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

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

April 23-24, 2014
Keck Center of the National Academies
500 5th Street NW
Washington, DC 20001
Health System Leaders Working Towards High Value Care through Integration of Care and Research

Table of Contents

SECTION 1: WORKSHOP FRAMING MATERIALS
- Agenda
- Planning Committee members
- Participant list

SECTION 2: BACKGROUND MATERIALS
- Integrating clinical research and practice
  - GroupHealth Foundation. 2014. “Partnership for Innovation: World-class research, provider-driven innovation.”
  - GroupHealth Research Institute. 2014. “From Evidence to Everyday: Practical research for better health.”
- Defining the value proposition of continuously learning health care
- Creating the conditions for sustainability
- Addressing issues of regulatory oversight
- Governance that accelerates progress and sustainability
- Fostering the well-prepared stakeholder culture
  - Institute of Medicine. 2013. “Partnering with Patients to Drive Shared Decisions, Better Value, and Care Improvement.”
SECTION 3: ORGANIZATIONAL BACKGROUND
• IOM Roundtable on Value & Science-Driven Health Care
  - Roundtable background information and roster
  - Roundtable charter and vision
  - Clinical Effectiveness Research Innovation Collaborative background information
  - Digital Learning Collaborative background information
• Patient-Centered Outcomes Research Institute
  - PCORnet: The National Patient-Centered Clinical Research Network
  - Why PCORnet Exists

SECTION 4: BIOGRAPHIES AND MEETING LOGISTICS
• Planning Committee biographies
• Speaker biographies
• Location, hotel, and travel
**HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH**

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

**A LEARNING HEALTH SYSTEM ACTIVITY**
IOM ROUNDTABLE ON VALUE & SCIENCE-DRIVEN HEALTH CARE

APRIL 23-24, 2014
KECK CENTER
500 FIFTH ST, NW
WASHINGTON, DC

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**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.

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**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 clinical research and practice: 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 lead to greater efficiency, better value, and/or improved health, including a discussion of the value proposition, and its components, which has led some organizations to embrace and succeed in gaining value. |
| Moderator: Hal Luft, Palo Alto Medical Foundation |

The REDUCE MRSA Trial
Susan Huang, University of California Irvine

Improve Care Now Network
Uma Kotagal, Cincinnati Children’s

Group Health Cooperative
David Grossman, Group Health

The High Value Health Care Collaborative
Edward Havranek, Denver Health

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 stakeholders groups of key importance to health systems leaders (eg. patients/families, clinicians, payers). |
| Session presentation: |
| Is the time right for continuously learning health care? |
| Sarah Greene, Patient-Centered Outcomes Research Institute |

Panel respondents: |
| 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*

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<th>Time</th>
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<tr>
<td>12:00 pm</td>
<td>Lunch</td>
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### 1:00 pm Creating the conditions for sustainability

This session will explore the business and financial issues and opportunities presented to organizations by moving towards continuous learning and improvement.

Moderator: *Lew Sandy*, UnitedHealth Group

*Session presentation:*
**Creating the conditions for sustainability**  
*Brent James*, Intermountain Healthcare

*Panel respondents:*
**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*, National Coordinator for Health IT

*Q&A and Open Discussion*

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### 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:*
**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

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**Governance that accelerates progress and sustainability**

This session will focus on issues of institutional governance of continuous learning activities.

Moderator: *Paul Wallace*, Optum Labs

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**Session presentations:**

- **Aligning research with institutional goals**  
  *James Rohack*, Baylor Scott White

- **Data sharing in a competitive environment**  
  *Mary Brainerd*, HealthPartners

- **Governing inter-institutional research**  
  *John Steiner*, Kaiser Permanente Colorado and HMO Research Network

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**Summary and preview for day 2**

*Eric Larson*, Planning Committee Chair, Group Health Research Institute

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**Reception**

**Adjourn**

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**Day 2: Thursday April 24, 2014**

8:30 am  
Coffee and light breakfast available

**Welcome and 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**

**Creating a culture of learning**  
*Peter Knox*, Bellin Health

**Clinician engagement**  
*Peter Margolis*, Cincinnati Children’s

**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 systems 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 Nevin*, Christiana Care Health System

**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, box lunches available for pick up

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Barbara E. Bierer, MD, Brigham and Women's Hospital
Mary K. Brainerd, MBA, HealthPartners, Inc.
Meighan Girgus, MBA, American Heart Association
Regina Holliday, Artist and Patient Data Activist
Brent James, MD, Intermountain Healthcare
Uma R. Kotagal, MBBS, MSc, Cincinnati Children's Hospital Medical Center
David Labby, MD, Health Share of Oregon
Jonathan B. Perlin, MD, PhD, MSHA, Hospital Corporation of America
Lewis G. Sandy, MD, UnitedHealth Group
Joe V. Selby MD, MPH, Patient-Centered Outcomes Research Institute
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HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH

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Agency for Healthcare Research and Quality
HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH

April 23-24, 2014

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

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

This is a problem the learning health system should be able to address, and we and our colleagues recently reported a head-to-head comparison of the three strategies.\(^3\) The study of 43 hospitals and more than 74,000 patients provided strong evidence that decolonizing all patients prevented 44 percent of blood stream infections.

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

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

Richard Platt, MD, MS, is Professor and Chair of the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute. Susan Huang, MD, MPH, is an Associate Professor of Infectious Diseases and Medical Director of Epidemiology and Infection Prevention at the University of California, Irvine. Jonathan Perlin, MD, PhD, is the Chief Medical Officer at Hospital Corporation of America, Inc.

References

Suggested Citation: Platt, R., S.S. Huang, and J. Perlin. 2013. A win for the learning health system. Commentary, Institute of Medicine, Washington, DC. http://www.iom.edu/WinforLHS.
Note: Authored commentaries in this IOM Series draw on the experience and expertise of field leaders to highlight health and health care innovations they feel have the potential, if engaged at scale, to foster transformative progress toward the continuously learning health system envisioned by the IOM. Statements are personal, and are not those of the IOM or the National Academies.

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

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

Information on the IOM’s Learning Health System work may be found at www.iom.edu/learninghealthsystem
From evidence to everyday

Practical research for better health
What do bike helmets, breast cancer screening, and yoga have in common? All are everyday strategies for staying healthy that were shown to be effective by research at Group Health.

Group Health Research Institute produces timely, relevant results that help turn innovative ideas into better health and health care for people everywhere.

From testing new vaccines to helping people quit smoking to finding ways to delay or prevent Alzheimer’s disease, our practical research has helped millions of people worldwide lead healthier, happier lives.
Bringing research results to life since 1983

Who we are

Group Health Research Institute is the non-proprietary, public-interest research center within Group Health Cooperative, a nonprofit health system based in Seattle, WA. Group Health provides coverage and care for more than 600,000 people in Washington and North Idaho.

We are an interdisciplinary faculty more than 60 members strong, mainly PhD or MD investigators with expertise spanning health services, behavioral science, epidemiology, biostatistics, economics, health informatics, and other fields.

We are experienced scientific collaborators and founding members of several influential research consortia, including the HMO Research Network, the National Institutes of Health’s Vaccine Treatment and Evaluation Units, and the National Cancer Institute’s Breast Cancer Surveillance Consortium.

We are an integral part of Seattle’s biomedical core thanks to longstanding partnerships with the University of Washington, Fred Hutchinson Cancer Research Center, and Seattle Children’s Research Institute.

What we do

We study health and health care as experienced in everyday settings by everyday people, producing results that are built to work in the real world—not just in a research environment.

We create a learning health care system within Group Health—where our researchers, providers, administrators, and patients work together to turn advances in research into better health.

We share our results in the public domain—disseminating our findings widely through publications, presentations, and traditional and social media to help inform people around the country and the world.

We work with other scientists nationwide as consultants, co-investigators, and leaders of multi-site studies that use the vast data resources, population diversity, and statistical power needed to answer health care’s toughest questions.

We do practical research that helps people everywhere stay healthy and get the care they need.
A single mother starts taking an antidepressant, receiving follow-up care via online messaging with a psychiatric nurse. As her symptoms improve, she resumes many of her favorite activities—including making home-cooked meals for her kids. People who received online follow-up care for depression in addition to usual care were more likely to improve and were more satisfied with their care. (Journal of General Internal Medicine, 2011)

A construction worker who supports a family of four is on the verge of quitting his job due to back pain that just won’t go away. He enrolls in a yoga class, and his pain starts to ease. Soon, he is promoted to lead carpenter. Yoga classes were linked to better back-related function and diminished symptoms from chronic low back pain in the largest U.S. yoga study to date. (Archives of Internal Medicine, 2011)

A couple often brings groceries to her aging mother, who doesn’t get out much anymore. They worry that Alzheimer’s disease is a risk. So they start walking with her several evenings a week—a habit she continues well into her 80s. Seniors who exercised three or more times a week had a 30-40 percent lower risk for developing dementia than did those who exercised less often. (Annals of Internal Medicine, 2006)

A busy executive doesn’t have time for doctor visits. Instead, he gets tested for colon cancer using a home screening kit. His test results are abnormal, so he has a colonoscopy that finds and removes polyps before they develop into cancer. Colorectal cancer screening rates doubled among people who were overdue for it, largely because of increased use of home screening kits. (Annals of Internal Medicine, 2013)

Practical research for better health
Research: It’s in our DNA.

Since its founding in 1947, transforming health care through research has been part of Group Health’s vision. Our founders established Group Health Research Institute in 1983—seizing the unique opportunity to promote public health by studying real-world, population-based care delivery.

And now, as health care changes faster than ever, we are studying those changes as they happen. Our research will continue to discover practical ways to achieve good health—for generations to come.

From childhood to old age, Group Health research sheds light on innovations that improve the health of local communities, the nation, and the world.

Learn more at grouphealthresearch.org.

1730 Minor Avenue, Suite 1600
Seattle, WA 98101
206-287-2900
Surgery for complex spine problems is among the highest-risk interventions in medical practice. Thanks in part to a Partnership for Innovation grant, our team recently developed a new multidisciplinary approach that lowers that risk by two thirds. Published in the medical journal *Spine Deformity*, our results provide critical information to help medical teams at Group Health and around the country reduce complications while improving performance and patient outcomes.

Rajiv Sethi, MD, Group Health orthopedic surgeon, Department of Neurosurgery

Do you have an innovative idea? Any Group Health staff member can apply for a grant from the Partnership for Innovation. Applications are accepted in early spring each year. Learn more on Connection at: http://incontext.ghc.org/foundation/PartnershipforInnovation.html or email foundation.ghc@ghc.org or call 1-866-389-5532

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Your gift will help continue these projects and fund new ones. Visit www.ghc.org/foundation. Click “Donate Now.”

A woman with a new pregnancy has so many questions. Health care providers can answer some. Practical advice from fellow expectant parents can address others. In a new model of prenatal care, the midwifery practices at Bellevue and Tacoma Group Health Medical Centers are helping pregnant women and their partners share knowledge and experiences. The Centering Pregnancy pilot brings together soon-to-be-moms in 11 group gatherings scheduled throughout their pregnancies.

“I learned things I never would have thought to ask at a regular doctor visit,” says Nomi Verma, whose daughter Jayna was born in July. “We had some second-time moms in the group who told us what to expect, offered great advice, and answered our questions.”

Facilitated group discussions “promote a sense that the women are in charge and involved in their own care.”

Each group begins with 8 to 12 women at the same stage of pregnancy. Often their partners attend. A nurse midwife and medical assistant facilitate the meetings, which start out monthly, then move to twice-monthly as due dates get closer. About a month after the babies are born, the group reunites to coo over them.

“Centering Pregnancy is a model that fits well with Group Health’s philosophy of prevention, shared decision making, and health care literacy,” says Ms. McConnell.

“I’m so glad I went,” Ms. Verma adds.
One path to affordable excellence

A three-way collaboration makes the Partnership for Innovation possible, the rigorous expertise of our research institute, the voices of clinical teams, and the generosity of our donors. Between 2003 and 2013, Foundation donors invested more than $7 million into patient-centered care pilot projects conceived of and carried out here at Group Health.

If you’re a Group Health staff member with an idea that could make a difference, we want to hear from you. We may help craft a pilot project that not only gives your work its best chance of success but also makes its data accessible to others.

Keep in mind: This program is made possible by donors to our Foundation and the front-line staff who believe that Group Health holds the solution to the big challenges in health care.

Primary care doctors and dermatologists speed skin cancer diagnosis with Group Health Foundation support.

Human skin can grow a rich array of unrelied oddities, from harmless moles to dangerous melanomas. For primary care physicians, differentiating benign from dangerous or dangerous is not always easy. But with support from the Partnership for Innovation, we might be improving through collaboration between primary care doctors and dermatologists.

For a dermatologist, a picture is worth a thousand words—or maybe a million.

"For a dermatologist, a picture is worth a thousand words," says Andrew Shors, MD, at Central Specialty on Capitol Hill, "or maybe a million." Before telemedicine, the dermatologists relied on written notes from family physicians about patients’ lesions and colors. "The words couldn’t describe the skin condition clearly," he says. "But if we see a photo of a melanoma, we can say, ‘That patient needs to be seen tomorrow.’ Dr. Shors believes telemedicine gets patients studying the effectiveness of the telemedicine pilot with a $25,928 grant from the Partnership for Innovation.

