if they had worked alone. Corwin, referring to a three-institution data-sharing agreement that involves Columbia University, Weill Cornell, and New York-Presbyterian, noted that while they are difficult to create, such agreements, when done right, are effective.

James Weinstein of the Dartmouth–Hitchcock Medical Center said that the entire health care system needs to be reinvented because it is unsustainable as is. He advised PCORI not to be "too precious," and he admonished the industry to work more collaboratively to meet the challenges that it faces.

Grossman asked whether PCORI should expand its agenda to go beyond the health care delivery system. Selby responded that PCORI's mandate as defined in its authorizing legislation is clearly focused on comparative CER, but it has become clear that clinical care cannot fail to take account of the socioeconomic circumstances, and as a result, PCORI's portfolio is already extending into areas of population health.

Gallin said that he has a concern about the rapid recruitment of patients to participate in studies. What he wants, he said, is a smart database of patient populations that researchers could tap into to identify a patient

not only by diagnosis but also by phenotype and genotype in order to generate with precision a cohort of patients who would be available because of some spadework that had been done in advance. Selby responded that developing the ability to identify patients eligible for specific trials using the EHR and other data is exactly what PCORnet is supposed to enable. The challenge that he sees is identifying those trials that have the biggest potential impact so that they can be prioritized and not overwhelm individual health care systems. "Once a system is convinced that the right trials are getting done," he said, "then I think the notion of building infrastructure and talking to the patient population about the fact that a trial or trials are under way becomes more embraceable." Lucila Ohno-Machado from the University of California, San Diego, agreed with the idea of a master list of patients, but she suggested that it include information about a patient's contact preferences. The technology for creating such a list exists, she said, and what is needed now is an effort to educate patients on the importance of research, both to themselves and for the health care system.

Tobin said that he believes there is promise in PCORnet's creating code that smaller health systems could use to extract information from their EHRs that could be turned into meaningful analyses and be benchmarked against others. "I think this is going to be a by-product of all of the studies conducted under PCORnet," he said. Tobin noted the importance of capturing and disseminating such software applications in a way that can be downloaded and implemented at low cost in practices where research may be less well integrated.

Lipstein had two suggestions for PCORI that came from his perspective as both a CEO and a member of PCORI's board. The first suggestion was to identify PCORI-funded investigators who are building a career doing CER and track them longitudinally to show that they can get promoted and that they can receive awards and recognition in the academic community. "The idea is to begin to profile individuals and celebrate their success across the academic community," Lipstein said. The second suggestion was for PCORI and the American Association of Medical Colleges to work together to teach methods of patient engagement that get patients to participate actively in improving their own health and becoming involved in research. He said that this type of effort would have the potential of addressing the fact that investigators who submitted wonderful grants to AHRQ or NIH have not been scoring well with PCORI because they do not understand patient engagement.

Robert Kaplan from AHRQ asked Selby if PCORI is thinking about how to spread the message about the value of research and learning to the majority of institutions that are not part of the academic medical center community. Selby responded that there are community-based delivery systems that do engage in research and that do place value on efforts to

develop a learning health system. PCORI's goal is to use these forward-thinking systems as examples of how to improve care and reduce costs that can be shared with the rest of the health care system.

Implementation and Dissemination at Scale

DePinho stressed how important it is to implement widely the findings of research because the gap between new knowledge and standard of care in the community at the level of the nonspecialist is significant and growing because the torrent of new information makes it impossible to stay current. As an example, he said that when the FDA approves a new anticancer agent, it gets used immediately at major academic medical centers, but that on average it takes 7 years before that new information gets incorporated into routine care in community oncology practices. "So from my perspective," he said, "we need to extend this envelope that we're talking about, not just to what we're doing at Columbia or MD Anderson and within health care systems, but how that does actually drive acquisition of knowledge and new ideas at the level of the patient and at the level of the primary care physician and the patient."

Steele continued that train of thought by noting that as inefficient as the nation's health care system is at taking a new drug and putting it into practice, it is even more difficult to change the business model for medical oncology as a whole, which is something that has to happen in order to reduce the total cost of care in a meaningful way. In his view, there are three ways to generalize and scale. One is to have the insurance companies associated with major health plans, such as Geisinger's insurance company, work with other providers to try to reproduce the special relationship that exists when you have provider and insurer under the same organizational umbrella. The second approach is through consolidation, where organizations that engage in continuous learning and change take over those organizations that cannot figure out how to change and that do not have a sustainable business model. The third approach is to take as much intellectual property as possible out into the field as part of the organization's business model, turning learning and innovation into what would essentially be a consulting business.

Hochman was not as pessimistic in his assessment of what smaller institutions are capable of accomplishing. One point that he stressed was that informed patients can be a route for getting new information into the hands of local physicians. "I think there's going to be a time where a patient is going to know about the study that's at MD Anderson before the doctor will," he said. Corwin, responding to a question from Jerry Krishnan of the University of Illinois Hospital and Health Sciences System about how to set priorities for dissemination from large to small systems, said there is

an artificial divide between academic and nonacademic health systems. "I think that first and foremost we need to have established venues for communicating between these two systems," Corwin said, "because I think that there are informal mechanisms but not formal mechanisms. I think there's much more in common than what separates us, and I think it is important for us to understand what's important at the academic center and the nonacademic health system, and this will not be successful unless we bring those large systems into the discussion in a tangible way."

Wyatt Decker from the Mayo Clinic Arizona spoke of the need for speed in driving waste out of clinical practice and moving to a population health model. In his view, he said, most of this effort does not involve research but merely small tests of change and lean process redesign. In that respect, he said, he saw the workshops as playing a critical role in determining how to ensure that the research community remains relevant to the rapid evolution that is "necessary for the very survival of all of our own institutions." As the CEO of an institution that is not a typical university, he said his view of research has been focused on meeting the unmet needs of patients. He acknowledged that what is typically translational or clinical research is taking place at far too slow of a pace, and he said he is encouraged by what PCORI is doing in this space.

Steve Allen of Nationwide Children's Hospital in Columbus, Ohio, said that children need to be developing every day and that, as a result, the responsiveness of the system needs to be faster when dealing with a population that is made up predominantly of children so that interventions can be enacted more quickly. Grossman reiterated earlier comments about the challenges of executing and getting desired outcomes on a system-wide basis. "I'm really fascinated by those organizations that have managed to connect their ideas with outcomes," Grossman said. "We're very good, but we're not where we need to be."

Kirch stated that what concerns him most, as a former CEO and as someone who visits many institutions, is that there is no consensus on the pace of change that is needed. Honesty is needed in recognizing that it is a minority of institutions that are creating value through learning, he said. Most institutions are trying to drive cost out, but they are not linking that to value, and they are not viewing research as a useful tool. "So I think one of the challenges for PCORI and for the IOM is to not delude ourselves that the passionate and highly effective group you hear from in a meeting like this is by any means the majority," he said. Another thing that he expressed concern about is the lack of support for this type of research from health systems' governance structures that are still largely concerned with the next quarter's profit margin.

Partnerships and Engagement

Holly Peay with the DuchenneConnect PPRN said that she supports the idea of engaging patients around the definition of value and sees that as an interesting way of framing patient engagement. Although it is important to consider that patient engagement taken to an extreme can be burdensome to both patient and health care system alike, she said, discussions about value can help better connect patients and health care systems to their communities.

Bray Patrick-Lake reinforced the idea that many speakers had stated during the workshop that the key to reforming the health care system so that it is both economically viable and patient-centered is to forge partnerships with patient groups. She noted that this is particularly important in making decisions such as those highlighted in the Choosing Wisely campaign, where the guidance is often that less care can be better. Eric Larson noted that this partnership approach is a unique and foundational principle for PCORI and that he did not think that PCORnet will be sustainable unless it is driven by questions that matter to both CEOs and patients.

Steele pointed out the disconnect that often exists between what patients understand and what physicians think patients understand. Geisinger is starting to address this gap, he said, by opening up progress notes to patients so that patients can see what their physicians or nurse practitioners have said about them. He sees this as an example of the beginnings of a fundamentally different relationship between the person who is getting care and the person who is delivering care. Although it is a small step, he sees it as a step in the right direction.

Sean Tunis from the Center for Medical Technology Policy suggested that the community might start encouraging patients to become more insistent that health care systems engage in learning activities. He also proposed that the National Committee for Quality Assurance could develop a certification for a learning system that meets certain standards.

Michael Dinneen of the U.S. Department of Defense said that the Department has had to redesign its health system over the past 12 years in order to address the casualties from the Iraq and Afghanistan wars and that part of this redesign involved creating the Defense Health Agency, which has the specific goals of serving as an integrator in a system of care and to incorporate advanced analytics, measurement, improvement, and coordination across the Department's health system. He said that this effort has been informed by the experiences of Geisinger and Kaiser Permanente and that the Department's financial resources may allow it to experiment in ways that other systems may not have the luxury of doing and therefore contribute to the overall effort.

DePinho said that MD Anderson is working with AT&T on issues involving connectivity between the health system and the consumer with

regard to things such as monitoring devices and interoperability at the level of the consumer. It is also working with IBM and its cognitive computing platform to manage the personal welfare of individual patients. As an example, he said that work is now ongoing to determine how many colonoscopies a person will need over the life course, given family history, genomics, diet, and other lifestyle factors. He said that he considers this effort as something that addresses personalized wellness. "What is exciting to us now is that we actually have all the component parts," he said. DePinho added that the goal is to take the four or five factors that would have a profound impact on the overall health and well-being of each person and tailor the system's monitoring and response capabilities based on those specific factors. He predicts this would have a profound impact on the health care system and health care economics. MD Anderson is currently piloting such a system across its network, including in areas in which there is no academic medical center.

John Warner from the UT Southwestern Medical Center summarized his views with two points. First, he said, achieving the necessary pace of change will require that hospitals invest in patient-centered outcomes research, which in turn will require systems to collaborate and share more effectively. Doing research collaboratively, he said, would make this a sustainable investment for many health care systems. The second point he made is that cost data need to be incorporated into the clinical data networks.

Jonathan Silverstein from NorthShore University HealthSystem informed the workshop that Epic, the EHR vendor, is creating a data research network that has a convergent direction with what is happening at PCORnet. He also said that 61 organizations have signed on to a set of principles regarding moving toward continuous learning in health which came from a series of meetings involving ONC and the IOM. He said he has seen that organizations that do not have a well-established research infrastructure want to participate in these efforts and benefit from the activities that are going on at an advanced level at other institutions. These smaller health systems want to know how to contribute their data and use the software being developed to extract information and model activities in their own systems.

The Health Care Industry Landscape

Darrell Kirch of the Association of American Medical Colleges commented that the current wave of consolidation among health systems for business reasons may not be leaving the time or energy to think about constructing systems in terms of what would create the biggest learning opportunities. Corwin agreed with that assessment, but he added that, with

consolidation, access to larger patient populations under the same organizational umbrella creates an opportunity to do more population health research and then share data across a large swath of the health care system. He also said that he thinks that hospital systems still give more weight to advancing the public good than to consolidation for consolidation's sake, even given the economics of health care today.

Hochman agreed with Corwin and said that Providence Health is spending much more time thinking about what the architecture of the health care system should look like beyond the walls of the hospital. For example, Providence is creating a new division of population health that will coordinate learning and knowledge transfer across the entire system.

Steele said that Geisinger's consolidation activities are being driven by a desire to move into areas in which its patients live so that not all care has to be administered in the same place that training and research occur. Geisinger is also being driven, Steele said, by the conviction that its model of being both a payer and provider creates a value proposition that competitors either cannot match or are not interested in matching.

Workforce Issues

In response to a question about whether the right type of investigators are involved in developing a learning health system, Steele said that there needs to be more work done on how to use observational data in a much more systematic way. RCTs, even of the sort that uses cluster randomization, are not going to answer 80 percent of the questions that need to be answered, he said, and there needs to be more methodology research to make use of observational data. DePinho said that MD Anderson realized that it had gaps in its expertise when it came to making the best use of its data and that is why it turned to IBM, AT&T, Google, and PricewaterhouseCoopers. He noted that this is the first time that these companies have worked together because they also recognize that they did not have all of the necessary bandwidth, knowledge, and capabilities needed for this effort. Yet, despite all of this assembled expertise, putting together all of the pieces is difficult, and DePinho estimated that it will take about 24 months to create and test the system that is coming together through this combined effort.

Concerning the barriers that he sees, Decker said that a lack of adequate analytics makes it difficult to get the clinical data needed at speed to transform practice and conduct research. He added that most of the research community that is involved in generating new knowledge to transform the health care system does not have the skill sets necessary to enable rapid transformation. He is attacking this last obstacle by hiring health economists and experts in big data, as opposed to bench-trained researchers, and he is providing discretionary funds to Mayo Clinic staff who are interested

in redesigning practice. "We're really asking our scientific community to step up and help us grow," he said, "and if they can do that, we may be able to help fund them or provide bridge funding. If they can't, then we say, Your work may be important, but you're going to have to look for other funding sources." Another aspect of getting research aligned with transformation is overcoming the cultural issues surrounding academic reward and promotion in light of the kind of research that the health system expects from the research community. Responding to these comments, Selby said that he was thinking about a program that would take physicians into a residency program that would simultaneously provide training in the clinic and training toward an M.B.A. or master's degree in public health. He added that he believes the CDRNs are locations for analytic expertise from which the community at large can draw support.

PCORI's Sarah Greene commented on the fact that the nurses and information technology staff who will have to be active in embedding research into care do not have research support as one of their performance goals, and they do not have training in research. Kaplan responded that AHRQ is concerned about these types of workforce issues. Kirch commented that he does not think there is that much of a problem with regard to systems that recognize, reward, and promote researchers who are doing applied scholarship or the scholarship of care delivery. Most institutions have loosened their promotion systems to create tracks that will allow for this, he said. The bigger problem, he said, is the lack of people trained to do this kind of research. He said he believes that there is an opportunity to use what he called blended learning modalities and online learning to create learning communities that can produce a cadre of people who have at least some expertise in the science of care delivery.

Lisa Harris from Eskenazi Health, a safety net health care system serving the inner city of Indianapolis, noted that her system has been building an EHR for more than 40 years and has been using these data to improve almost every aspect of quality, safety, effectiveness, and efficiency of care. "We are thriving as a safety net health care system because of basically being a learning health care system over four decades," she said, adding that her system is going to engage in an effort to use its experience to teach physicians nationwide how to use an EHR effectively. The challenge that she is facing as the CEO of Eskenazi Health is that 10 years ago the health system made the decision to take its homegrown EHR and transition to a vended system, but now that system is being sunsetted by the vendor. "My question is, Do we believe there is a collective opportunity to influence vendors to maybe take more of, if not a patient-centered approach, at least a health system–centered approach that I think would allow us to continue the things that we're talking about collectively?"

11

Recurring Workshop Themes

During the final session of the workshop series, Eric Larson, the planning committee chair, and Michael McGinnis from the IOM reviewed several points that were mentioned repeatedly over the course of the series.

The business imperative for continuous improvement

As a sector, health care has an unprecedented opportunity to use its current and developing data and methodological resources to drive continuous improvement, McGinnis noted. A key target of this opportunity is to move toward the triple aim through the delivery of high-value care in a manner informed by the best, most timely evidence—evidence that can be useful to decision makers, clinicians, and patients. This includes, he highlighted, learning from other sectors and working together to drive innovation in the area of learning from routinely collected data.

Culture that produces value at speed

Larson acknowledged that 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. The nation's health care system needs performance change and time horizons that are more rapid than those created by the standard research structure, he said. Demonstrating that integrated knowledge-generation efforts such as PCORnet can enable fast, focused studies will be a key to winning support from CEOs for creating a sustainable learning system.

Failing fast and forward

Health system leaders are most interested in studies that not only will generate usable information quickly but have the potential to provide valuable knowledge even when they fail, Larson reiterated from earlier workshop discussions and presentations. Although maintaining a willingness to fail can be difficult in health care, it is an essential attribute of a learning system. Key components of such a system, he summarized, are transparency to stakeholders, failing fast, and learning from experience and sharing those lessons.

The economic case for infrastructure for continuous learning

Accountability and continuous quality improvement are at the foundation of a responsible business model, McGinnis stated, noting that most health care organizations have recently made substantial investments in informatics and analytics capabilities. This expensive basic infrastructure could create important added value if the informatics and analytics capabilities are applied to knowledge-generation efforts that have an impact on moving toward higher-value care and that contribute to the improved efficiency of integrated research. The inclusion of cost information, such as activity-based costing, to this infrastructure was suggested by several workshop participants.

Alignment of research with organizational goals and priorities

Larson highlighted a point made by several workshop speakers that every organization has a finite bandwidth, not only in terms of financial resources but also with regard to institutional energy. Therefore, he noted, better alignment of research initiatives with performance improvement initiatives and consideration of implementation potential and provider burden in research design can maximize the impact of that research.

Sustainability in patient partnerships

Partnerships with patients at all stages of priority setting, knowledge generation, and implementation can be drivers of sustainability of continuous learning and improvement in health care. Larson highlighted that, throughout the workshop, speakers mentioned that patients want practical research that addresses their concerns and questions, they are eager to participate when these conditions are met, and they have taken an increasingly active role in driving research priorities themselves. He noted that new platforms and methodologies provide opportunities to better capture the patient experience and perspective both in routine care and from outside the health care system and to use this to drive learning.