"We get all ideas for improving care here in the clinic," says Dr. Shors, "but we don’t have the resources or time to test these hypotheses in any one clinic. That’s a truly scientific." Group Health Research Institute investigators worked with Dr. Shors and his team to set up the telemedicine pilot so it could be properly tested with useful data collected directly from patient experiences. Dr. Shors says, "That couldn’t happen without the support from the Foundation’s donors or the scientists from the Institute."
Defining the Value Proposition of Continuously Learning Health Care
Clinicians and health systems face widespread challenges, including integration of meaningful use, payment reforms, and caring for newly insured persons. They are also challenged to keep up with rapid scientific discovery and address escalating costs. Reorganizing U.S. health care and changing its practices to render better, more affordable care requires transformation in how health systems generate and apply knowledge. The “rapid-learning health system”—posited as a conceptual strategy to spur such transformation—leverages recent developments in health information technology and a growing health data infrastructure to access and apply evidence in real time, while simultaneously drawing knowledge from real-world care-delivery processes to promote innovation and health system change on the basis of rigorous research. This article describes an evolving learning health system at Group Health Cooperative, the 6 phases characterizing its approach, and examples of organization-wide applications. This practical model promotes bidirectional discovery and an open mind at the system level, resulting in willingness to make changes on the basis of evidence that is both scientifically sound and practice-based. Rapid learning must be valued as a health system property to realize its full potential for knowledge generation and application.


For author affiliations, see end of text.

LEARNING HEALTH SYSTEM FOUNDATION AND PHASES

The conceptual foundation of the rapid-learning health system has both human and technological aspects. Human factors include stakeholders motivated by a desire to continuously improve the system for patients. They must understand the organization’s leadership and decision-making culture and be willing to be vulnerable and transparent, learning both from mistakes and successes. Trust among leaders, clinicians, and researchers facilitates change, collaboration, and explicit identification of problems and innovative solutions. Technology supports use of current, robust data to guide clinical and administrative decision making based on evidence and reporting systems that are accessible system-wide, allowing learning to permeate organizations. Making clinically relevant knowledge accessible at the point of care by leveraging technology is a distinctive characteristic of rapid-learning health systems (9, 10).

Scanning and Surveillance

The rapid-learning process begins with problem identification and characterization. Learning health systems are inherently observant—seeking new information and data from many sources. Within Group Health, clinicians and administrators regularly use data to identify gaps in patient experience, quality, and efficiency and then search for
evidence-based solutions. Internal surveillance is supplemented by scans of emerging clinical and health-services research for potential solutions. The PCMH pilot at Group Health stemmed from internal recognition that solving problems in patient experience, staff burnout, quality, and costs was critical for organizational vitality (11) and that research literature on primary care, chronic illness, and the medical home pointed to redesign opportunities. Similarly, the opioid-prescribing initiative at Group Health arose from federally funded observational research indicating excess death in persons receiving opiates for noncancer pain at Group Health and elsewhere (4); review of patient care outcomes; and local factors, such as the introduction of state-level practice guidelines.

Design

Participatory design involves key stakeholders to ensure that their ideas are considered and that end products meet their specific needs. By blending research evidence with daily experiences of a frontline workforce, a learning organization leverages evidence about “what works” in the context of its own setting, population, available resources, and organizational culture. For health care systems, one-size-fits-all solutions are rare; effective strategies usually have multiple components and require local tailoring at the microsystem level (12). The PCMH design work and opioid safety improvements each involved primary care clinicians, content experts, information technology personnel, researchers, and clinic staff to develop core components for the entire system and elements that could vary locally. The opioid-prescribing initiative combined design and prototyping into an intensive week-long workshop where representatives from across the organization defined new care processes, developed standardized patient education materials, and identified specialty care consultants to help manage complex cases. This intensive effort, based on best available evidence, allowed all stakeholders to iteratively develop and refine the tools and resources needed to improve prescribing safety. In both cases (PCMH and opioid work), the design work benefited from participation by an array of stakeholders, including patients. Although we have not developed a prescriptive staffing model for the rapid-learning health system, we have realized success by bringing together groups who are committed to achieving benefits through implementation and translation and who possess subject matter expertise, an understanding of the underlying data and information technology systems, clinical and care delivery experience, change management expertise, and research methods knowledge. Ideally, these
Implementing the Learning Health System

Persons work together from design through dissemination to ensure ongoing learning and adaptation.

Implementation

It is risky and often counterproductive to introduce wholesale innovations in complex systems without pilot-testing on a small scale—ideally, by using a control or similar benchmark. Innovations are often regarded skeptically by clinicians and managers, and the interplay of the innovation and current practices cannot be predicted. Piloting the PCMH at 1 Group Health clinic facilitated understanding of the interdependent variables that could affect successful spread to other clinics; the PCMH team identified core elements necessary for the model to work across the organization and those that could vary. The experiences of “early adopters” guided this implementation-and-spread process. In the opioid initiative, the implementation activities were prototyped during the design phase and packaged in a cohesive manner to be spread system-wide. The package included electronic medical record–based guidelines, online clinician training, standardized patient education materials, and a care plan template, which is also available in the electronic medical record. This multifaceted implementation strategy led to high clinician engagement and stronger partnerships between researchers and clinical leaders (5).

Evaluation

Predefined evaluation with timely feedback ensures that implementation of a change can guide subsequent actions. Ideally, the evaluation includes feedback from everyone affected. Group Health used real-time clinical, utilization, and cost data and brief surveys of practitioners and patients to form a comprehensive picture of intended and unintended outcomes of the new PCMH model. A mixed-methods approach was used to gather both quantitative and qualitative insights about the effect of the model on patients and staff and adherence to PCMH principles and processes. The evaluation identified features that would facilitate PCMH adoption system-wide. A rigorous prototype evaluation was valuable because system-wide implementation would require major investments and widespread redesign. In a rapidly changing health care environment, decision makers require timely results, so pragmatic research designs—deployed quickly to produce “good-enough” data—are well-suited to the pace of contemporary health care. Abernethy and colleagues (10) have underscored this point, noting the importance of balancing rigor and the efficient generation of generalizable evidence.

Adjustment

Learning health systems are neither insular nor myopic; they actively seek and apply objective evidence about improving care. The Group Health PCMH demonstration occurred while other systems were testing similar changes, meaning that emerging evidence could be incorporated, as could refinements based on the internal evaluation, similar to “plan–do–check–adjust” cycles that are cornerstones of quality improvement (13). Each clinic has made modest adjustments reflective of its staff composition, clinic volume, and panel sizes; however, core elements of the model, such as the use of virtual medicine and using staff to the full extent of their licensure, were standardized from clinic to clinic (14). Formal evaluation of the opioid safety work at Group Health is under way.

Dissemination

Open discussion of evaluation findings with internal stakeholders reinforces a learning culture. Although Group Health researchers remain committed to peer-reviewed publication to contribute to generalizable knowledge, peer-reviewed literature alone is often not a sufficient dissemination channel for health care transformation; decision makers rely on information sources (for example, trade journals, industry webinars, and informal storytelling), and the lag time for academic publications is a problem for work that can potentially inform ongoing health care delivery. Deliberate and timely internal dissemination processes to describe why the prototype PCMH worked, for example, or sharing the researchers’ work on opioid overuse in noncancer pain were critical for continuous learning and improvement. Researchers may often overlook these key steps if they view other researchers as their primary audience. We believe that learning health care systems require effective communication channels directed toward internal and external stakeholders.

To date, the PCMH and opioid initiatives have benefited from strong internal and external dissemination efforts, including peer-reviewed articles coauthored by researchers and clinical leaders (4, 5, 11–13), use of internal communication vehicles (newsletters, staff Web site, and leadership meetings) to promote awareness of these initiatives, and reports in lay media. In another recent learning health initiative, Group Health researchers and radiologists partnered to document and disseminate information about the rapid surge in use of high-end imaging in the organization, enabling radiology clinical leaders to inform the rest of the system of these findings in real time. This spurred system-wide efforts to develop and install decision support to improve use of imaging across the organization before the findings were published (6).

Conclusion

The hallmarks of the rapid-learning health system are the vital partnership between research and clinical operations and a shared commitment to leverage scientific knowledge and evaluation for rapid, point-of-care improvements. Given that clinical medicine is constantly adapting to ongoing discoveries, this concept of rapid-learning health care is a practical model that promotes bidirectional discovery and an open mind at the system level—resulting in willingness to make changes on the basis of evidence that is both scientifically sound and practice-based. Moving this concept from action requires a culture and an infrastruc-
ture to facilitate rapid learning combined with strong leadership support. The PCMH pilot project catalyzed organizational change and helped cement the rapid-learning culture at Group Health, benefiting subsequent initiatives in opioid prescribing, shared decision making, high-end imaging, and value-based benefit design, among others. However, rapid learning is not automatic and can be humbling. Communication, engagement, flexibility, and an ongoing commitment to study changes in real time must be institutionalized and valued as system properties. The nation’s investment in medical research demands that we do more with the knowledge we generate. Rapid-learning health systems can ensure a return on that investment.

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References

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Less Is More

How Less Health Care Can Result in Better Health

If some medical care is good, more care is better. Right? Unfortunately, this is often not the case. Across the United States, the rate of use of common medical services varies markedly, but measures of health are not better in areas where more services are provided. In fact, the opposite is true—some measures of health are worse in areas where people receive more health services.

How can more health care lead to worse health outcomes? Almost all tests, imaging procedures, drugs, surgery, and preventive interventions have some risk of adverse effects. In some cases, these harms have been proven to outweigh benefits—for example, treating asymptomatic women with postmenopausal hormone therapy. In other cases, services become widely used with inadequate proof of benefit. For example, arthroscopic debridement of the knee for treatment of osteoarthritis was performed about 650,000 times per year in the United States in the late 1990s, despite the fact that the procedure had not been shown to be beneficial. Randomized trials subsequently demonstrated no benefit of this procedure—but all patients were exposed to the pain and risk associated with surgery.

See also pages 747, 751, 765, 772, 779, and 784

Even if a medical service has been shown to provide a clear benefit in selected groups, using this service in different groups, especially those with less severe disease or lower risk for disease, can result in harm. For example, antidepressants have been shown in multiple randomized trials to be an effective treatment for severe depression but have little benefit in persons with less severe depression. Antidepressants are widely used in persons with mild depression, the known adverse effects of these drugs will outweigh the benefits. Even if the relative benefit of a medical service is the same, overuse in a low-risk population can result in harm. For example, screening mammography is probably just as effective in reducing the risk of dying of breast cancer in younger women as in older women. But because the absolute risk of dying of breast cancer is lower in younger women than in older women, the absolute benefit is lower. But the adverse effects of mammography—false-positive findings, biopsies, anxiety, and overdiagnosis and treatment of latent cancers—is the same and may overwhelm the benefit. Finally, harm can occur when tests and procedures are repeated unnecessarily. For example, repeated computed tomographic scanning to “follow” documented renal stones has no clear clinical purpose but is associated with a significant risk of radiation-induced cancers.

In the United States, the debate about decreasing the overuse of medical services has focused on the expense of unneeded care. And in fact, reducing the use of medical services in high-use regions of the United States has been estimated to reduce the overall cost of care about 20%. Cost cutting as a justification for reducing the use of medical services is met with suspicion by many people who equate reducing the volume of care to rationing. Rationing implies that the care being withheld is beneficial and is being withheld simply to save money. But as we have noted above, there are many areas of medicine where not testing, not imaging, and not treating actually result in better health outcomes.

“Less is More,” a new series in the Archives, will highlight situations in which the overuse of medical care may result in harm and in which less care is likely to result in better health. For example, a series of articles in this issue of the Archives documents serious adverse effects of proton pump inhibitors, including increased rates of fractures, Clostridium difficile infection, and recurrence of diarrhea caused by C difficile; previous reports have also documented an increased risk of pneumonia. Harm will result if these commonly used medications are prescribed for conditions for which there is no benefit, such as nonulcer dyspepsia.

There are many reasons why clinicians in the United States may provide more care than is needed. These include payment systems that reward procedures disproportionately compared with talking to patients, expectations of patients who equate testing and interventions with better care, the glamour of technology, the fact that it may be quicker to order a test or write a prescription than explain to a patient why they are not being treated, and of course, defensive medicine. Another reason is “technology creep.” After a device is approved for use with a high-risk population in which there is a proven benefit, its use often expands to lower-risk groups in which the benefit does not outweigh the risk.

Evidence suggests that providing excessive health care service is most likely to occur in situations in which there is not strong evidence to document the benefit and harms of the service. The Archives aims to address this deficit by publishing articles that provide evidence that performing “more” of certain health care activities results in “less” health. Appropriate articles should compare strategies that provide more health care service with those that
provide less and should include a comprehensive assessment of both benefits and harms. We will also publish commentaries on these articles and clinical vignettes illustrating how more care can lead to worse outcomes. Our hope is that these vignettes will generate future studies on ways to do more by doing less.

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REFERENCES

Creating the Conditions for Sustainability
The Strategy That Will Fix Health Care


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HIGHLIGHT: Providers must lead the way in making value the overarching goal

In health care, the days of business as usual are over. Around the world, every health care system is struggling with rising costs and uneven quality despite the hard work of well-intentioned, well-trained clinicians. Health care leaders and policy makers have tried countless incremental fixes, attacking fraud, reducing errors, enforcing practice guidelines, making patients better "consumers," implementing electronic medical records, but none have had much impact.

It's time for a fundamentally new strategy. At its core is maximizing value for patients: that is, achieving the best outcomes at the lowest cost. We must move away from a supply-driven health care system organized around what physicians do and toward a patient-centered system organized around what patients need. We must shift the focus from the volume and profitability of services provided, physician visits, hospitalizations, procedures, and tests, to the patient outcomes achieved. And we must replace today's fragmented system, in which every local provider offers a full range of services, with a system in which services for particular medical conditions are concentrated in health-delivery organizations and in the right locations to deliver high-value care.

Making this transformation is not a single step but an overarching strategy. We call it the "value agenda." It will require restructuring how health care delivery is organized, measured, and reimbursed. In 2006, Michael Porter and Elizabeth Teisberg introduced the value agenda in their book Redefining Health Care. Since then, through our research and the work of thousands of health care leaders and academic researchers around the world, the tools to implement the agenda have been developed, and their deployment by providers and other organizations is rapidly spreading.

The transformation to value-based health care is well under way. Some organizations are still at the stage of pilots and initiatives in individual practice areas. Other organizations, such as the Cleveland Clinic and Germany's Schön Klinik, have undertaken large-scale changes involving multiple components of the value agenda. The result has been striking improvements in outcomes and efficiency, and growth in market share.

There is no longer any doubt about how to increase the value of care. The question is, which organizations will lead the way and how quickly can others follow? The challenge of becoming a value-based organization should not be underestimated, given the entrenched interests and practices of many decades. This transformation must come from within. Only physicians and provider organizations can put in place the set of
interdependent steps needed to improve value, because ultimately value is determined by how medicine is practiced. Yet every other stakeholder in the health care system has a role to play. Patients, health plans, employers, and suppliers can hasten the transformation, and all will benefit greatly from doing so.

Defining the Goal

The first step in solving any problem is to define the proper goal. Efforts to reform health care have been hobbled by lack of clarity about the goal, or even by the pursuit of the wrong goal. Narrow goals such as improving access to care, containing costs, and boosting profits have been a distraction. Access to poor care is not the objective, nor is reducing cost at the expense of quality. Increasing profits is today misaligned with the interests of patients, because profits depend on increasing the volume of services, not delivering good results.

In health care, the overarching goal for providers, as well as for every other stakeholder, must be improving value for patients, where value is defined as the health outcomes achieved that matter to patients relative to the cost of achieving those outcomes. Improving value requires either improving one or more outcomes without raising costs or lowering costs without compromising outcomes, or both. Failure to improve value means, well, failure.

Embracing the goal of value at the senior management and board levels is essential, because the value agenda requires a fundamental departure from the past. While health care organizations have never been against improving outcomes, their central focus has been on growing volumes and maintaining margins. Despite noble mission statements, the real work of improving value is left undone. Legacy delivery approaches and payment structures, which have remained largely unchanged for decades, have reinforced the problem and produced a system with erratic quality and unsustainable costs.

All this is now changing. Facing severe pressure to contain costs, payors are aggressively reducing reimbursements and finally moving away from fee-for-service and toward performance-based reimbursement. In the U.S., an increasing percentage of patients are being covered by Medicare and Medicaid, which reimburse at a fraction of private-plan levels. These pressures are leading more independent hospitals to join health systems and more physicians to move out of private practice and become salaried employees of hospitals. (For more, see the sidebar "Why Change Now?") The transition will be neither linear nor swift, and we are entering a prolonged period during which providers will work under multiple payment models with varying exposure to risk.

Why Change Now?

Most hospitals and physician groups still have positive margins, but the pressure to consider a new strategic framework has increased dramatically.

Market forces are driving increasing numbers of hospital mergers and acquisitions, and the number of hospital beds has declined in the U.S. from 3 beds per 1,000 people in 1999 to 2.6 in 2010. Reimbursement rates are under pressure. Physician income has remained static over the past decade, and physicians know that simply working harder, faster, or longer can't compensate for their steadily increasing expenses. Meanwhile, national retailers like Walmart, CVS, and Walgreens are going after the primary care market on a large scale, by offering in-store clinics that provide basic services at prices as much as 40% below what physicians' offices charge.

These developments are not unique to the United States: A similar story is playing out in virtually every national health care system across the globe.
The economics of health care are changing, too. A provider's ability to increase fee-for-service revenue is threatened from every direction. U.S. government payors (Medicare and Medicaid) raise payment levels each year minimally, if at all. Yet most providers have been losing money on Medicare and Medicaid patients for a decade or more, and the magnitude of those losses only increases each year. Exacerbating the problem, the proportion of patients covered by government programs is growing: Medicaid will expand substantially in many states in 2014, as the Affordable Care Act is implemented, and the aging of the population will increase the percentage of Medicare patients for years beyond that. Reimbursement for these patients will continue to be pressured by tight federal and state government budgets. National Institutes of Health research cuts will make matters even worse for academic medical centers.

In the past, providers would cover losses from Medicare and Medicaid and from uninsured populations by demanding higher payment rates from commercial insurance plans, often winning increases of 8% to 10% per year. Those days are over. Employers are looking for decreases in their health care costs, and they're getting them by engaging in price negotiations, reducing benefits, raising deductibles, and expanding "narrowed network" products that direct patients to providers that accept lower rates or prove better outcomes. A program recently introduced by the California Public Employees' Retirement System (CalPERS) and Anthem Blue Cross, for example, requires many employees seeking a hip or knee replacement to use only hospitals that have agreed to a bundled fee for the procedure, or to pay the difference if they choose a higher-priced provider outside the network.

The intensifying pressure from employers and insurers for transparent pricing is already beginning to force providers to explain, or eliminate, hard-to-justify price variations. In our state, Massachusetts, the price for a brain MRI ranges from $625 to $1,650. And prices can vary by more than 50% for the same procedure in the same hospital, depending on the patient's insurer and the insurance product.

Patients will be asked to pay more and more. The percentage of the population in high-deductible health plans is now well into double digits, and it is rising. Many employees in these plans are increasingly unwilling or are simply unable to pay historical charges, and providers incur losses or bad publicity, or both, as they try to collect on the debts.

Provider organizations understand that, without a change in their model of doing business, they can only hope to be the last iceberg to melt. Facing lower payment rates and potential loss of market share if they charge higher prices, they have no choice but to improve value and be able to "prove it." As one senior executive recently told us, "We've been able to hide our prices for years inside insurance products, but that's going to end as more and more people move into new, high-deductible products. We are going to have to be able to communicate exactly what we are giving patients, employers, and insurers for their money." He's right.

In this environment, providers need a strategy that transcends traditional cost reduction and responds to new payment models. If providers can improve patient outcomes, they can sustain or grow their market share. If they can improve the efficiency of providing excellent care, they will enter any contracting discussion from a position of strength. Those providers that increase value will be the most competitive. Organizations that fail to improve value, no matter how prestigious and powerful they seem today, are likely to encounter growing pressure. Similarly, health insurers that are slow to embrace and support the value agenda, by failing, for example, to favor high-value providers, will lose subscribers to those that do.

The Strategy for Value Transformation
The strategic agenda for moving to a high-value health care delivery system has six components. They are interdependent and mutually reinforcing; as we will see, progress will be easiest and fastest if they are advanced together. (See the exhibit "The Value Agenda.")

**The Value Agenda**

The strategic agenda for moving to a high-value health care delivery system has six components. They are interdependent and mutually reinforcing. Progress will be greatest if multiple components are advanced together.

The current structure of health care delivery has been sustained for decades because it has rested on its own set of mutually reinforcing elements: organization by specialty with independent private-practice physicians; measurement of "quality" defined as process compliance; cost accounting driven not by costs but by charges; fee-for-service payments by specialty with rampant cross-subsidies; delivery systems with duplicative service lines and little integration; fragmentation of patient populations such that most providers do not have critical masses of patients with a given medical condition; siloed IT systems around medical specialties; and others. This interlocking structure explains why the current system has been so resistant to change, why incremental steps have had little impact (see the sidebar "No Magic Bullets"), and why simultaneous progress on multiple components of the strategic agenda is so beneficial.

**No Magic Bullets**

The history of health care reform has featured a succession of narrow "solutions," many imposed on provider organizations by external stakeholders and introduced with great fanfare. For the most part, the solutions have focused on the levers that particular stakeholders can push and have been designed to preserve existing roles. None of them tackle the underlying strategic and structural problems that work against value for patients.
Individually and collectively, these "magic bullets" have inspired false hope and distracted attention from the real work at hand. Disappointment with their limited impact has created skepticism that value improvement in health care is possible and has led many to conclude that the only solution to our financial challenges in health care is to ration services and shift costs to patients or taxpayers.

A realistic assessment of these piecemeal reforms reveals that none of them, or even all of them taken together, address the root causes of low value. While many of the steps are useful, there is no substitute for the strategic transformation the value agenda requires.

**Regulation to combat physician fraud and self-dealing**

Fraud and self-dealing occur, but enforcement here does not address the root causes of low-value health care. Regulations intended to reduce self-dealing can actually impede progress toward improving value, by inhibiting integrated care across specialties.

**Consumer-driven health care**

To date, incentives that encourage people to be better health care "consumers" have done little more than shift costs to patients. Also, consumer shopping can have only limited impact in a fragmented system where information about outcomes and price is lacking.

**Evidence-based medicine (requiring providers to report compliance with guidelines)**

Research-based practice guidelines are of course desirable, but compliance with them does not necessarily lead to improved outcomes or efficiency. Guidelines cover only a small slice of the overall care cycle and fail to reflect many individual patient circumstances. Rapid advances in medical knowledge constantly improve the state of the art, which means that providers are measured on compliance with guidelines that are often outdated.

**New, more convenient models of primary care**

New models of delivering routine primary care in lower-cost settings (such as retail clinics) have a role, but they will do little to address the bulk of health care costs, most of which are generated by care for more-complex diseases. Also, retail clinics and other adjuncts to primary care practices are not equipped to provide holistic and continuous care for healthy patients or acute and preventive care for patients with complex, chronic, or acute conditions.

**Global capitation to control spending**

Capitation, a payment model in which providers receive a flat fee for taking care of an individual enrolled in a health care plan, covering any and all needed services, provides a strong incentive to reduce spending but not necessarily to improve value. Patients and providers alike worry about the lack of alignment of a single global payment with patients' interests. This payment model also exposes providers to risks over which they have little control. Capitation motivates providers to offer every service line in an attempt to keep spending internal, instead of providing only services where they can offer excellent value.

**Reduction of medical errors**

Reducing errors is essential, but errors are just one of the outcomes that matter to patients. Reducing errors does not itself lead to a redesign of overall care that improves value.
Care coordination, especially for expensive patients

If care coordinators are simply layered on top of a fragmented and dysfunctional delivery system, savings are modest (4% to 7% at best). When coordination takes place organically in IPUs, savings can reach 30% or more.

Electronic medical records (EMR)

Information technology is a powerful tool for enabling value-based care. But introducing EMR without restructuring care delivery, measurement, and payment yields limited benefits. And siloed IT systems make cost and outcomes measurement virtually impossible, greatly impeding value improvement efforts.

The components of the strategic agenda are not theoretical or radical. All are already being implemented to varying degrees in organizations ranging from leading academic medical centers to community safety-net hospitals. No organization, however, has yet put in place the full value agenda across its entire practice. Every organization has room for improvement in value for patients, and always will.

1: Organize into Integrated Practice Units (IPUs)

At the core of the value transformation is changing the way clinicians are organized to deliver care. The first principle in structuring any organization or business is to organize around the customer and the need. In health care, that requires a shift from today's siloed organization by specialty department and discrete service to organizing around the patient's medical condition. We call such a structure an integrated practice unit. In an IPU, a dedicated team made up of both clinical and nonclinical personnel provides the full care cycle for the patient's condition.

IPUs treat not only a disease but also the related conditions, complications, and circumstances that commonly occur along with it, such as kidney and eye disorders for patients with diabetes, or palliative care for those with metastatic cancer. IPUs not only provide treatment but also assume responsibility for engaging patients and their families in care, for instance, by providing education and counseling, encouraging adherence to treatment and prevention protocols, and supporting needed behavioral changes such as smoking cessation or weight loss.

In an IPU, personnel work together regularly as a team toward a common goal: maximizing the patient's overall outcomes as efficiently as possible. They are expert in the condition, know and trust one another, and coordinate easily to minimize wasted time and resources. They meet frequently, formally and informally, and review data on their own performance. Armed with those data, they work to improve care, by establishing new protocols and devising better or more efficient ways to engage patients, including group visits and virtual interactions. Ideally, IPU members are co-located, to facilitate communication, collaboration, and efficiency for patients, but they work as a team even if they're based at different locations. (See the sidebar "What Is an Integrated Practice Unit?")

What Is an Integrated Practice Unit?

1) An IPU is organized around a medical condition or a set of closely related conditions (or around defined patient segments for primary care).