Implementation at scale

Larson noted that several workshop speakers suggested that research without implementation does little to advance the development of a continuously learning health care system, and implementation that does not go beyond individual hospitals or health plans falls short of the transformational potential needed to effect major change. In that regard, he suggested that there is a need to advance the science of implementation and to make better use of the knowledge that already exists within the confines of individual health systems.

Good governance to enable big impacts

Effective, skillful governance promotes sustainability of research, summarized McGinnis, both in terms of the ability to develop shared research assets to conduct studies and in terms of developing a community of researchers and stakeholders who reuse and develop those assets. Governance structures, he noted, need to be flexible enough to adapt to the legitimate needs of those projects while also being inclusive enough to gather knowledge from each of the hospitals, health care systems, and networks of systems that are part of PCORnet and collate them into some organized whole in order to develop common models of analyzing data. One key governance focus, he highlighted, has to be on shortening the cycle time from when research generates evidence to when health system management triggers organizational change.

The ethical imperative for improvement

That ethics-relevant policies must be in place in a learning health care system and that those policies need to be transparent about ongoing learning and engage patients in a manner that informs decisions about which studies need consent and further protections, Larson noted as a theme mentioned by workshop speakers. As these learning activities proceed, ongoing evaluation of what types of learning activities need review and consent should become a standard part of the health care system, he suggested. IRBs play an important role in providing oversight of clinical research, but too often IRBs do not have the expertise to understand how comparative effectiveness research differs from investigator-initiated, hypothesis-driven clinical trials.

Partnerships to drive learning

A hallmark of successful continuously learning health systems is the partnership that develops among clinicians, patients, and health system leaders, noted McGinnis. Strong partnerships, particularly those that in-

clude patients, he highlighted, will be just as important for realizing the full potential of PCORnet as the network's ability to generate the data needed to inform a learning health system.

A continuous improvement workforce

McGinnis suggested that realization of a continuously learning health system will depend on a workforce that is trained and experienced in the skills needed to integrate research and the practice of health care delivery. This, he noted, has implications for the education and training of future clinicians, researchers, and health care administrators as well as in the design of career incentives for young professionals.

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Appendix A

Workshop Agendas

Health System Leaders Working Toward High-Value Care Through Integration of Care and Research (Workshop 1)

❖

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

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A Learning Health System Activity
IOM Roundtable on Value & Science-Driven Health Care

April 23–24, 2014
Keck Center
500 Fifth Street, NW
Washington, DC

MEETING GOALS

1. Broaden and deepen health systems' **leadership awareness** of the prospects for and from a continuously learning health system.
2. Foster the development of a **shared commitment**, vision, and strategy among health system leaders for building and maintaining the networked capacity.
3. Identify **common applications** in meeting health systems responsibilities for science, technology, ethics, regulatory oversight, business, and governance.
4. **Consider and learn** from models and examples of productive integration of research with care delivery programs.

5. Explore **strategic opportunities** for executive, clinical, and research leaders to forge working partnerships for progress.
6. Consider the particular opportunities for **CEO leadership** in building, growing, and making full use of the infrastructure necessary.

Day 1: Wednesday, April 23, 2014

8:00 am Coffee and light breakfast available

8:30 am **Welcome, Introductions, and Overview**
This session will include welcomes from the IOM, the activity sponsor, and the Planning Committee chair. Comments will include an overview of the series and meeting goals, a brief discussion of the scope of the meeting, and a review of the agenda.

Welcome from the IOM
Michael McGinnis, Institute of Medicine

Opening remarks, workshop series, and meeting overview
Joe Selby, Patient-Centered Outcomes Research Institute
Eric Larson, Planning Committee Chair, Group Health Research Institute

8:45 am **Integrating Care Delivery and Clinical Research: Case Examples**
This session will highlight examples of organizations that are on the leading edge of integrating care delivery and research in a way that has led to greater efficiency, better value, and improved health, including a discussion of the value proposition, which has led some organizations to embrace and succeed in gaining value, and its components.

Moderator: *Hal Luft*, Palo Alto Medical Foundation

Session presentations (10-minute presentations, each followed by moderated panel discussion among all speakers):

The REDUCE MRSA trial
Susan Huang, University of California, Irvine

Improve Care Now Network
Uma Kotagal, Cincinnati Children's Hospital

Group Health Cooperative
David Grossman, Group Health

The High Value Healthcare Collaborative
Edward Havranek, Denver Health

Suggested guidance for speakers:

1. How do you describe your project/network to the CEO of your organization?
2. What results were you able to achieve in terms of improving health care value? What were the key factors that allowed you to achieve these results?
3. What are the lessons that you would pass along to organizational and research leaders hoping to move their institutions toward greater integration of research and care?

Q&A and Open Discussion

10:15 am **Break**

10:30 am **Defining the Value Proposition of Continuously Learning Health Care**
This session will give a brief introduction to the vision for a continuously learning health system, including a brief review of past and current research network efforts, an explicit description of the proposed value proposition for health systems' leaders, and brief discussions of value propositions for stakeholder groups of key importance to health system leaders (e.g., patients and families, clinicians, payers).

Session presentation (15 minutes):

Is the time right for continuously learning health care?
Sarah Greene, Patient-Centered Outcomes Research Institute

Panel respondents (5-minute comments followed by moderated panel discussion):

Increasing efficiency and eliminating waste
Thomas Graf, Geisinger Health System

Improving our ability to choose wisely
Rita Redberg, University of California, San Francisco

Establishing infrastructure to pay for value
Trent Haywood, Blue Cross Blue Shield Association

Q&A and Open Discussion

12:00 pm **Lunch**

1:00 pm **Creating the Conditions for Sustainability**
This session will explore the business and financial issues and opportunities presented to organizations by moving toward continuous learning and improvement.

Moderator: *Lew Sandy*, UnitedHealth Group

Session presentation (15 minutes):

Creating the conditions for sustainability
Brent James, Intermountain Healthcare

Panel respondents (5-minute comments followed by moderated panel discussion):

Evaluation and improvement of care delivery
Thomas Garthwaite, HCA, Inc.

Improving care for me and patients like me
Sally Okun, PatientsLikeMe

Leveraging data for improvement
Karen DeSalvo, Office of the National Coordinator for Health Information Technology

Q&A and Open Discussion

2:30 pm **Break**

2:45 pm **Addressing Issues of Regulatory Oversight**
This session will take on the challenges and opportunities around the legal and ethical oversight of integrating care and research efforts.

Moderator: *Barbara Bierer*, Brigham and Women's Hospital

Session presentation (15 minutes):

An ethical framework for learning health systems
Nancy Kass, Johns Hopkins University

Panel of example approaches to dealing with oversight challenges:

Susan Huang, University of California, Irvine

James Weinstein, Dartmouth–Hitchcock

Christopher Forrest, Children's Hospital of Philadelphia

Q&A and Open Discussion

4:15 pm **Governance That Accelerates Progress and Sustainability**
This session will focus on issues of institutional governance of continuous learning activities.

Moderator: *Paul Wallace*, Optum Labs

Session presentations (10 minutes each):

Aligning research with institutional goals
James Rohack, Baylor Scott & White

Data sharing in a competitive environment
Mary Brainerd, HealthPartners

Governing interinstitutional research
John Steiner, Kaiser Permanente Colorado and HMO Research Network

Q&A and Open Discussion

5:45 pm **Summary and Preview for Day 2**

6:00 pm **Adjourn**

Day 2: Thursday, April 24, 2014

8:30 am Coffee and light breakfast available

9:00 am **Welcome and Overview**
Opening remarks and meeting overview
Eric Larson, Planning Committee Chair, Group Health Research Institute

9:15 am **Fostering the Well-Prepared Stakeholder Culture**
This session will take on challenges and opportunities in the engagement of clinicians, patients, families, and the public in integrating care and research efforts.

Moderator: *Jean Slutsky*, Patient-Centered Outcomes Research Institute

Session presentations (10 minutes each):

Creating a culture of learning
Peter Knox, Bellin Health

Clinician engagement
Peter Margolis, Cincinnati Children's Hospital

Patient engagement
Bray Patrick-Lake, PCORnet Executive Leadership Committee

Q&A and Open Discussion

10:45 am **Break**

11:00 am **Priority Opportunities for CEO Leadership to Make a Difference**
This session will draw on previous sessions and discussions to identify and prioritize the key issues for health system leadership in moving toward greater integrated care and knowledge-generation activities, including whether a shared value proposition is the key to sustainability.

Moderator: *Michael McGinnis*, Institute of Medicine

Panel:
Raymond Baxter, Kaiser Permanente

David Labby, Health Share of Oregon

Patricia Smith, Alliance of Community Health Plans

Janice Nevine, Christiana Cares

Q&A and Open Discussion

12:30 pm **Summary and Next Steps**
Parting comments from the sponsor and chair
Joe Selby, Patient-Centered Outcomes Research Institute
Eric Larson, Planning Committee Chair, Group Health Research Institute

Comments and thank-you from the IOM
Michael McGinnis, Institute of Medicine

1:00 pm **Adjourn**

Health System Leaders Working Toward High-Value Care Through Integration of Research and Practice (Workshop 2)

❖

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

❖

A Learning Health System Activity
IOM Roundtable on Value & Science-Driven Health Care

June 20, 2014
National Academy of Sciences Building
2101 Constitution Avenue, 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**

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**
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**
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 Cancer Center

Rodney Hochman, Providence Health and Services
Steven Corwin, New York-Presbyterian Hospital

Open Discussion (55 minutes)

11:15 am **Introduction to PCORI's Research Network**
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**

12:25 pm **Clinical Data Research Networks**
This session will include brief presentations from PCORNet clinical data research networks leadership on their progress and plans.

Patient Outcomes Research to Advance Learning (PORTAL) Network (10 minutes)
Elizabeth McGlynn and Ray Baxter, Kaiser Permanente

New York City Clinical Data Research Network (10 minutes)
Rainu Kaushal, Weill Cornell Medical College

Open Discussion (20 minutes)

1:10 pm **Multiuse Infrastructure for Continuous Learning**
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 (20 minutes)
Patrick Conway, Centers for Medicare & Medicaid Services
Brent James, Intermountain Healthcare
Scott Armstrong, Group Health Cooperative and MedPAC
John Warner, University of Texas Southwestern Medical Center

Open Discussion (55 minutes)

2:25 pm **Break**

2:40 pm **Open Discussion of Needs, Opportunities, and Strategies**
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**

4:00 pm **Adjourn**

Appendix B

Biographical Sketches of Workshop Speakers

Scott Armstrong is president and chief executive officer (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. Mr. Armstrong is a commissioner of the Medicare Payment Advisory Commission, a 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.

Raymond J. Baxter, Ph.D., 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 (KP'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 at Princeton University. He serves on the advisory boards of the University of California (UC), Berkeley, School of Public Health and the Duke University Institute for Health Innovation, the board of the CDC (Centers for Disease Control and Prevention) Foundation, the Global Agenda Council on Health of the World Economic Forum, and the board of Archimedes, Inc., and he is a member of the Institute of Medicine's (IOM's) Roundtable on Population Health Improvement. In 2001 UC 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, M.D., 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 (NIH) in Bethesda, Maryland, 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 Re-

search Protection Programs, serving as its president from 2003 to 2007, and was on the board of directors of the Federation of American Societies for Experimental Biology. 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 Academy of Sciences (NAS) Committee on Science, Technology, and the Law, and on the Secretary's Advisory Committee for Human Research Protections, U.S. Department of Health and Human Services (HHS), for which she serves as chair.

Mary Brainerd, M.B.A., has been a leader in health care since 1984. Prior to joining HealthPartners in 1992, Ms. 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 CEO of Blue Plus. Before that, she was a marketing instructor in the graduate program at Metropolitan State University. Ms. Brainerd is one of the founding CEOs of the Itasca Project, a group of 40 government, civic, and business leaders addressing the issues that affect long-term economic growth, including jobs, education, transportation, and economic disparities. She also serves on the boards of Minnesota Life/Securian, the Minnesota Council of Health Plans, The St. Paul Foundation, the Minneapolis Federal Reserve, and SurModics.

Patrick Conway, M.D., M.Sc., is the deputy administrator for innovation and quality and chief medical officer at the Centers for Medicare & Medicaid Services (CMS). He leads the Center for Clinical Standards and Quality (CCSQ) and the Center for Medicare & 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, whose annual budget exceeds $2 billion, is a major force for quality and transformation across Medicare, Medicaid, the Children's Health Insurance Program, 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, Dr. Conway was director of hospital medicine and an associate professor at Cincinnati Children's Hospital. He was also assistant vice president of outcomes performance, responsible for leading measurement, including the electronic health record

(EHR) measures, and facilitating improvement of health outcomes across the health care system. Other relevant experience includes previous work as the chief medical officer at HHS in the Office of the Assistant Secretary for Planning and Evaluation. In 2007–2008, 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 (ARHQ). He also served as executive director of the Federal Coordinating Council on Comparative Effectiveness Research (CER), coordinating the investment of the $1.1 billion for CER in the Recovery Act. He was a Robert Wood Johnson Foundation (RWJF) 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 has 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 a 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, M.D., was named CEO of New York-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 health care 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 New York-Presbyterian Hospital, a position he held beginning in 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 New York-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 New York-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 of 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 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 Veterans Health Administration (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 New York-Presbyterian/Columbia Division of Nursing.

Ronald A. DePinho, M.D., 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 he has served on numerous advisory boards in the public and private sectors, including being co-chair of advisory boards for the National Cancer Institute (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 IOM of the NAS. 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 NAS. He is a founder of a number of biopharmaceutical companies focused on cancer therapies and diagnostics.

Karen DeSalvo, M.D., M.P.H., M.Sc., is a physician who has focused her 20-year career on improving access to affordable, high-quality care for all people, with a focus on vulnerable populations and improving overall health. She has done this through direct patient care, medical education, and policy and administrative roles and as a researcher. As the National Coordinator for Health Information Technology, she is leading the nation's charge to promote, adopt, and meaningfully use health information technology in order to achieve better care and lower costs in health care and improve the overall health of everyone in America. Before joining HHS, she was health commissioner for the City of New Orleans and New Orleans Mayor Mitchell Landrieu's senior health policy advisor. While there, she transformed the outmoded health department into a modern and effective one and restored health care to devastated areas of the city, including leading the establishment of a public hospital. Prior to joining the mayor's administration, Dr. DeSalvo was a professor of medicine and vice dean for community affairs and health policy at the Tulane University School of Medicine. A physician with training and experience in internal medicine and public health, following Hurricane Katrina she was a leader in building an innovative and award-winning model of neighborhood-based primary care and mental health services, with a sophisticated health information technology infrastructure for low-income, uninsured, and other types of

vulnerable individuals. Dr. DeSalvo served as president of the Louisiana Health Care Quality Forum, the state's lead for the health information exchange, and as president of the National Association of Chiefs of General Internal Medicine. She has served on the boards of the National Association of County and City Health Officials and the Society of General Internal Medicine. Dr. DeSalvo was recognized as a "Woman of Excellence in Health Care" by the Louisiana Legislative Women's Caucus. In 2013 *Governing Magazine* named Dr. DeSalvo one of nine public officials of the year. The American Medical Student Association recognized her with a Women's Leader Award in 2014. She earned her medical doctorate and master's degree in public health from Tulane University and a master's in clinical epidemiology from the Harvard School of Public Health. She has an honorary doctorate from her undergraduate institution, Suffolk University.

Victor J. Dzau, M.D., became the eighth president of the IOM on July 1, 2014. Before that he was chancellor for health affairs and the James B. Duke Professor of Medicine at Duke University and the past president and CEO of Duke University Health System. Previously Dr. Dzau had been the Hersey Professor of Theory and Practice of Medicine and the chairman of medicine at Harvard Medical School's Brigham and Women's Hospital and, before that, the chairman of Department of Medicine at Stanford University. Dr. Dzau has made a significant impact on medicine through his seminal research in cardiovascular medicine and genetics, his pioneering work in the discipline of vascular medicine, and, recently, his leadership in health care 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 and translational sciences to clinical care and promote transformative innovation in health. As one of the world's preeminent academic health leaders, Dr. Dzau advises governments, corporations, and universities worldwide. He has served as a member of the council of the IOM and of the Advisory Committee to the Director of the NIH and as the 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, the governing board of Duke–National University Singapore Medical School, and a 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 its Global Agenda Council on Personalized and Precision Medicine. In 2011 he led a partnership among Duke University, the World Economic Forum, and McKinsey. He 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 the Max Planck Institute; the Commemorative Gold Medal from Ludwig Maximillian 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 six honorary doctorates.

Thomas L. Garthwaite, M.D., is the chief operating officer and vice president of the HCA Clinical Services Group. Before joining HCA, Dr. Garthwaite served as the executive vice president and chief medical officer for Catholic Health East, the director and chief medical officer of the Los Angeles County Department of Health Services, and under secretary for health at the Veterans Health Administration (VHA) in Washington, DC. At the U.S. Department of Veterans Affairs (VA) he helped lead the transformation of the system to achieve excellence in care quality and implement its use of computerized health records.