2) Care is delivered by a dedicated, multidisciplinary team of clinicians who devote a significant portion of their time to the medical condition.

3) Providers see themselves as part of a common organizational unit.
4) The team takes responsibility for the full cycle of care for the condition, encompassing outpatient, inpatient, and rehabilitative care, and supporting services (such as nutrition, social work, and behavioral health).

5) Patient education, engagement, and follow-up are integrated into care.

6) The unit has a single administrative and scheduling structure.

7) To a large extent, care is co-located in dedicated facilities.

8) A physician team captain or a clinical care manager (or both) oversees each patient's care process.

9) The team measures outcomes, costs, and processes for each patient using a common measurement platform.

10) The providers on the team meet formally and informally on a regular basis to discuss patients, processes, and results.

11) Joint accountability is accepted for outcomes and costs.

Take, for example, care for patients with low back pain, one of the most common and expensive causes of disability. In the prevailing approach, patients receive portions of their care from a variety of types of clinicians, usually in several different locations, who function more like a spontaneously assembled "pickup team" than an integrated unit. One patient might begin care with a primary care physician, while others might start with an orthopedist, a neurologist, or a rheumatologist. What happens next is unpredictable. Patients might be referred to yet another physician or to a physical therapist. They might undergo radiology testing (this could happen at any point, even before seeing a physician). Each encounter is separate from the others, and no one coordinates the care. Duplication of effort, delays, and inefficiency is almost inevitable. Since no one measures patient outcomes, how long the process takes, or how much the care costs, the value of care never improves.

The impact on value of IPUs is striking. Compared with regional averages, patients at Virginia Mason's Spine Clinic miss fewer days of work (4.3 versus 9 per episode) and need fewer physical therapy visits (4.4 versus 8.8).

Contrast that with the approach taken by the IPU at Virginia Mason Medical Center, in Seattle. Patients with low back pain call one central phone number (206-41-SPINE), and most can be seen the same day. The "spine team" pairs a physical therapist with a physician who is board-certified in physical medicine and rehabilitation, and patients usually see both on their first visit. Those with serious causes of back pain (such as a malignancy or an infection) are quickly identified and enter a process designed to address the specific diagnosis. Other patients will require surgery and will enter a process for that. For most patients, however, physical therapy is the most effective next intervention, and their treatment often begins the same day.

Virginia Mason did not address the problem of chaotic care by hiring coordinators to help patients navigate the existing system, a "solution" that does not work. Rather, it eliminated the chaos by creating a new system in which caregivers work together in an integrated way. The impact on value has been striking. Compared with regional averages, patients at Virginia Mason's Spine Clinic miss fewer days of work (4.3 versus 9 per episode) and need fewer physical therapy visits (4.4 versus 8.8). In addition, the use of MRI scans to evaluate low back pain has decreased by 23% since the clinic's launch, in 2005, even as outcomes have improved. Better care has actually lowered costs, a point we will return to later. Virginia Mason has also increased revenue through increased productivity, rather than depending on more fee-for-service visits to drive revenue from unneeded or duplicative tests and care. The clinic sees about 2,300 new patients per year compared with 1,404 under the old system, and it does so in the same space and with the same number of staff members.
Wherever IPUs exist, we find similar results, faster treatment, better outcomes, lower costs, and, usually, improving market share in the condition. But those results can be achieved only through a restructuring of work. Simply co-locating staff in the same building, or putting up a sign announcing a Center of Excellence or an Institute, will have little impact.

IPUs emerged initially in the care for particular medical conditions, such as breast cancer and joint replacement. Today, condition-based IPUs are proliferating rapidly across many areas of acute and chronic care, from organ transplantation to shoulder care to mental health conditions such as eating disorders.

Recently, we have applied the IPU model to primary care (see Michael E. Porter, Erika A. Pabo, and Thomas H. Lee, "Redesigning Primary Care," *Health Affairs*, March 2013). By its very nature, primary care is holistic, concerned with all the health circumstances and needs of a patient. Today's primary care practice applies a common organizational structure to the management of a very wide range of patients, from healthy adults to the frail elderly. The complexity of meeting their heterogeneous needs has made value improvement very difficult in primary care, for example, heterogeneous needs make outcomes measurement next to impossible.

In primary care, IPUs are multidisciplinary teams organized to serve groups of patients with similar primary and preventive care needs, for example, patients with complex chronic conditions such as diabetes, or disabled elderly patients. Different patient groups require different teams, different types of services, and even different locations of care. They also require services to address head-on the crucial role of lifestyle change and preventive care in outcomes and costs, and those services must be tailored to patients' overall circumstances. Within each patient group, the appropriate clinical team, preventive services, and education can be put in place to improve value, and results become measureable.

This approach is already starting to be applied to high-risk, high-cost patients through so-called Patient-Centered Medical Homes. But the opportunity to substantially enhance value in primary care is far broader. At Geisinger Health System, in Pennsylvania, for example, the care for patients with chronic conditions such as diabetes and heart disease involves not only physicians and other clinicians but also pharmacists, who have major responsibility for following and adjusting medications. The inclusion of pharmacists on teams has resulted in fewer strokes, amputations, emergency department visits, and hospitalizations, and in better performance on other outcomes that matter to patients.

**2: Measure Outcomes and Costs for Every Patient**

Rapid improvement in any field requires measuring results, a familiar principle in management. Teams improve and excel by tracking progress over time and comparing their performance to that of peers inside and outside their organization. Indeed, rigorous measurement of value (outcomes and costs) is perhaps the single most important step in improving health care. Wherever we see systematic measurement of results in health care, no matter what the country, we see those results improve.

Yet the reality is that the great majority of health care providers (and insurers) fail to track either outcomes or costs by medical condition for individual patients. For example, although many institutions have "back pain centers," few can tell you about their patients' outcomes (such as their time to return to work) or the actual resources used in treating those patients over the full care cycle. That surprising truth goes a long way toward explaining why decades of health care reform have not changed the trajectory of value in the system.

When outcomes measurement *is* done, it rarely goes beyond tracking a few areas, such as mortality and safety. Instead, "quality measurement" has gravitated to the most
easily measured and least controversial indicators. Most "quality" metrics do not
gauge quality; rather, they are process measures that capture compliance with
practice guidelines. HEDIS (the Healthcare Effectiveness Data and Information Set)
scores consist entirely of process measures as well as easy-to-measure clinical
indicators that fall well short of actual outcomes. For diabetes, for example,
providers measure the reliability of their LDL cholesterol checks and hemoglobin A1c
levels, even though what really matters to patients is whether they are likely to
lose their vision, need dialysis, have a heart attack or stroke, or undergo an
amputation. Few health care organizations yet measure how their diabetic patients
fare on all the outcomes that matter.

It is not surprising that the public remains indifferent to quality measures that
may gauge a provider's reliability and reputation but say little about how its
patients actually do. The only true measures of quality are the outcomes that matter
to patients. And when those outcomes are collected and reported publicly, providers
face tremendous pressure, and strong incentives, to improve and to adopt best
practices, with resulting improvements in outcomes. Take, for example, the Fertility
Clinic Success Rate and Certification Act of 1992, which mandated that all clinics
performing assisted reproductive technology procedures, notably in vitro ferti-
lization, provide their live birth rates and other metrics to the Centers for Disease
Control. After the CDC began publicly reporting those data, in 1997, improvements
in the field were rapidly adopted, and success rates for all clinics, large and small,
have steadily improved. (See the exhibit "Outcomes Measurement and Reporting Drive
Improvement.")

**Outcomes Measurement and Reporting Drive Improvement**

Since public reporting of clinic performance began, in 1997, in vitro fertilization
success rates have climbed steadily across all clinics as process improvements have
spread.

![Graph showing in vitro fertilization success rates](image)

**Measuring outcomes that matter to patients.**

Outcomes should be measured by medical condition (such as diabetes), not by specialty
(podiatry) or intervention (eye examination). Outcomes should cover the full cycle
of care for the condition, and track the patient's health status after care is
completed. The outcomes that matter to patients for a particular medical condition
fall into three tiers. (For more, see Michael Porter's article "Measuring Health
Outcomes: The Outcome Hierarchy," New England Journal of Medicine, December 2010.)
Tier 1 involves the health status achieved. Patients care about mortality rates, of course, but they're also concerned about their functional status. In the case of prostate cancer treatment, for example, five-year survival rates are typically 90% or higher, so patients are more interested in their providers' performance on crucial functional outcomes, such as incontinence and sexual function, where variability among providers is much greater.

Outcomes That Matter to Patients: A Hierarchy

In measuring quality of care, providers tend to focus on only what they directly control or easily measured clinical indicators. However, measuring the full set of outcomes that matter to patients by condition is essential in meeting their needs. And when outcomes are measured comprehensively, results invariably improve.

Tier 1: Health status achieved or retained

Survival
Example: Hip Replacement
Mortality rate (inpatient)

Degree of health or recovery
Functional level achieved
Pain level achieved
Extent of return to physical activities
Ability to return to work

Tier 2: Process of recovery

Time to recovery
Time to begin treatment
Time to return to physical activities
Time to return to work

Disutility of care or treatment process (for instance, diagnostic errors, ineffective care, treatment-related discomfort, complications, adverse effects)

Delays and anxiety
Pain during treatment
Length of hospital stay
Infection
Pulmonary embolism
Deep-vein thrombosis
Myocardial infarction
Need for re-operation
Delirium

Tier 3: Sustainability of health

Sustainability of health or recovery
Nature of recurrences
Maintained functional level
Ability to live independently
Need for revision or replacement

**Long-term consequences of therapy (for instance, care-induced illnesses)**

Loss of mobility due to inadequate rehabilitation
Risk of complex fracture
Susceptibility to infection
Stiff knee due to unrecognized complications
Regional pain syndrome

Tier 2 outcomes relate to the nature of the care cycle and recovery. For example, high readmission rates and frequent emergency-department "bounce backs" may not actually worsen long-term survival, but they are expensive and frustrating for both providers and patients. The level of discomfort during care and how long it takes to return to normal activities also matter greatly to patients. Significant delays before seeing a specialist for a potentially ominous complaint can cause unnecessary anxiety, while delays in commencing treatment prolong the return to normal life. Even when functional outcomes are equivalent, patients whose care process is timely and free of chaos, confusion, and unnecessary setbacks experience much better care than those who encounter delays and problems along the way.

Tier 3 outcomes relate to the sustainability of health. A hip replacement that lasts two years is inferior to one that lasts 15 years, from both the patient's perspective and the provider's.

Measuring the full set of outcomes that matter is indispensable to better meeting patients' needs. It is also one of the most powerful vehicles for lowering health care costs. If Tier 1 functional outcomes improve, costs invariably go down. If any Tier 2 or 3 outcomes improve, costs invariably go down. A 2011 German study, for example, found that one-year follow-up costs after total hip replacement were 15% lower in hospitals with above-average outcomes than in hospitals with below-average outcomes, and 24% lower than in very-low-volume hospitals, where providers have relatively little experience with hip replacements. By failing to consistently measure the outcomes that matter, we lose perhaps our most powerful lever for cost reduction.

Over the past half dozen years, a growing array of providers have begun to embrace true outcome measurement. Many of the leaders have seen their reputations, and market share, improve as a result. A welcomed competition is emerging to be the most comprehensive and transparent provider in measuring outcomes.

The Cleveland Clinic is one such pioneer, first publishing its mortality data on cardiac surgery and subsequently mandating outcomes measurement across the entire organization. Today, the Clinic publishes 14 different "outcomes books" reporting performance in managing a growing number of conditions (cancer, neurological conditions, and cardiac diseases, for example). The range of outcomes measured remains limited, but the Clinic is expanding its efforts, and other organizations are following suit. At the individual IPU level, numerous providers are beginning efforts. At Dartmouth-Hitchcock's Spine Center, for instance, patient scores for pain, physical function, and disability for surgical and nonsurgical treatment at three, six, 12, and 24 months are now published for each type of low back disorder.

Providers are improving their understanding of what outcomes to measure and how to collect, analyze, and report outcomes data. For example, some of our colleagues at Partners HealthCare in Boston are testing innovative technologies such as tablet
computers, web portals, and telephonic interactive systems for collecting outcomes data from patients after cardiac surgery or as they live with chronic conditions such as diabetes. Outcomes are also starting to be incorporated in real time into the process of care, allowing providers to track progress as they interact with patients.

To accelerate comprehensive and standardized outcome measurement on a global basis, we recently cofounded the International Consortium for Health Outcomes Measurement (ICHOM). ICHOM develops minimum outcome sets by medical condition, drawing on international registries and provider best practices. It brings together clinical leaders from around the world to develop standard outcome sets, while also gathering and disseminating best practices in outcomes data collection, verification, and reporting. Just as railroads converged on standard track widths and the telecommunications industry on standards to allow data exchange, health care providers globally should consistently measure outcomes by condition to enable universal comparison and stimulate rapid improvement.

**Measuring the cost of care.**

For a field in which high cost is an overarching problem, the absence of accurate cost information in health care is nothing short of astounding. Few clinicians have any knowledge of what each component of care costs, much less how costs relate to the outcomes achieved. In most health care organizations there is virtually no accurate information on the cost of the full cycle of care for a patient with a particular medical condition. Instead, most hospital cost-accounting systems are department-based, not patient-based, and designed for billing of transactions reimbursed under fee-for-service contracts. In a world where fees just keep going up, that makes sense. Existing systems are also fine for overall department budgeting, but they provide only crude and misleading estimates of actual costs of service for individual patients and conditions. For example, cost allocations are often based on charges, not actual costs. As health care providers come under increasing pressure to lower costs and report outcomes, the existing systems are wholly inadequate.

Existing costing systems are fine for overall department budgeting, but they provide only crude and misleading estimates of actual costs of service for individual patients and conditions.

To determine value, providers must measure costs at the medical condition level, tracking the expenses involved in treating the condition over the full cycle of care. This requires understanding the resources used in a patient's care, including personnel, equipment, and facilities; the capacity cost of supplying each resource; and the support costs associated with care, such as IT and administration. Then the cost of caring for a condition can be compared with the outcomes achieved.

The best method for understanding these costs is time-driven activity-based costing, TDABC. While rarely used in health care to date, it is beginning to spread. Where TDABC is being applied, it is helping providers find numerous ways to substantially reduce costs without negatively affecting outcomes (and sometimes even improving them). Providers are achieving savings of 25% or more by tapping opportunities such as better capacity utilization, more-standardized processes, better matching of personnel skills to tasks, locating care in the most cost-effective type of facility, and many others.

For example, Virginia Mason found that it costs $4 per minute for an orthopedic surgeon or other procedural specialist to perform a service, $2 for a general internist, and $1 or less for a nurse practitioner or physical therapist. In light of those cost differences, focusing the time of the most expensive staff members on work that utilizes their full skill set is hugely important. (For more, see Robert Kaplan and Michael Porter's article "How to Solve the Cost Crisis in Health Care,"HBR September 2011.)
Without understanding the true costs of care for patient conditions, much less how costs are related to outcomes, health care organizations are flying blind in deciding how to improve processes and redesign care. Clinicians and administrators battle over arbitrary cuts, rather than working together to improve the value of care. Because proper cost data are so critical to overcoming the many barriers associated with legacy processes and systems, we often tell skeptical clinical leaders: "Cost accounting is your friend." Understanding true costs will finally allow clinicians to work with administrators to improve the value of care, the fundamental goal of health care organizations.

3: Move to Bundled Payments for Care Cycles

Neither of the dominant payment models in health care, global capitation and fee-for-service, directly rewards improving the value of care. Global capitation, a single payment to cover all of a patient's needs, rewards providers for spending less but not specifically for improving outcomes or value. It also decouples payment from what providers can directly control. Fee-for-service couples payment to something providers can control, how many of their services, such as MRI scans, they provide, but not to the overall cost or the outcomes. Providers are rewarded for increasing volume, but that does not necessarily increase value.

The payment approach best aligned with value is a bundled payment that covers the full care cycle for acute medical conditions, the overall care for chronic conditions for a defined period (usually a year), or primary and preventive care for a defined patient population (healthy children, for instance). Well-designed bundled payments directly encourage teamwork and high-value care. Payment is tied to overall care for a patient with a particular medical condition, aligning payment with what the team can control. Providers benefit from improving efficiency while maintaining or improving outcomes.

Sound bundled payment models should include: severity adjustments or eligibility only for qualifying patients; care guarantees that hold the provider responsible for avoidable complications, such as infections after surgery; stop-loss provisions that mitigate the risk of unusually high-cost events; and mandatory outcomes reporting.

Governments, insurers, and health systems in multiple countries are moving to adopt bundled payment approaches. For example, the Stockholm County Council initiated such a program in 2009 for all total hip and knee replacements for relatively healthy patients. The result was lower costs, higher patient satisfaction, and improvement in some outcomes. In Germany, bundled payments for hospital inpatient care, combining all physician fees and other costs, unlike payment models in the U.S., have helped keep the average payment for a hospitalization below $5,000 (compared with more than $19,000 in the U.S., even though hospital stays are, on average, 50% longer in Germany). Among the features of the German system are care guarantees under which the hospital bears responsibility for the cost of rehospitalization related to the original care.

In the U.S., bundled payments have become the norm for organ transplant care. Here, mandatory outcomes reporting has combined with bundles to reinforce team care, speed diffusion of innovation, and rapidly improve outcomes. Providers that adopted bundle approaches early benefitted. UCLA's kidney transplant program, for example, has grown dramatically since pioneering a bundled price arrangement with Kaiser Permanente, in 1986, and offering the payment approach to all its payors shortly thereafter. Its outcomes are among the best nationally, and UCLA's market share in organ transplantation has expanded substantially.

Employers are also embracing bundled payments. This year, Walmart introduced a program in which it encourages employees who need cardiac, spine, and selected other surgery to obtain care at one of just six providers nationally, all of which have
high volume and track records of excellent outcomes: the Cleveland Clinic, Geisinger, the Mayo Clinic, Mercy Hospital (in Springfield, Missouri), Scott & White, and Virginia Mason. The hospitals are reimbursed for the care with a single bundled payment that includes all physician and hospital costs associated with both inpatient and outpatient pre- and post-operative care. Employees bear no out-of-pocket costs for their care, travel, lodging, and meals for the patient and a caregiver are provided, as long as the surgery is performed at one of the centers of excellence. The program is in its infancy, but expectations are that Walmart and other large employers will expand such programs to improve value for their employees, and will step up the incentives for employees to use them. Sophisticated employers have learned that they must move beyond cost containment and health promotion measures, such as co-pays and on-site health and wellness facilities, and become a greater force in rewarding high-value providers with more patients.

As bundled payment models proliferate, the way in which care is delivered will be transformed. Consider how providers participating in Walmart’s program are changing the way they provide care. As clinical leaders map the processes involved in caring for patients who live outside their immediate area, they are learning how to better coordinate care with all of patients’ local physicians. They’re also questioning existing practices. For example, many hospitals routinely have patients return to see the cardiac surgeon six to eight weeks after surgery, but out-of-town visits seem difficult to justify for patients with no obvious complications. In deciding to drop those visits, clinicians realized that maybe local patients do not need routine postoperative visits either.

Providers remain nervous about bundled payments, citing concerns that patient heterogeneity might not be fully reflected in reimbursements, and that the lack of accurate cost data at the condition level could create financial exposure. Those concerns are legitimate, but they are present in any reimbursement model. We believe that concerns will fall away over time, as sophistication grows and the evidence mounts that embracing payments aligned with delivering value is in providers' economic interest. Providers will adopt bundles as a tool to grow volume and improve value.

4: Integrate Care Delivery Systems

A large and growing proportion of health care is provided by multisite health care delivery organizations. In 2011, 60% of all U.S. hospitals were part of such systems, up from 51% in 1999. Multisite health organizations accounted for 69% of total admissions in 2011. Those proportions are even higher today. Unfortunately, most multisite organizations are not true delivery systems, at least thus far, but loose confederations of largely stand-alone units that often duplicate services. There are huge opportunities for improving value as providers integrate systems to eliminate the fragmentation and duplication of care and to optimize the types of care delivered in each location.

To achieve true system integration, organizations must grapple with four related sets of choices: defining the scope of services, concentrating volume in fewer locations, choosing the right location for each service line, and integrating care for patients across locations. The politics of redistributing care remain daunting, given most providers' instinct to preserve the status quo and protect their turf. Some acid-test questions to gauge board members' and health system leaders' appetite for transformation include: Are you ready to give up service lines to improve the value of care for patients? Is relocating service lines on the table?

Define the scope of services.
A starting point for system integration is determining the overall scope of services a provider can effectively deliver, and reducing or eliminating service lines where they cannot realistically achieve high value. For community providers, this may mean exiting or establishing partnerships in complex service lines, such as cardiac surgery or care for rare cancers. For academic medical centers, which have more heavily resourced facilities and staff, this may mean minimizing routine service lines and creating partnerships or affiliations with lower-cost community providers in those fields. Although limiting the range of service lines offered has traditionally been an unnatural act in health care, where organizations strive to do everything for everyone, the move to a value-based delivery system will require those kinds of choices.

Concentrate volume in fewer locations.

Second, providers should concentrate the care for each of the conditions they do treat in fewer locations. The stated promise of consumer-oriented health care, "We do everything you need close to your home or workplace", has been a good marketing pitch but a poor strategy for creating value. Concentrating volume is essential if integrated practice units are to form and measurement is to improve.

Numerous studies confirm that volume in a particular medical condition matters for value. Providers with significant experience in treating a given condition have better outcomes, and costs improve as well. A recent study of the relationship between hospital volume and operative mortality for high-risk types of cancer surgery, for example, found that as hospital volumes rose, the chances of a patient's dying as a result of the surgery fell by as much as 67%. Patients, then, are often much better off traveling longer distance to obtain care at locations where there are teams with deep experience in their condition. That often means driving past the closest hospitals.

Organizations that progress rapidly in adopting the value agenda will reap huge benefits, even if regulatory change is slow.

Concentrating volume is among the most difficult steps for many organizations, because it can threaten both prestige and physician turf. Yet the benefits of concentration can be game-changing. In 2009, the city of London set out to improve survival and prospects for stroke patients by ensuring that patients were cared for by true IPUs, dedicated, state-of-the-art teams and facilities including neurologists who were expert in the care of stroke. These were called hyper-acute stroke units, or HASUs. At the time, there were too many hospitals providing acute stroke care in London (32 of them) to allow any to amass a high volume. UCL Partners, a delivery system comprising six well-known teaching hospitals that serve North Central London, had two hospitals providing stroke care, University College London Hospital and the Royal Free Hospital, located less than three miles apart. University College was selected to house the new stroke unit. Neurologists at Royal Free began practicing at University College, and a Royal Free neurologist was appointed as the overall leader of the stroke program. UCL Partners later moved all emergency vascular surgery and complex aortic surgery to Royal Free.

These steps sent a strong message that UCL Partners was ready to concentrate volume to improve value. The number of stroke cases treated at University College climbed from about 200 in 2008 to more than 1,400 in 2011. All stroke patients can now undergo rapid evaluation by highly experienced neurologists and begin their recovery under the care of nurses who are expert in preventing stroke-related complications. Since the shift, mortality associated with strokes at University College has fallen by about 25% and costs per patient have dropped by 6%.

Choose the right location for each service.
The third component of system integration is delivering particular services at the locations at which value is highest. Less complex conditions and routine services should be moved out of teaching hospitals into lower-cost facilities, with charges set accordingly. There are huge value improvement opportunities in matching the complexity and skills needed with the resource intensity of the location, which will not only optimize cost but also increase staff utilization and productivity. Children's Hospital of Philadelphia, for instance, decided to stop performing routine tympanostomies (placing tubes into children's eardrums to reduce fluid collection and risk of infection) at its main facility and shifted those services to suburban ambulatory surgery facilities. More recently, the hospital applied the same approach to simple hypospadias repairs, a urological procedure. Relocating such services cut costs and freed up operating rooms and staff at the teaching hospital for more-complex procedures. Management estimated the total cost reduction resulting from the shift at 30% to 40%.

In many cases, current reimbursement schemes still reward providers for performing services in a hospital setting, offering even higher payments if the hospital is an academic medical center, another example of how existing reimbursement models have worked against value. But the days of charging higher fees for routine services in high-cost settings are quickly coming to an end. (See again the sidebar "Why Change Now?")

Integrate care across locations.

The final component of health system integration is to integrate care for individual patients across locations. As providers distribute services in the care cycle across locations, they must learn to tie together the patient's care across these sites. Care should be directed by IPUs, but recurring services need not take place in a single location. For example, patients with low back pain may receive an initial evaluation, and surgery if needed, from a centrally located spine IPU team but may continue physical therapy closer to home. Wherever the services are performed, however, the IPU manages the full care cycle. Integrating mechanisms, such as assigning a single physician team captain for each patient and adopting common scheduling and other protocols, help ensure that well-coordinated, multidisciplinary care is delivered in a cost-effective and convenient way.

5: Expand Geographic Reach

Health care delivery remains heavily local, and even academic medical centers primarily serve their immediate geographic areas. If value is to be substantially increased on a large scale, however, superior providers for particular medical conditions need to serve far more patients and extend their reach through the strategic expansion of excellent IPUs. Buying full-service hospitals or practices in new geographic areas is rarely the answer. Geographic expansion should focus on improving value, not just increasing volume.

Targeted geographic expansion by leading providers is rapidly increasing, with dozens of organizations such as Vanderbilt, Texas Children's, Children's Hospital of Philadelphia, MD Anderson Cancer Center, and many others taking bold steps to serve patients over a wide geographic area.

Geographic expansion takes two principle forms. The first is a hub-and-spoke model. For each IPU, satellite facilities are established and staffed at least partly by clinicians and other personnel employed by the parent organization. In the most effective models, some clinicians rotate among locations, which helps staff members across all facilities feel they are part of the team. As expansion moves to an entirely new region, a new IPU hub is built or acquired.
Patients often get their initial evaluation and development of a treatment plan at the hub, but some or much care takes place at more-convenient (and cost-effective) locations. Satellites deliver less complicated care, with complex cases referred to the hub. If complications occur whose effective management is beyond the ability of the satellite facility, the patient's care is transferred to the hub. The net result is a substantial increase in the number of patients an excellent IPU can serve.