Thomas Graf, M.D., is the chief medical officer for population health and longitudinal care service lines for Geisinger Health System. Dr. Graf is responsible for the Value Re-Engineering of the Care Continuum and other population health initiatives for Geisinger including the accountable care organization portfolio and, with CMS, the Physician Group Practice Transitions Demonstration and Bundled Payments for Care Improvement. He leads the community practice, internal medicine, pediatrics, psychiatry, and care continuum service lines in coordinating and accelerating population-health-related activities across 22 counties in central and northeast Pennsylvania. He is recognized nationally as a leader in medical home and post-acute care redesign.

Sarah Greene, M.P.H., is a senior program officer with the 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, PCORnet. Ms. Greene's research has included patient-centered communication, health literacy, quality of cancer care, improving the human subjects research process, and optimization of multisite collaboration. 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. Most recently, as a health care strategy consultant for Group Health Cooperative, she led initiatives on improving patient service, cancer outcomes measurement, and branding. Greene has authored numerous manuscripts focused on development and implementation of multicenter research, and she created ResearchToolkit.org, which aggregates publicly available resources related to conduct of health research studies. She received both an M.P.H., with an emphasis in epidemiology, and a B.A. in psychology and Italian from Indiana University.

David Grossman, M.D., M.P.H., is currently the medical director for population and purchaser strategy at Group Health Cooperative and also a senior investigator at the Group Health Research Institute. As a senior medical enterprise medical director, he serves as the medical director assisting with population strategy for some of Group Health's largest purchasers, including the Federal Employee Health Benefit Program and Washington Public Employees Benefit Board. He also leads the new enterprise strategy on population health management and has overseen the development of clinical guidelines for preventive and care management interventions and policy. In addition to his roles with the Health Plan Division, Dr. Grossman also is a senior research investigator for the Group Health Research Institute, where he has led many highly applied research and evaluation projects in his career. Dr. Grossman currently leads the Institute's participation in both the Kaiser Permanente Research Affiliates evidence-based practice center and federally funded research studies, including a study for value-based insurance design. He has more than 120 publications encompassing many aspects of injury control, Native American health, health services research, and evidenced-based medicine and has been recognized by CDC as one of the most influential injury and violence prevention professionals over the past 20 years. He is also a professor of health services and an adjunct professor of pediatrics at the University of Washington. He

works as a part-time board-certified pediatrician at Group Health's Factoria Medical Center. Dr. Grossman has served on a number of key regional and national advisory boards, including the Task Force for Community Preventive Services, CDC (Community Guide, current); Washington Health Alliance, member of board and treasurer (current); U.S. Preventive Services Task Force (USPSTF) (2008–2013); board of scientific counselors, CDC (2004–2013).

Ed Havranek, M.D., directs the Center for Health Systems Research at Denver's safety net health care system, Denver Health (DH). The center is engaged in a broad range of activities, including leading DH's engagement in the High Value Healthcare Collaborative and developing patient-centered outcomes research infrastructure at DH under a grant from the Agency for Healthcare Research and Quality. He is also a professor of medicine at the University of Colorado School of Medicine. He graduated from the University of Vermont College of Medicine and trained in internal medicine at the University of Colorado Health Sciences Center and in cardiology at the University of Wisconsin Hospital. He has been on the faculty in Colorado since 1991. From 1999 to 2005 he was also a clinical coordinator for the National Heart Care project, a nationwide quality-improvement effort in heart failure and acute myocardial infarction sponsored by CMS. His personal research interests are currently focused on the effects of racial and ethnic bias on health care.

Trent Haywood, M.D., J.D., is chief medical officer for the Blue Cross Blue Shield Association (BCBSA), a national federation of 37 independent, community-based, and locally operated Blue Cross and Blue Shield companies. The Blue System is the nation's largest health insurer, covering more than 100 million people, or approximately one in three Americans. As the association's chief medical officer, Dr. Haywood is responsible for the Office of Clinical Affairs, which includes the Center for Clinical Effectiveness, the Center for Clinical Practices, and the Center for Clinical Value. Dr. Haywood leads the National Council of Physician Executives, which consists of chief medical officers and chief pharmacy executives who guide the clinical direction across BCBS companies. Dr. Haywood provides clinical leadership for the 5.3-million-member Federal Employee Program. In addition, Dr. Haywood provides clinical guidance to Blue Health Intelligence, an independent licensee of the BCBSA.

Rodney F. Hochman, M.D., 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 CEO of Swedish Health Services. He and his team

helped transform Swedish and positioned the organization for a strong, stable future. In his 5 years at Swedish he strengthened the community safety net, created a strong culture of safety, and reinvented 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 and legal and corporate compliance divisions. Prior to that position, he had served as Sentara's chief medical officer and senior vice president beginning in 1998. Before joining Sentara, Dr. Hochman held numerous executive-level positions during 5 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 (AHA'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 11 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.

Susan Huang, M.D., M.P.H., is an associate professor in the Division of Infectious Diseases and the Health Policy Research Institute at the University of California (UC), Irvine, School of Medicine and is the medical director of epidemiology and infection prevention at UC Irvine Health. She received her M.D. from the Johns Hopkins University School of Medicine and her M.P.H. from the Harvard School of Public Health in quantitative methods. Her clinical epidemiologic research has focused on health care–associated infections—identifying the population burden, risk factors for acquisition and disease sequelae, and preventive strategies for containment. Dr. Huang is currently the lead investigator of three randomized clinical trials on preventing methicillin-resistant *Staphylococcus aureus* disease and other health care–associated infections. She serves as a member of the Healthcare Infec-

tion Control Practices Advisory Committee, a 14-member federal advisory committee that develops guidelines on infection control and prevention in health care settings. She is also a member of the board of scientific counselors for the Antibiotic Resistance Working Group for CDC, the Antibiotic Resistance Committee for the Infectious Diseases Society of America, and the Clinical Effectiveness Research Innovation Collaborative at the IOM.

Brent C. James, M.D., M.Stat., is the executive director of the Institute for Health Care Delivery Research and vice president of medical research and continuing medical education at Intermountain Healthcare. He 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 the delivery of health care stand at another critical crossroads. If the health care field is to successfully bridge the quality chasm defined by the IOM, a new and innovative approach to the practice of health care is mandatory. Dr. James feels strongly that the time has come to shift from "craft-based" practice to evidence-directed teams focused on patient care. In addition to his duties at Intermountain Healthcare, Dr. James is an adjunct professor at the University of Utah School of Medicine in the 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 task forces and committees that examine health care quality and cost control, including AHRQ, and his most recent appointment is 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 recognizing his vision and energy in making the U.S. health care system better.

Nancy Kass, Sc.D., is the Phoebe R. Berman Professor of Bioethics and Public Health in the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health and is deputy director for public health in the Berman Institute of Bioethics. In 2009–2010 Dr. Kass was based in Geneva, Switzerland, where she was working with the World Health Organization Ethics Review Committee Secretariat. Dr. Kass received her B.A. from Stanford University, completed doctoral training in health policy from the Johns Hopkins School of Public Health, and was awarded a National Research Service Award to complete a postdoctoral fellowship in bioethics at the Kennedy Institute of Ethics at Georgetown

University. Dr. Kass conducts empirical work in bioethics and health policy. Her publications are primarily in the field of U.S. and international research ethics, HIV/AIDS ethics policy, public health ethics, and ethics of public health preparedness. She is co-editor of *HIV, AIDS and Childbearing: Public Policy, Private Lives* (Oxford University Press, 1996). Dr. Kass co-chaired the NCI Committee to Develop Recommendations for Informed Consent Documents for Cancer Clinical Trials, and she served on the NCI's central institutional review board. She has served as consultant to the President's Advisory Committee on Human Radiation Experiments, to the National Bioethics Advisory Commission, and to the NAS. Current research projects examine ethics for a learning health care system, including quality improvement and comparative effectiveness, informed consent in randomized trials, ethics issues that arise in international health research, and ethics and public health preparedness. Dr. Kass teaches the Bloomberg School of Public Health's course on U.S. and International Research Ethics and Integrity, is the director of the school's Ph.D. program in bioethics and health policy, and is the director of the Johns Hopkins Fogarty African Bioethics Training Program. Dr. Kass is an elected member of the IOM and a fellow of the Hastings Center.

Rainu Kaushal, M.D., M.P.H., 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 health care delivery interventions and models. Dr. Kaushal is also executive director of the Center for Healthcare Informatics and Policy, the Frances and John L. Loeb Professor of Medical Informatics at Weill Cornell Medical College, and chief of health care policy and research at New York-Presbyterian Hospital/Weill Cornell Medical Center. Dr. Kaushal's extensive research portfolio covers topics central to health care 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 health care 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, 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 PCORI 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 2014–2015 class of the prestigious Hedwig van Ameringen Executive Leadership in Academic Medicine Program for Women at Drexel Univer-

sity College of Medicine. She has more than 125 scholarly publications, has served on numerous national and international advisory committees, has formally consulted with other researchers as well as with policy makers, and has served on editorial boards for health care journals as well as on several study sections for AHRQ. Dr. Kaushal is a frequent invited national and international speaker.

Pete Knox, M.S., executive vice president and chief learning and innovation officer of Bellin Health System, has been associated with Bellin Health in Green Bay, Wisconsin, in a variety of leadership roles for the past 34 years. Mr. Bellin has been on the leading edge of quality for many years and is recognized nationally for superior results. In his current role he is responsible for population health strategies, physician networks, employer strategies, learning and innovation, and execution of strategy. In addition, he is a consultant for health care and other organizations and is a senior fellow at the Institute for Healthcare Improvement. His book titled *The Business of Health Care* is being used by a number of universities and organizations across the country and he is currently working on a second book, *The Strategy Execution Playbook*.

Uma R. Kotagal, M.B.B.S., M.Sc., 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 she 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 as 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 M.B.B.S. 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 she 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 IOM.

David Labby, M.D., Ph.D., is chief medical officer of Health Share of Oregon, a coordinated care organization with more than 160,000 enrollees in the tricounty 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 Ph.D. in cultural anthropology.

Eric B. Larson, M.D., M.P.H., MACP, is the vice president for research of Group Health and the 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 an RWJF Clinical Scholars and an M.P.H. program at the University of Washington (UW), and then served as chief resident of University Hospital in Seattle. He served as medical director of University of Washington Medical Center and as associate dean for clinical affairs from l989 to 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 the 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 chair of the board of regents of the American College of Physicians from 2004 to 2005. He is an elected member of the IOM.

Harold S. Luft, Ph.D., is director of the Palo Alto Medical Foundation Research Institute and professor emeritus in the Philip R. Lee Institute for Health Policy Studies at UC San Francisco, where he was director from 1993 through 2007. Dr. Luft received degrees in economics from Harvard University and was a postdoctoral fellow there. He is an elected member of the IOM. He served 6 years on the IOM Council, chaired the national advisory council of the predecessor to ARHQ, and served 10 years on the board of AcademyHealth. From 1997 to 2006 he was senior associate editor and then co-editor of *Health Services Research*. His research has covered a wide range of topics, including health maintenance organizations,

hospital competition, volume, quality and outcomes of hospital care, risk assessment and risk adjustment, health care reform, and the use of information and incentives to increase value. He has authored or co-authored more than 200 articles in scientific journals and 5 books, including *Total Cure: The Antidote to the Health Care Crisis* (Harvard University Press, 2010).

Peter Margolis, M.D., Ph.D., is a professor of pediatrics and the director of research at the James M. Anderson Center for Health System Excellence at Cincinnati Children's Hospital Medical Center. His work encompasses the application and study of quality-improvement methods in a broad range of areas, including primary and sub-specialty care, communities, and public health settings, to improve the health outcomes of children, families, and communities. In 2006 Dr. Margolis' joined Cincinnati Children's Hospital Medical Center to create a new center focused on health care quality. Dr. Margolis has worked extensively with the certifying boards and specialty societies to assist them in designing programs that will enable physicians to meet new maintenance of certification requirements focused on systems thinking and performance in practice. He is principle investigator of an National Institutes of Health Roadmap transformative research grant on redesigning systems for chronic illness care and several grants from ARHQ and PCORI aimed at developing learning health systems.

J. Michael McGinnis, M.D., M.A., M.P.P., is a physician, epidemiologist, and long-time contributor to national and international health programs and policy. An elected member of the IOM of the NAS, he has since 2005 also served as the 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 RWJF's 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, and Clinton), during which time he conceived and launched a number of initiatives of ongoing policy importance, including the Healthy People national goals and objectives, USPSTF, 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,UC Los Angeles (UCLA), Princeton, and Duke universities. He is a graduate of UC 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, Ph.D., 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 United States 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 IOM. 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 IOM Board of Health Care Services, and the Reagan–Udall Foundation for the Food and Drug Administration (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 M.P.P. 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.

Janice Nevin, M.D., M.P.H., became Christiana Care Health System's chief medical officer in 2011. As chief medical officer, Dr. Nevin is primarily responsible for advancing the mission of Christiana Care with regard to patient safety, clinical excellence, and patient satisfaction. She works closely with system leadership, clinical chairs, physicians, nursing leaders,

and others to ensure that patient-centered outcomes achieve system goals. She is also Christiana Care's patient safety officer and provides oversight of Christiana Care's medical education programs, including the Delaware Branch Campus of Jefferson Medical College and 280 residents and fellows. Dr. Nevin completed a program in executive education at Harvard Business School in 2010 and a fellowship in physician executive leadership at Health Management Academy in 2009. From 2008 until her appointment as chief medical officer, Dr. Nevin served as the senior vice president and executive director of Christiana Care Wilmington as well as the associate chief medical officer. In this role she was responsible for all clinical activity and operations at the Christiana Care Wilmington campus. In addition she provided leadership for the $210 million expansion project that began in 2009 at the Wilmington campus. Dr. Nevin worked with nursing leadership to develop a patient- and family-centered focus at Wilmington. The project led to the development of several new initiatives that emphasize patient- and family-centered care and resulted in significant improvements in preventing hospital-acquired infections, reductions in length of stay, increased patient satisfaction scores, and improvements in quality measures. From 2002 to 2008 Dr. Nevin was the chair of the Department of Family and Community Medicine at Christiana Care Health System. During this time she was also the medical director of the Christiana Care Visiting Nurse Association and clinical chair of Women First, the Community Center of Excellence in Women's Health. Before joining Christiana Care Health System, Dr. Nevin was a faculty member and the residency program director in the Department of Family and Community Medicine at Jefferson Medical College. Dr. Nevin graduated from Harvard University in 1981 and received her doctorate in medicine with honors from Jefferson Medical College in 1987. She completed her family-medicine residency at Thomas Jefferson University Hospital in 1990 and received her master's degree in public health in community health services from the University of Pittsburgh Graduate School of Public Health in 1992. She also finished a 2-year faculty-development fellowship in family medicine at St. Margaret Hospital in Pittsburgh.

Sally Okun, R.N., M.M.H.S., is the vice president for advocacy, policy, and patient safety at PatientsLikeMe in Cambridge, Massachusetts. She is responsible for patient voice and advocacy initiatives, participates in health policy discussions at the national and global level, and acts as the company's liaison with government and regulatory agencies. She joined PatientsLikeMe in 2008 as the manager of health data integrity and patient safety, overseeing the site's medical ontology, including the curation of patient-reported health data and patient folksonomy. In 2009 she developed the PatientsLikeMe Drug Safety and Pharmacovigilance Platform to meet adverse event report-

ing obligations of industry partners while collaborating in a social media environment. Ms. Okun participates on numerous collaboratives of the IOM's Roundtable on Value & Science-Driven Health Care and the Committee on Core Metrics for Better Health at Lower Cost. Ms. Okun serves on the Advisory Panel on Patient Engagement for PCORI, the National Quality Forum's Person-Centered Care and Outcomes Committee, the scientific advisory committee for the Reagan–Udall Foundation's Innovation in Medical Evidence Development and Surveillance Program, and the program advisory board of the Schwartz Center for Compassionate Health Care. Ms. Okun is a frequent speaker at clinical, advocacy, and policy events, and in April 2013 she was the first nurse invited to give a TEDMED talk at Kennedy Center. Prior to joining PatientsLikeMe, Ms. Okun, a registered nurse, practiced as a community-based palliative and end-of-life care specialist and project consultant contributing to clinical, research, and educational projects with multiple collaborators, including Brown University, Harvard Medical School, the Massachusetts Department of Mental Health, the Hospice Education Network, and RWJF. Ms. Okun received her master's degree from the Heller School for Social Policy and Management at Brandeis University. She completed study of palliative care and ethics at Memorial Sloan Kettering Cancer Center and was a fellow at the National Library of Medicine Program in Biomedical Informatics.