This model is becoming more common among leading cancer centers. MD Anderson, for example, has four satellite sites in the greater Houston region where patients receive chemotherapy, radiation therapy, and, more recently, low-complexity surgery, under the supervision of a hub IPU. The cost of care at the regional facilities is estimated to be about one-third less than comparable care at the main facility. By 2012, 22% of radiation treatment and 15% of all chemotherapy treatment were performed at regional sites, along with about 5% of surgery. Senior management estimates that 50% of comparable care currently still performed at the hub could move to satellite sites, a significant untapped value opportunity.

The second emerging geographic expansion model is clinical affiliation, in which an IPU partners with community providers or other local organizations, using their facilities rather than adding capacity. The IPU provides management oversight for clinical care, and some clinical staff members working at the affiliate may be employed by the parent IPU. MD Anderson uses this approach in its partnership with Banner Phoenix. Hybrid models include the approach taken by MD Anderson in its regional satellite program, which leases outpatient facilities located on community hospital campuses and utilizes those hospitals' operating rooms and other inpatient and ancillary services as needed.

Local affiliates benefit from the expertise, experience, and reputation of the parent IPU, benefits that often improve their market share locally. The IPU broadens its regional reach and brand, and benefits from management fees, shared revenue or joint venture income, and referrals of complex cases.

The Cleveland Clinic's Heart and Vascular Institute, a pioneering IPU in cardiac and vascular care, has 19 hospital affiliates spanning the Eastern seaboard. Successful clinical affiliations such as these are robust, not simply storefronts with new signage and marketing campaigns, and involve close oversight by physician and nurse leaders from the parent organization as well as strict adherence to its practice models and measurement systems. Over time, outcomes for standard cases at the Clinic's affiliates have risen to approach its own outcomes.

Vanderbilt's rapidly expanding affiliate network illustrates the numerous opportunities that arise from affiliations that recognize each partner's areas of strength. For example, Vanderbilt has encouraged affiliates to grow noncomplex obstetrics services that once might have taken place at the academic medical center, while affiliates have joint ventured with Vanderbilt in providing care for some complex conditions in their territories.

6: Build an Enabling Information Technology Platform

The preceding five components of the value agenda are powerfully enabled by a sixth: a supporting information technology platform. Historically, health care IT systems have been siloed by department, location, type of service, and type of data (for instance, images). Often IT systems complicate rather than support integrated, multidisciplinary care. That's because IT is just a tool; automating broken service-delivery processes only gets you more-efficient broken processes. But the right kind of IT system can help the parts of an IPU work with one another, enable measurement and new reimbursement approaches, and tie the parts of a well-structured delivery system together.
A value-enhancing IT platform has six essential elements:

**It is centered on patients.**

The system follows patients across services, sites, and time for the full cycle of care, including hospitalization, outpatient visits, testing, physical therapy, and other interventions. Data are aggregated around patients, not departments, units, or locations.

**It uses common data definitions.**

Terminology and data fields related to diagnoses, lab values, treatments, and other aspects of care are standardized so that everyone is speaking the same language, enabling data to be understood, exchanged, and queried across the whole system.

**It encompasses all types of patient data.**

Physician notes, images, chemotherapy orders, lab tests, and other data are stored in a single place so that everyone participating in a patient's care has a comprehensive view.

**The medical record is accessible to all parties involved in care.**

That includes referring physicians and patients themselves. A simple "stress test" question to gauge the accessibility of the data in an IT system is: Can visiting nurses see physicians' notes, and vice versa? The answer today at almost all delivery systems is "no." As different types of clinicians become true team members, working together in IPUs, for example, sharing information needs to become routine. The right kind of medical record also should mean that patients have to provide only one set of patient information, and that they have a centralized way to schedule appointments, refill prescriptions, and communicate with clinicians. And it should make it easy to survey patients about certain types of information relevant to their care, such as their functional status and their pain levels.

**The system includes templates and expert systems for each medical condition.**

Templates make it easier and more efficient for the IPU teams to enter and find data, execute procedures, use standard order sets, and measure outcomes and costs. Expert systems help clinicians identify needed steps (for example, follow-up for an abnormal test) and possible risks (drug interactions that may be overlooked if data are simply recorded in free text, for example).

**The system architecture makes it easy to extract information.**

In value-enhancing systems, the data needed to measure outcomes, track patient-centered costs, and control for patient risk factors can be readily extracted using natural language processing. Such systems also give patients the ability to report outcomes on their care, not only after their care is completed but also during care, to enable better clinical decisions. Even in today's most advanced systems, the critical capability to create and extract such data remains poorly developed. As a result, the cost of measuring outcomes and costs is unnecessarily increased.

The Cleveland Clinic is a provider that has made its electronic record an important enabler of its strategy to put "Patients First" by pursuing virtually all these aims. It is now moving toward giving patients full access to clinician notes, another way to improve care for patients.

**Getting Started**
The six components of the value agenda are distinct but mutually reinforcing. Organizing into IPUs makes proper measurement of outcomes and costs easier. Better measurement of outcomes and costs makes bundled payments easier to set and agree upon. A common IT platform enables effective collaboration and coordination within IPU teams, while also making the extraction, comparison, and reporting of outcomes and cost data easier. With bundled prices in place, IPUs have stronger incentives to work as teams and to improve the value of care. And so on.

Implementing the value agenda is not a one-shot effort; it is an open-ended commitment. It is a journey that providers embark on, starting with the adoption of the goal of value, a culture of patients first, and the expectation of constant, measurable improvement. The journey requires strong leadership as well as a commitment to roll out all six value agenda components. For most providers, creating IPUs and measuring outcomes and costs should take the lead.

As should by now be clear, organizations that progress rapidly in adopting the value agenda will reap huge benefits, even if regulatory change is slow. As IPUs' outcomes improve, so will their reputations and, therefore, their patient volumes. With the tools to manage and reduce costs, providers will be able to maintain economic viability even as reimbursements plateau and eventually decline. Providers that concentrate volume will drive a virtuous cycle, in which teams with more experience and better data improve value more rapidly, attracting still more volume. Superior IPUs will be sought out as partners of choice, enabling them to expand across their local regions and beyond.

Maintaining market share will be difficult for providers with nonemployed physicians if their inability to work together impedes progress in improving value. Hospitals with private-practice physicians will have to learn to function as a team to remain viable. Measuring outcomes is likely to be the first step in focusing everyone's attention on what matters most.

All stakeholders in health care have essential roles to play. (See the sidebar "Next Steps: Other Stakeholder Roles.") Yet providers must take center stage. Their boards and senior leadership teams must have the vision and the courage to commit to the value agenda, and the discipline to progress through the inevitable resistance and disruptions that will result. Clinicians must prioritize patients' needs and patient value over the desire to maintain their traditional autonomy and practice patterns.

**Next Steps: Other Stakeholder Roles**

The transformation to a high-value health care delivery system must come from within, with physicians and provider organizations taking the lead. But every stakeholder in the health care system has a role to play in improving the value of care. Patients, health plans, employers, and suppliers can hasten the transformation by taking the following steps, and all will benefit greatly from doing so.

Providers that cling to today's broken system will become dinosaurs. Reputations that are based on perception, not actual outcomes, will fade. Maintaining current cost structures and prices in the face of greater transparency and falling reimbursement levels will be untenable. Those organizations, large and small, community and academic, that can master the value agenda will be rewarded with financial viability and the only kind of reputation that should matter in health care, excellence in outcomes and pride in the value they deliver.

**LOAD-DATE:** November 12, 2013

**LANGUAGE:** ENGLISH
Addressing Issues of Regulatory Oversight
Calls are increasing for American health care to be organized as a learning health care system, defined by the Institute of Medicine as a health care system “in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care.” We applaud this conception, and in this paper, we put forward a new ethics framework for it. No such framework has previously been articulated. The goals of our framework are twofold: to support the transformation to a learning health care system and to help ensure that learning activities carried out within such a system are conducted in an ethically acceptable fashion.

A moral framework for a learning health care system will depart in important respects from contemporary conceptions of clinical and research ethics. The dominant paradigm in research ethics and in federal regulations has relied on a sharp distinction between research and practice—a segregation model that dates to the influential publications of the National Commission for the Protection of Human Subjects in the 1970s. The learning health care system, by contrast, proposes that it is acceptable and indeed essential to integrate research and practice. From this perspective, the dominant ethical paradigm from the 1970s to the present time is antithetical to and problematic for the learning health care system, at a time when clinical practice is far from optimal and learning to improve care is sorely needed. Several hundred thousand people die needlessly each year from medical mistakes. There is reason to believe that adult patients receive only approximately 50 percent of recommended therapies, and that up to 30 percent of health care spending is wasted. The need to improve health care is urgent, yet the current ethics paradigm may hinder improvement. For example, the expansion of one of the most successful quality improvement interventions ever—saving thousands of lives by preventing central line-associated bloodstream infections in intensive care units—was almost halted due to concerns about research ethics oversight. But few have come forward to express concern and oversight for the thirty thousand or so people who will die unnecessarily each year in the United States from this type of infection.

Quality improvement and comparative effectiveness research are emblematic of the kinds of ongoing learning activities that a learning health care system is designed to promote. As we argue in the first article in this supplement to the Hastings Center Report, quality improvement and comparative effectiveness research bring into sharp relief the problems with the criteria traditionally used to distinguish research and practice. The fuzziness of the distinction, coupled with the oversight burdens that are required of research but not of practice, creates dubious incentives to redesign quality improvement and comparative effectiveness activities in ways that minimize the likelihood that they will be classified as research.
Securing just health care requires a constantly updated body of evidence about the effectiveness and value of health care interventions and of alternative ways to deliver and finance health care.

A Moral Justification of the Learning Health Care System

The traditional principles that provide the moral grounding for human subjects protection in the United States became cemented as the cornerstones of research ethics in the 1970s during a period of intense societal focus on civil rights and on egregious violations of rights that occurred in highly publicized research scandals. Since the 1970s, the dominant concern has been to protect patients and other subjects from risk, abuse, and unjust distributions of the burdens of research.

An ethical imperative that was less central in bioethics in the 1970s—namely, the establishment of a just health care system—provides an important moral reason, generally overlooked, for a rapid transformation to a learning health care system. There is considerable disagreement about the design of a just health care system and how health care should be organized and financed to achieve it, but arguably there is broad agreement that, at minimum, a just system is one in which present and future generations are able to access adequate health care services without the imposition of undue financial burdens on patients and their families. The obstacles to securing a just health care system, so defined, are complex and include cultural, economic, and political as well as scientific and public health challenges. That said, securing just health care requires a constantly updated body of evidence about the effectiveness and value of health care interventions and of alternative ways to deliver and finance health care. A learning health care system is critical to the efficient and systematic collection and dissemination of this evidence, and we think it is a necessary condition of achieving the goal of creating and maintaining a just health care system.

The societal goal of a just health care system provides only one of three independent and equally important ethical justifications for the transition to learning health care systems. The other two are the goals of high-quality health care and economic well-being. By “high-quality health care” we mean, at minimum, technically competent health care that is based on the strongest clinical evidence and is delivered with the highest achievable patient safety. By “economic well-being” we mean, at minimum, a society in which current and future generations have the economic resources necessary to live a decent human life over the course of the life span. The im-
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<tr>
<th>Obligation</th>
<th>Parties Bearing the Obligation</th>
<th>Synopsis of the Obligation for Learning Activities</th>
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<tbody>
<tr>
<td>Respect the rights and dignity of patients&lt;sup&gt;1&lt;/sup&gt;</td>
<td>• researchers</td>
<td>• Assess the impact of a learning activity on the rights, respect, and dignity of patients</td>
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<td></td>
<td>• clinicians</td>
<td>• Assess whether a learning activity limits patient choice, as well as the value to patients of any choices so affected</td>
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<td>Respect clinician judgments</td>
<td>• researchers</td>
<td>• Assess the impact of a learning activity on the exercise of clinician judgment</td>
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<td></td>
<td>• clinicians</td>
<td>• Assess the importance of any restriction on the exercise of clinician judgment for the health and autonomy interests of patients</td>
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<td>Provide optimal clinical care to each patient</td>
<td>• researchers&lt;sup&gt;2&lt;/sup&gt;</td>
<td>• Assess the expected net clinical benefit for patients affected by the learning activity, compared to the net clinical benefit they likely would have experienced if their clinical care had not been affected by the learning activity</td>
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<td>• purchasers</td>
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<tr>
<td>Avoid imposing nonclinical risks and burdens on patients</td>
<td>• researchers</td>
<td>• Assess the nonclinical risks and burdens to patients affected by a learning activity, compared to the nonclinical risks and burdens they likely would have experienced if they had not been affected by the learning activity</td>
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<td>• clinicians</td>
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<td>• purchasers</td>
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<tr>
<td>Address health inequalities</td>
<td>• researchers</td>
<td>• Assess whether the risks and burdens of a learning activity will fall disproportionately on patients who are already disadvantaged</td>
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<td></td>
<td>• clinicians</td>
<td>• Assess whether the learning activity will disproportionately benefit patients who are already socially and economically advantaged</td>
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<td>• health care systems administrators</td>
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<td></td>
<td>• payers</td>
<td>• Assess whether a learning activity will help advance the goal of reducing unjust inequalities in health and health care or can be designed to do so</td>
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<tr>
<td>Conduct continuous learning activities that improve the quality of clinical care and health care systems</td>
<td>• researchers</td>
<td>• Conduct and contribute to learning activities as a matter of role-specific, professional responsibility</td>
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<td></td>
<td>• clinicians</td>
<td>• Assess the extent to which a learning activity will likely contribute to the quality, fairness, or value of health care services and systems by assessing the soundness of the learning activity’s objectives, design, and plans for dissemination and implementation</td>
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<tr>
<td>Contribute to the common purpose of improving the quality and value of clinical care and health care systems</td>
<td>• patients</td>
<td>• Participate in learning activities that are consonant with other obligations in the framework intended to respect the rights and interests of patients; participate in activities deemed acceptable to go forward without patients’ express informed consent</td>
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<td>• Consider participation in learning activities that because of their impact on the framework’s other obligations cannot ethically go forward without express informed consent</td>
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<sup>1</sup>This framework has implications for family members, loved ones, and surrogates of patients. Both the first and the seventh obligation extend to family members, loved ones, and surrogates when patients are children or adults whose competence is permanently or temporarily compromised and when adult patients want or need their loved ones to be involved in their care.

<sup>2</sup>If researchers do not otherwise have clinical duties to the patients who are affected by a learning activity, then they do not shoulder an obligation to provide patients with optimal clinical care.
We should assess both whether a learning activity unduly limits the choices of patients and the value of those choices to patients. Many decisions in health care are not likely to engage values of central importance to the patient.

importance of efficient and real-time learning to the securing of quality health care is indisputable. The relationship between learning in health care and economic well-being is perhaps less apparent but is arguably as important. Broad agreement exists that the pace at which U.S. health care costs continue to escalate constitutes a serious threat to the economic prospects of the country, individuals, and families; continuous, efficient learning in health care is essential (though not sufficient) to the slowing of this pace and thus to economic well-being.\(^1\)

The goals of just health care, high-quality health care, and economic well-being provide independent moral reasons for the transformation of current health care organizations into learning health care systems. These goals underlie our aim in this paper to present a framework of moral obligations that both integrates and alters some basic ideas in our current research ethics and clinical ethics paradigms. For some readers, the need to improve health care quality may be the most important reason for the transition to a learning health care system, and possibly even the only justificatory reason they accept. This rationale is narrower than our three-reasons approach, but in no way undermines the moral imperative to move to learning health care systems. The improvement of health care quality is a sufficient reason alone. So, too, is a commitment to ensuring economic well-being.

What Counts as a Learning Activity?

A learning activity is one that both 1) involves the delivery of health care services or uses individual health information, and 2) has a targeted objective of learning how to improve clinical practice or the value, quality, or efficiency of the systems, institutions, and modalities through which health care services are provided. All such activities are learning activities, even if they have typically been categorized as clinical research, clinical trials, comparative effectiveness research, quality improvement research, quality improvement practice, patient safety practice, health care operations, quality assurance, or evidence-based management. We do not contest these labels or classification schemes, but they also do not control or influence our analysis. For our purposes, they are all “learning activities.”

Health care services include a wide range of interventions and interactions in which professionals are involved with patients, sometimes over long periods of time. They include encounters between patients and health care professionals in the traditional settings in which clinical services are provided, as well as in settings such as patients’ homes, pharmacies, and the workplace, and they may occur virtually through telemedicine or other Internet-based modalities. Health information includes any information that relates to an individual’s physical or mental health, the health care services provided to an individual, or the payment for an individual’s health care, whether in the past, present, or future.\(^2\)

The Basic Structure of the Framework

The framework we propose consists of seven obligations: 1) to respect the rights and dignity of patients; 2) to respect the clinical judgment of clinicians; 3) to provide optimal care to each patient; 4) to avoid imposing nonclinical risks and burdens on patients; 5) to reduce health inequalities among populations; 6) to conduct responsible activities that foster learning from clinical care and clinical information; and 7) to contribute to the common purpose of improving the quality and value of clinical care and health care systems.

Respecting patient rights and dignity and avoiding nonclinical risks (obligations 1 and 4) appear in most contemporary discussions of research ethics. Respecting the judgment of clinicians and providing patients with optimal clinical care (obligations 2 and 3) are presuppositions of traditional medical ethics—as, for example, in the influential catalogue of norms in Thomas Percival’s classic volume, Medical Ethics.\(^3\)

Variations of these four obligations are prominent in contemporary discussions of research ethics. Respecting the judgment of clinicians and providing patients with optimal clinical care (obligations 2 and 3) are presuppositions of traditional medical ethics—as, for example, in the influential catalogue of norms in Thomas Percival’s classic volume, Medical Ethics.\(^3\)

Obligations 5, 6, and 7 are specific to the learning health care system context. These three obligations substantially revise traditional conceptions of the moral foundations of research ethics and clinical ethics. Obligations 5 and 6 have more than one obligation-bearer, as presented in Table 1, with the obligations falling on clinicians, investigators, health care institutions, those responsible for institutional policies and practices, payers, and purchasers. Patients are the obligation-bearers in obligation 7, which proposes to sharply reform current rules and guidelines. This obligation placed on patients to contribute, under limited and appropriate condi-
tions, to learning that is integrated with their clinical care is not present in conventional accounts of either clinical ethics or research ethics, where the assumption is that no such obligation exists.

All seven obligations are relevant to judgments about the ways in which a learning activity can negatively or positively affect the rights or interests of patients and professionals. The term “rights” refers to justified claims to something that individuals and groups can legitimately assert against other individuals or groups. The associated term “interests” refers to that which is in an individual’s interest—that is, that which supports an individual’s well-being or welfare in a given circumstance. We use the term “risk” to refer exclusively to a risk of “harm,” meaning a thwarting, defeating, or setting back of an individual’s interests.17

Seven Fundamental Obligations

Each of the seven obligations in the framework constitutes a necessary condition, within a learning health care system, of an adequate ethics. In the absence of any one of these obligations, the framework would lose a basic norm, rendering the framework deficient. However, we do not claim that this set of obligations establishes a set of sufficient conditions in a comprehensive ethical framework. Future work can be expected to specify these abstract rules to provide more granular guidance for institutions and their specific contexts and to perhaps add additional general obligations.

The seven norms presented below have some overlapping content, but no one norm can be reduced to one or more of the others. They are not morally weighted or placed in a hierarchical order of importance. Questions of weight and priority can be assessed only in specific contexts. When these norms come into conflict in particular learning activities, the goal will be to show either that one norm is of overriding importance in that context or that at least some demands of each of the conflicting norms can be satisfied, whereas others cannot.

1) The obligation to respect patients. Moral obligations to respect the rights and dignity of persons are not controversial in either clinical ethics or research ethics.18 Examples of respecting rights include obtaining informed consent, soliciting and accepting advance directives, protecting the confidentiality of health information, and evaluating the effectiveness of health care in terms of outcomes that matter to patients. Respecting the dignity of patients requires health professionals to express respectful attitudes and to treat patients as having an inherent moral worth by, for example, helping patients understand what is happening to them and following the lead of patients in involving their families and friends in their care.

Among the rights most discussed in research ethics and clinical ethics is the right to have one’s autonomy respected. The obligation to respect patient autonomy is also central to the framework we are proposing, but unlike some bioethics literature, the framework does not give it undue deference or overriding importance.19 Respecting autonomy is primarily about allowing persons to shape the basic course of their lives in line with their values and independent of the control of others.20 Not all health care decisions are likely to be attached to a significant autonomy interest of individual patients, and deference of the wrong sort can constitute a moral failure to take adequate care of patients rather than an instance of showing respect.

In interpreting the obligation to respect autonomy in learning health care contexts, we should assess both whether a learning activity unduly limits the choices of patients and the value of those choices to patients. Many decisions in health care—such as how often simple laboratory tests should be repeated during a hospitalization or whether medications should be dispensed by one qualified professional or another—are not likely to engage values of central importance to the patient.21 Learning activities that relate to such decisions can be undertaken by health professionals and institutional officials without a violation of obligations to respect the rights or dignity of patients.

2) The obligation to respect clinician judgment. The importance of clinician judgment to professional practice is well established, although what is meant by clinician judgment is not always clear. We use the term “judgment” broadly to mean the clinician’s considered beliefs about how best to care for a patient in light of multiple considerations and influences, including personal professional experience, the experience of colleagues and mentors, scientific evidence, and the clinician’s understanding of the patient’s values and priorities. Respect for clinicians’ judgments is justified for two reasons. First, the exercise of clinical judgment can further the health interests of patients in achieving the best clinical outcome.22 Second, the exercise of clinical judgment can advance the autonomy interests of patients because clinicians are often well positioned to ascertain and be responsive to their values and preferences.

Not all constraints on the behavior of clinicians—such as requirements to write notes for a supervisor or to use a uniform method for dosing orders—interfere with the exercise of clinician judgment. Some other constraints interfere with the exercise of clinician judgment, but to varying degrees. For example, formularies requiring physicians to prescribe only one branded drug among several in the same class may have little if any negative impact on the health and autonomy interests of patients that respect for clinician judgment is intended to serve. Learning activities that impose constraints of these types would be compatible with the obligation to respect clinician judgment.
When learning activities target areas in which there is clinical uncertainty about best practices or limited empirical evidence, the importance of respecting clinician judgment is weakened.

One problem with the obligation to respect clinician judgments is that even the most well-intentioned judgments of clinicians can be subject to some form of bias. A key precept of evidence-based medicine is that clinician judgment may not result in the best health outcomes for patients, especially when there is an absence of good empirical evidence or that evidence does not factor in the forming of the judgment. Evaluating the strength of the obligation to respect clinician judgment usually entails a contextual assessment of the likely impact of any proposed restriction on the exercise of clinician judgment on patients' health or autonomy interests. When learning activities target areas in which there is clinical uncertainty about best practices or limited empirical evidence, the likelihood that unrestricted clinician judgment will advance the health interests of patients is lessened, and the importance of respecting clinician judgment is weakened. For example, for most patients, there is currently little empirical evidence to support a clinician's judgment that a particular first-line hypertension drug is better than another. The obligation to respect clinician judgment in this context is not as stringent as in a case where clinician judgment is based on more robust evidence or is responsive to patient preferences for different therapeutic options.

3) The obligation to provide optimal care to each patient. Obligations to promote the welfare of others take on specific forms in health care, usually formulated as role obligations. Professional codes underscore the moral responsibilities of professionals to advance the welfare interests of each patient by providing the patient with optimal care aimed at securing the best possible clinical outcome. "Clinical outcome" encompasses the interests patients have in the promotion, preservation, and restoration of their health and the mitigation of pain, suffering, and disability. During the course of clinical care, clinical risks and burdens—in comparison to the nonclinical risks and burdens that the patients could be expected to experience if their care had not been affected by that activity. In assessing net clinical benefit, the risks in routine clinical practice should be considered. Some learning activities are likely to increase the prospects for net clinical benefit, whereas others are likely to decrease it. An activity designed to evaluate the impact of a computer-generated prompt to clinicians to double-check medication dosage may itself have a positive impact on the net clinical benefits for patients; it may reduce the risk that they will be harmed by a medical error. By contrast, depending on the context, a randomized clinical trial of a first-in-class medication may decrease patients' prospects for net clinical benefit relative to what would be expected if these patients receive approved medical therapies. Other learning activities—such as a prospective observational study that relies only on electronic health data to compare widely used interventions—are likely to have no appreciable effects on net clinical benefit. Accordingly, the impact of a learning activity on net clinical benefit is specific to the particulars of the activity and the related clinical context, but it is morally essential that such assessments be made in a learning health care context.

4) The obligation to avoid imposing nonclinical risks and burdens. Health care focuses on the health-related interests of patients and the reduction of risks of health-related harms, but obligations to avoid inflicting other kinds of harm and burden also apply in health care. Clinical care and clinical information can be provided or used in ways that affect patients' interests in financial well-being, social standing and reputation, employment and insurance opportunities, dignity, privacy, and the joy of spending time with family and loved ones.

The impact of a learning activity in imposing nonclinical risks and burdens—in comparison to the nonclinical risks and burdens that the patients could be expected to experience if their clinical care did not involve the learning activity—is a moral consideration. For example, the risk that health information will be disclosed inappropriately sometimes increases as a result of a learning activity, and such disclosures can be monitored and reduced through security protections. Learning activities also may impose burdens beyond those needed for patients' usual clinical care, such as extra visits to clinical facilities.
5) The obligation to address unjust inequalities. Our framework is rooted in a broader conception of obligations of justice than the conception that dominates traditional research ethics. Fundamental to traditional formulations and to the regulation of research are moral requirements that subject selection be fair and that the distribution of research benefits and burdens be just.24 Our framework supports the commitment to these injunctions, which are historically rooted in concerns about the abuse of disadvantaged or vulnerable subjects in research. However, these injunctions carve out only a piece of the territory of justice that needs to be considered in the ethics of a learning health care system.