Bray Patrick-Lake, M.F.S., who is director of stakeholder engagement for the Clinical Trials Transformation Initiative (CTTI), supports efforts to actively engage patient advocacy organizations and other stakeholders in CTTI efforts to improve clinical trials. She also implements strategies to enhance awareness of CTTI's work, particularly with patient advocates, and to extend the impact of CTTI results and recommendations. In 2010, after being a patient in an aborted clinical trial, Ms. Patrick-Lake founded the PFO Research Foundation in response to the lack of definitive scientific information regarding the condition of patent foramen ovale. Ms. Patrick-Lake has served as a patient representative at FDA on a variety of advisory committees and panels, in work groups for the European Medicines Agency and the National Institute of Neurological Disorders and Stroke at NIH, as a guest lecturer and an external reviewer for the IOM, and as a patient stakeholder or co-investigator for AHRQ and PCORI grants. She is a member of the PCORnet Coordinating Center's Executive Leadership Committee, the ACC Foundation's Patient-Centered Care (PC3) Shared Decision Making Workgroup, DIA's Patient Fellowship Selection Committee, and the TVT Registry Stakeholder Advisory Committee and is a board member for the Alliance for Headache Disorders Advocacy. She holds a B.S. in zoology from the University of Georgia and a master of forensic sciences degree from National University in La Jolla, California.

Jonathan B. Perlin, M.D., Ph.D., M.S.H.A., FACP, FACMI, is the president of clinical services and chief medical officer of the 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 EHRs throughout HCA, improving clinical "core measures" to benchmark levels, and leading patient safety programs to eliminate preventable complications and health care-associated infections. Before joining HCA in 2006, Dr. Perlin was Under Secretary for Health in the VA. Nominated by the President and confirmed by the Senate as the senior-most physician in the federal government and CEO of the VHA, Dr. Perlin led the nation's largest integrated health system. At the VHA, Dr. Perlin directed care to more than 5.4 million patients annually from more than 200,000 health care professionals at 1,400 sites, including hospitals, clinics, nursing homes, counseling centers, and other facilities, with an operating and capital budget of more than $34 billion. A champion for the implementation of EHRs, Dr. Perlin led the VHA quality performance to international recognition, as reported in academic literature and lay press and as evaluated by RAND, the IOM, and others. Dr. Perlin has served previously on numerous boards and commissions, including the National Quality Forum and The Joint Commission, and he currently serves on the boards of the National Patient Safety Foundation and Meharry Medical College. He chairs the HHS Health Information Technology Standards Committee and has been elected chair of the AHA for 2015. Recognized perennially as one of the most influential physician executives in the United States by *Modern Healthcare* magazine, Dr. Perlin has received numerous awards, including Distinguished Alumnus in Medicine and Health Administration from his alma mater, the Chairman's Medal from the National Patient Safety Foundation, and the Founders Medal from the Association of Military Surgeons of the United States, and he is one of a dozen honorary members of the Special Forces Association and Green Berets. Broadly published in health care quality and transformation, Dr. Perlin is a fellow of the American College of Physicians and of 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.

Rita F. Redberg, M.D., M.Sc., has been a cardiologist and a professor of medicine and the director of women's cardiovascular services at UC San

Francisco since 1990. Dr. Redberg is currently the chief editor of *JAMA Internal Medicine* (formerly *Archives of Internal Medicine*) and has spearheaded the journal's new focus on health care reform and "less is more," which highlights areas of health care with no known benefit and definite risks. Her research interests are in the area of health policy and technology assessment and how to promote high-value care, focusing on high-risk medical devices as well as the need for inclusion of women in clinical trials of such devices. Dr. Redberg is a member of the Medicare Payment Advisory Commission, which advises Congress on Medicare payment issues. She also served on the Medicare Evidence, Development and Coverage Advisory Committee from 2003 to 2006 and was reappointed in 2012 as chairwoman of the Medicare Evidence Development & Coverage Advisory Committee. Dr. Redberg is a member of the California Technology Assessment Forum, the Medical Policy Technology and Advisory Committee, and the FDA Cardiovascular Devices Expert Panel, and she is a consultant for the Center for Medical Technology Policy. She has given congressional testimony multiple times in hearings related to the issue of balancing safety and innovation in medical device approvals. Dr. Redberg worked in the office of Senator Hatch and with the Senate Judiciary Committee on FDA-related matters during her tenure as a RWJF Health Policy Fellow from 2003 to 2006. Dr. Redberg was a member of the IOM's Learning Health Care Committee, which produced the report *Best Care at Lower Cost* in September 2012. She chaired the AHA/ACC Writing Group on Primary Prevention Performance Measures, is a member of the American College of Cardiology's Clinical Quality Committee, and serves on the Quality in Technology Work Group. She is on multiple technology assessment boards, including the Blue Cross Blue Shield Medical Advisory Panel and the California Technology Assessment Forum as well as the Institute of Clinical and Economic Review Advisory Board. Dr. Redberg has authored several books, including *You Can Be a Woman Cardiologist*, *Heart Healthy: The Step-by-Step Guide to Preventing and Healing Heart Disease*, and *Betty Crocker Cookbook for Women: The Complete Guide to Women's Health and Wellness at Every Stage of Life*. She has done hundreds of radio, television, and newspaper interviews on health-related topics, including being featured in the *New York Times*, the *Wall Street Journal*, *USA Today*, National Public Radio, and the *Today Show*. Dr. Redberg graduated from Cornell University and the University of Pennsylvania Medical School and has a master's of science in health policy and administration from the London School of Economics.

J. James Rohack, M.D., is the chief health policy officer for Baylor Scott & White Health. He is a board-certified senior staff cardiologist at Baylor Scott & White Central Division in Temple, Texas, where he holds the William R. Courtney Centennial Endowed Chair in Medical Humanities

and serves as the director of the Center for Healthcare Policy and medical director for system improvement of the Scott & White Health Plan. He is a full professor in both the Department of Medicine and the Department of Humanities at the Texas A&M University Health Science Center College of Medicine. He served as the 164th president of the American Medical Association (AMA) in 2009–2010, being the face of the AMA during the national debate on American health care reform. He has served as treasurer of the board of commissioners of The Joint Commission, chaired the National Advisory Council to AHRQ, was one of the principals of the Hospital Quality Alliance and a member of the National Priorities Partnership. He is currently serving as co-chair of the steering committee of the Texas Care Alliance as well as on the executive committee of the national High-Value Healthcare Collaborative. He has been recognized as 1 of the 50 Most Powerful Physician Executives in Health Care, 1 of the 100 Most Powerful People in Health Care, 1 of America's Top Physicians and Top Cardiologists, and the Texas Monthly Super Doctor.

Lewis G. Sandy, M.D., is the executive vice president of clinical advancement at the 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 and 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 and delivery innovation and policy. From 2003 to 2007, he was executive vice president 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 executive vice president of RWJF. 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 vice president 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 UC 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, M.D., M.P.H., is the first executive director of PCORI. A family physician, clinical epidemiologist, and health services researcher, he has dedicated his career to patient care, clinical research, and adminis-

tration. 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, Dr. 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 ongoing, two-way engagement channels with each of PCORI's key stakeholder groups, beginning with patients. Dr. 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 past 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, Dr. 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. Dr. Selby was elected to membership in the IOM in 2009. A native of Fulton, Missouri, Dr. Selby received his medical degree from Northwestern University, his training in family medicine from the Contra Costa County Family Medicine Program in Martinez, California, and his master's in public health from UC Berkeley. He served as a commissioned officer in the Public Health Service with the National Health Service Corps from 1976 to 1983 and received the Commissioned Officer's Award in 1981. Dr. Selby was appointed PCORI executive director on May 16, 2011.

Jean R. Slutsky, P.A., M.S.P.H., is the chief engagement and dissemination officer at 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, Ms. Slutsky directed the Center for Outcomes and Evidence at AHRQ, 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. Ms. Slutsky is particularly interested in pragmatic user-driven research and its implementation into health care decision making. Ms. Slutsky received her baccalaureate degree from the University of Iowa, trained as a physician assistant at the University of Southern California, and received an M.S.P.H. in health policy from the University of North Carolina at Chapel Hill.

Patricia Smith is president and CEO of the Alliance of Community Health Plans (ACHP), a national leadership organization in Washington, DC, that brings together high-quality, innovative health plans and provider groups.

A respected expert in delivery system reform, Medicare, and coordinated care issues, Ms. Smith works closely with ACHP's 22 member organizations nationwide to promote learning, innovation, and public policy solutions to improve health, health care, affordability, and consumer experience. Prior to leading ACHP, Ms. Smith served as director of the Medicare Advantage Group at CMS. During her 2 years at CMS, she played a lead role in implementing the health plan changes and the Medicare Part D drug benefit in the Medicare Advantage program. Ms. Smith was previously vice president at America's Health Insurance Plans and senior vice president for policy at ACHP from 2001 to 2004. For 15 years, she led federal health care lobbying efforts for AARP. Ms. Smith serves on the advisory board of the State of California's Health Benefits Review Board, Kaiser Permanente's Institute for Health Policy, the March of Dimes, and the Council of Accountable Physician Practices. She is a graduate of the College of William & Mary in Williamsburg, Virginia.

Glenn D. Steele, Jr., M.D., Ph.D., is president and CEO of Geisinger Health System, an integrated health services organization in central and northeastern Pennsylvania that is nationally recognized for its innovative use of the EHR 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 CEO of Deaconess Professional Practice Group in Boston, Massachusetts, and chairman of the department of surgery at New England Deaconess Hospital (Boston). 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 health care 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 IOM, Dr. Steele serves as a member on the Roundtable on Value & Science-Driven Health Care, 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. A fellow of the American College of Surgeons, Dr. Steele is a member of the American Surgical Association and the American Society of Clinical On-

cology and is past president of the Society of Surgical Oncology. Dr. Steele also serves on the following boards and national committees: Agency for Integrated Care 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 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. and is a 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. He is a former member of the Commonwealth Fund's Commission on a High Performance Health System, the National Commission for Quality Assurance's (NCQA's) Committee on Performance Measurement, and the AHA board of trustees, and he also served on the executive committee of the 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); the Eighth Annual (2010) AHA Health Research & Education Trust Award, and the HFMA Board of Directors' Award (2011). He has been named consecutive times to *Modern Healthcare*'s 50.

John Steiner, M.D., M.P.H., has been the senior director of the Institute for Health Research at Kaiser Permanente Colorado since 2008. He currently serves as chair of the Kaiser Permanente National Research Council and as chairman of the governing board of the national HMO Research Network. Dr. Steiner received his B.A. degree from Yale University, his M.D. from the University of Pennsylvania School of Medicine, his internal medicine training at the University of Colorado, and his M.P.H. degree from the University of Washington, where he was an RWJF Clinical Scholar. Prior to 2008 he was a tenured professor in the Department of Medicine at the University of Colorado School of Medicine and the director of the Colorado Health Outcomes Program. In 2005 he received the Florence R. Sabin Award from the University of Colorado Health Sciences Center for his contributions to the university and the people of Colorado. From 2007 to 2011 he was the chair of the health systems research scientific review group for AHRQ. Dr. Steiner is the author or co-author of more than 200 publications that reflect his research interests in access to care, health disparities, prevention

and treatment of cardiovascular disease and diabetes, medication adherence, and research training.

Paul Wallace, M.D., is the chief medical officer and senior vice president for clinical translation at Optum Labs, which was launched in early 2013 with the Mayo Clinic as a founding partner. Based in Cambridge, Massachusetts, Optum Labs is designed to develop and sustain a community of research and learning partners spanning multiple health sectors who will have access to unprecedented data resources to work collaboratively on some of the most critical problems in health care today. From 2011 to 2013 Dr. Wallace was a senior vice president and director of the Center for Comparative Effectiveness Research at the Washington, DC–based Lewin Group, and before that he was a medical director and clinician with Kaiser Permanente from 1989 to 2011. He was the executive director of Kaiser Permanente's Care Management Institute (CMI) from 2000 to 2005, and he led and contributed to several Kaiser Permanente national initiatives in evidence-based medicine, population health, and the use of health information technology. Dr. Wallace is currently chair of the board of directors for AcademyHealth and a board member of the eHealth Initiative, and he has served on national committees and boards for the IOM, NCQA, AHRQ, CMS, the Blue Cross and Blue Shield Technology Evaluation Center, the Center for Information Therapy, and the Care Continuum Alliance. Wallace is a graduate of the University of Iowa School of Medicine, and he completed further training in internal medicine and hematology at Strong Memorial Hospital and the University of Rochester.

John Warner, M.D., M.B.A., is CEO of the University of Texas (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 he was a member of the Duke cardiology faculty from 2000 to 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 the CEO

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 AHA, where he chairs the Advocacy Committee. He is past president of both the Dallas Division and the Southwest Affiliate of AHA.

James N. Weinstein, D.O., M.S., is the CEO and president of the Dartmouth–Hitchcock health system. The system includes New Hampshire's only academic medical center and a network of clinics across Vermont and New Hampshire that serve a patient population of 1.5 million. Under Dr. Weinstein's leadership, Dartmouth–Hitchcock is working to create a "sustainable health system" for patients, providers, payers, and communities. He is a member of the IOM. He serves on the IOM Committee on Advising the Social Security Administration on Disability. Most recently, Dr. Weinstein was one of four members appointed to the IOM Board on Population Health and Public Health Practice. Immediately prior to becoming CEO of Dartmouth–Hitchcock, Dr. Weinstein served as president of the Dartmouth–Hitchcock Clinic and director of The Dartmouth Institute for Health Policy and Clinical Practice (TDI). His dual positions as clinic president and TDI director allowed him to build critical linkages between the groundbreaking health services research of TDI and the clinical care at Dartmouth–Hitchcock. He is a founding member, along with the Mayo Clinic, Intermountain Healthcare, TDI, and Denver Health, of the national High Value Healthcare Collaborative, a partnership of 19 health systems across the country that have taken on the challenge of improving the quality of care while lowering costs. More than 70,000 physicians, who treat more than 100 million patients, are sharing best practices and data in an unprecedented partnership on behalf of patients. Dr. Weinstein is a leader in advancing "informed choice" to ensure that patients receive evidence-based, safe, effective, efficient, and appropriate care. In 1999 he established the first-in-the-nation Center for Shared Decision-Making at Dartmouth–Hitchcock, where patient preferences and values are an integral part of diagnostic and treatment decisions. He also pioneered the use of patient-reported outcomes in clinical practice in 1983, adding a new dimension to the process and clinical measurements traditionally used to judge the efficacy and value of care. This will become part of the federal government's meaningful use criteria for EHRs by 2017. He is an internationally renowned spine surgeon and health services researcher, with more than 280 published articles and in excess of $70 million in federal research funding. He founded the multidisciplinary Spine Center at Dartmouth–Hitchcock, which has become an international model for patient-centered

health care delivery. Additionally, he is editor in chief of *Spine*, an international, peer-reviewed, multidisciplinary journal, ranked No. 1 in its field by SCI. Dr. Weinstein holds the Peggy Y. Thomson Chair in the Evaluative Clinical Sciences at Dartmouth. He has been named 1 of "The 100 Most Influential People in Healthcare" by *Modern Healthcare* magazine and is frequently consulted by members of Congress and the administration on health policy and reform, and he has appeared before several panels and committees considering these issues.

Appendix C

Workshop Attendees

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

April 23–24, 2014

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Barbara E. Bierer, M.D.
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Brigham and Women's Hospital

Jeremy Boal, M.D.
Chief Medical Officer
Mount Sinai Health System

Mary K. Brainerd, M.B.A.
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HealthPartners

David Allen Brenner, M.D.
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Richard J. Brilli, M.D.
Chief Medical Officer
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Bradley Britigan, M.D.
Co-Chief Executive Officer and Dean
College of Medicine
University of Nebraska Medical Center

Diana Buist, Ph.D., M.P.H.
Senior Investigator
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Director of Analytics
Louisiana Public Health Institute

August Cervini, M.B.A.
Vice President, Research Administration
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Kevin B. Churchwell, M.D.
Executive Vice President, Health Affairs, and Chief Operating Officer
Boston Children's Hospital

Steven Clauser, Ph.D., M.P.A.
Director, Improving Healthcare Systems Research Program
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Elaine Collier, M.D.
Acting Director for the Division of Clinical Innovation
National Center for Advancing Translational Sciences

Patrick Conway, M.D.
Chief Medical Officer and Deputy Administrator for Innovation and Quality
Centers for Medicare & Medicaid Services

Erika Cottrell, Ph.D., M.P.P.
Research Assistant Professor, Obstetrics and Gynecology
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Brian P. Currie, M.D., M.P.H.
Vice President for Medical Research and Assistant Dean for Clinical Research
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Gregory Daniel, Ph.D., M.P.H., R.Ph.
Managing Director for Evidence Development and Innovation
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Emme Levin Deland, M.B.A.
Senior Vice President for Strategy
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Karen DeSalvo, M.D., M.P.H., M.Sc.
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology

Robert Dittus, M.D., M.P.H.
Associate Vice Chancellor for Public Health and Health Care
Senior Associate Dean for Population Health Sciences
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Allison DuBuisson
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Division of Health Care Quality and Outcomes
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Margo Edmunds, Ph.D.
Vice President, Evidence Generation and Translation
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Veterans Health Administration

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Program Director, CER Methods and Infrastructure
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Chief Operations Officer, Clinical Services Group
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Meighan Girgus, M.B.A.
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Tracy Glauser, M.D.
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Health System Leaders Working Toward High-Value Care Through Integration of Care and Research

June 20, 2014

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Glenn Daniel Steele, Jr., M.D., Ph.D.
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John Warner, M.D.
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