In agreement with the traditional conception, our framework sets a presumptive bar against learning activities whose potential negative effects—including imposition of nonclinical burdens or the worsening of prospects for net clinical benefit—fall disproportionately on socially and economically disadvantaged patients or groups of patients. This bar protects many individuals who are homeless, poorly educated, belong to groups that have been subject to historical and continuing prejudicial treatment, or lack access to health care and physicians. Also in need of monitoring are learning activities whose positive outcomes will disproportionately benefit patients who are already socially and economically advantaged—for example, activities that rely on access to the Internet in the home. This obligation requires those who propose learning activities to consider whether the activity can be carried out in such a way that its benefits extend to the less privileged.

In ways more expansive than traditional conceptions, the learning health care system ethics framework also imposes an affirmative obligation to direct learning activities toward aggressive efforts to reduce or eliminate unfair or unacceptable inequalities in the evidence base available for clinical decision-making, in health care outcomes, and in the respectfulness with which health care is delivered. For example, it is widely acknowledged that pregnant women often respond to medications differently than other adults, but the health needs of pregnant women are rarely the focus of clinical investigation because of concerns about the impact of the medications on the fetus. A learning health care system is well positioned to identify—and should mount—ethically acceptable learning activities to address what some have identified as unjust paucity of evidence about the management of chronic illness in pregnant women.25

Learning activities also should target disparities in clinical outcomes associated with widening educational differences in adult mortality from such health conditions as lung cancer and heart disease.26 Similarly, learning activities should find strategies to reduce the disrespectful ways in which patients in sickle-cell crisis are sometimes treated when they seek pain relief in emergency rooms. Unlike other patients presenting in severe pain, these patients, who are largely young African Americans and thus subject to unjust racial stereotyping, are often treated with suspicion by clinical staff, who view them not as people suffering from a dreadful disease but as drug users hoping to manipulate the system in search of opiates.27

Although reasonable people often disagree about precisely which inequalities are unjust and for what reasons,28 the narrowing of inequalities and the elimination of discrimination in care between minority and majority patients, economically impoverished and economically secure patients, and poorly educated and well-educated patients is a national priority in the United States and in many other countries.29 The learning health care ethics framework requires that learning activities be assessed to determine whether they perpetuate or exacerbate unjust inequalities and to determine whether they can be structured to advance the goal of reducing or eliminating inequalities and discrimination in health care. This role has not traditionally been at the forefront of the list of obligations of health care institutions, where these problems of unjust inequalities have been widely overlooked.

6) The obligation to conduct continuous learning activities that improve the quality of clinical care and health care systems. The third obligation of our framework—to provide each patient optimal clinical care—has been linked to clinical ethics requirements that clinicians stay current in their knowledge and their skills.30 Until recently, there has been little discussion of the need to augment this obligation with an affirmative responsibility on the part of clinicians to contribute to that knowledge base.31 This sixth obligation makes contribution to learning morally obligatory. It also extends its reach beyond health care professionals to institutions, payers, and purchasers of health care. We envision an unprecedented transformation of responsibilities in a learning health care system that applies to physicians in private practice, pharmaceutical companies, private hospitals, and so on. Because health care professionals, officials of health care institutions, and purchasers of health care have unique access to and control over clinical care and health information, they are uniquely positioned to seek, conduct, and contribute to learning activities that can advance health care quality, economic viability, and a just health care system. No other individuals, professionals, or institutions in society have such access or control.

The learning health care system ethics framework makes this sixth obligation foundational in the structuring of health professions and health care institutions. The obligation requires that every practitioner and institution accept a responsibility to feed information into the system that increases our knowledge. Each learning activity to be conducted within the system must be individually assessed for the extent to which it holds out the prospect of contributing to the improvement of health care services and systems. This assessment should include an evaluation of the soundness of the learning activity’s objectives, design, and plans for implementation or dissemination. Learning activities today may improve only the
specific health care settings in which a learning activity takes place, with only some activities and new information being transportable to a wider body of health care institutions. This current limitation will gradually be transformed into a vast array of interconnected learning activities.

7) The obligation of patients to contribute to the common purpose of improving the quality and value of clinical care and the health care system. Traditional codes, declarations, and government reports in research ethics and clinical ethics have never emphasized obligations of patients to contribute to knowledge as research subjects. These traditional presumptions need to change. Just as health professionals and organizations have an obligation to learn, patients have an obligation to contribute to, participate in, and otherwise facilitate learning. This obligation is justified by what we call a norm of common purpose. This norm of common purpose is similar to what John Rawls calls the principle of the common good, a principle presiding over matters that affect the interests of everyone.\(^{32}\) The common interest of members of a society in the health care system is that it be positioned to provide each person in the society with quality health care at a cost compatible with individual and societal economic well-being. We also have a common interest in supporting just institutions, including activities that reduce the unjust inequalities that were mentioned in obligation 5.

Securing these common interests is a shared social purpose that we cannot as individuals achieve. Our goals cannot be reached efficiently without near-universal participation in learning activities, through which patients benefit from the past contributions of other patients whose information has helped advance knowledge and improve care. Patients cannot discharge this obligation merely by paying a fee for the health care service they receive or by contributing to society through taxation or charitable contributions. No amount of money paid for health care services substitutes for direct participation in and contribution to learning activities. The knowledge necessary to secure a high-quality and just health care system cannot be obtained from information limited to a bounded number of patients at discrete points in time. A learning health care system must have continuous access to information about as many patients as possible to be efficient, affordable, fair, and of highest quality.

A related justification for obligation 7 is the reciprocal obligation that arises among strangers who occupy the role of patient over time. The philosopher David Hume expresses the general form of this duty of beneficence as follows: “All our obligations to do good to society seem to imply something reciprocal. I receive the benefits of society, and therefore ought to promote its interest.”\(^{33}\) In our framework, the discharge of obligations of reciprocity occurs through an established practice of making an appropriate and proportional return—returning benefit with proportional benefit, with all alike sharing, as a matter of moral obligation, the burdens necessary to produce these benefits.

In proposing that patients have an obligation to contribute to the common purpose of improving health care through learning, we are not proposing that patients have an affirmative moral obligation to participate in all learning activities regardless of the degree of additional risk or burden they may impose. Different learning activities will have differential effects on the rights and interests of patients and therefore will have different implications for patients’ obligations to participate in them. The first four obligations of this framework are intended to protect these rights and interests in the assessment of the overall ethical acceptability of particular learning activities. For example, some learning activities, such as randomized clinical trials of investigational new devices, would not be obligatory because of the potential to fail in meeting obligations 1 through 4. If this type of learning activity is otherwise ethically acceptable, however, then patients might choose to participate in it, though they should be informed and understand that they are under no obligation to do so. By contrast, other learning activities—such as participation in a registry, reviews of deidentified medical records, and being interviewed by health care staff to better improve the patient care experience—are likely to be instances in which patients do have an obligation to participate, assuming that the activities have a reasonable likelihood of improving health care quality and that appropriate data security protections are in place. These conditions are probably met currently in integrated health care systems that have invested in secure electronic health records and have mechanisms in place to adjust local norms of care in direct response to the results of learning activities.\(^{34}\)

The obligation of patients to contribute to health care learning is compatible with duties to inform patients about
learning activities and to solicit their express consent for some learning activities, as appropriate. The first obligation in our framework requires, as a matter of respect, that health care institutions have numerous and varied policies and practices in place to inform patients about the institution’s commitment to learning and about the specific learning activities that are currently underway and how they are being conducted. Activities such as randomized, controlled trials of an investigational new device could proceed only with patients’ express, affirmative agreement, obtained through a valid informed consent process.

As with the first obligation above, the obligation to contribute to learning can extend to family members, loved ones, and surrogates of patients, particularly when patients are children or adults whose competence is permanently or temporarily compromised. Whenever loved ones are intimately involved in the care of the patient, they may have information or insight critical to learning about and improving health care interventions and processes. For patients lacking cognitive or decisional capacities, loved ones and other surrogates can play a vital role in the ethics framework by representing and protecting patients’ interests during learning activities.

It has several times been asked in the bioethics literature whether there is a duty to serve as a research subject. Some have answered the question affirmatively. Their reasons have been premised on a conception of duties to participate reciprocally in a system that produces public goods from which we all benefit and in which no one should, in this respect, be a free rider. In certain circumstances, even compulsory participation has been proposed. Although similar justice-oriented grounds are central in some of our arguments, we are proposing a more pervasive level of participation, and participation of a different type, than previous writers have recommended. We make it a condition of participating in a learning health care system as a patient that one also participates in the learning activities that are integrated, on an ongoing basis, with the clinical care patients receive. The scope of participation that we are proposing is far more extensive and notably different from that proposed by previous writers on duties to participate in research.

Going Forward with the Learning Health Care System Ethics Framework

The framework we have proposed for a learning health care system departs significantly from previous frameworks in research and clinical ethics. Its most distinctive features are twofold. First, the framework eschews the moral relevance of the traditional distinction between research and practice in a learning health care environment, focusing attention instead on the moral obligations that should govern an integrated learning health care system. Second, the framework sets a moral presumption in favor of learning, in which health professionals and institutions have an affirmative obligation to conduct learning activities and patients have an affirmative obligation to contribute to these activities. This presumption is grounded in the claims that all parties benefit from this arrangement and that the societal goals of health care quality, just health care, and economic well-being require continuous learning through the integration of research and practice.

This framework will help facilitate the transformation to a learning health care system. Going forward, the next step will be to specify the framework’s implications for oversight policies and practices, including prior review and informed consent, and to determine precisely how the framework will interact with the current human subjects regulations and institutional review board system. Given that our framework rejects the moral relevance of the traditional distinction between research and practice in a learning health care system, different operational criteria for determining which activities should be subject to oversight policies, based on the seven moral obligations, will need watchful development. For example, future work will need to use multiple criteria to determine which activities require express prospective consent and which may be addressed by routine disclosures. Critical to this work is canvassing the views of patients and other stakeholders—an effort that is already under way. Although the hard work of specifying the policies and practices needed to implement the framework is just beginning, we close with a few preliminary observations—first, about the implications of the framework for clinical practice, and second, about the operationalization of the first and seventh obligations.

As we argue in the first article in this set, the underprotection of patients from unjustified and often preventable harms and burdens in clinical practice is a profoundly serious moral problem. We are not proposing, nor do we think it correct, that the solution to the underprotection problem is simply to expand the current review system for research. Multiple conditions and factors contribute to the underprotection problem, and a complex set of strategies will be needed to address the problem effectively. The learning health care ethics framework is intended to be one part of the solution. First, the framework makes obligatory the kinds of learning that are necessary to reduce the harms that occur in clinical environments and resolve the uncertainties that exist around many clinical practices. Second, the framework makes such learning easier to conduct; by reducing the overprotection of patients from learning activities that do not undermine their interests or rights, it facilitates learning that can help address the underprotection of patients in clinical practice. Put slightly differently, insofar as contemporary research ethics and oversight interfere with learning activities that could reduce errors and improve clinical effectiveness, the overprotection that results is itself a source of harm to patients’ interests.

Health care institutions and clinicians are constantly adopting new practices, ranging from platforms to support
clinical decision-making built on electronic health systems to minimally invasive and robotic surgery. These innovations are often introduced without systematic assessment of their impact, perhaps to avoid crossing the unwelcome and curious divide between practice and research. Our framework makes this distinction irrelevant to questions of oversight and provides reasons why health care institutions and professionals are obligated to accompany the introduction of such innovations—as well as practices that have never been rigorously evaluated—with a commitment to systematically learn about their effects on clinical outcomes, health care value, patients’ experience, and health disparities.

We envision that a learning health care system will adopt an array of policies and practices that provide a moral link between the first obligation—to respect the rights and dignity of patients—with the seventh obligation—that patients contribute to the common purpose of improving the quality of clinical care and the health care system. For example, the learning health care system would disclose to patients in multiple ways and at various times that learning occurs constantly throughout the health care system, and that the products of such learning are constantly updated and integrated into the system of care. Concrete examples would be provided of how care has been improved as a result of learning. Such disclosure serves to underscore to patients the system’s moral commitment to continuous learning, the relationship of that learning to the quality of care they will receive, and the system’s commitment to ensuring that patients are aware of continuing learning activities and their risks and benefits. Disclosure procedures might include information provided at initial interviews or at enrollment, in postings in waiting rooms, and in newsletters and Web sites. The best ways to communicate with patients must be identified and evaluated, and these approaches to disclosure should be shared with small hospitals and practices without the resources to do so on their own.

The health care system would likewise inform patients in routine and systematic ways of the policies that are in place to provide ethical oversight of learning activities, as well as how the confidentiality of their medical information will be maintained, how privacy is insured, how information is transmitted to other health care institutions, and the like. There would also be transparency in the conduct of learning activities. Transparency might be achieved by, for example, listing the steady flow of learning activities on system Web sites (and on paper, if requested) and by accountability to the public and to patients regarding what is learned in these activities, including whether and how a learning activity has improved clinical practice. In addition, a learning health care system would publicize to patients that, while they might not be informed routinely about each learning activity—since many have little, if any, effect on patients’ interests or rights—they will be adequately informed, and their consent sought, whenever a learning activity might have a negative impact on the quality of care or impose burdens above and beyond what they would otherwise experience.

Finally, we appreciate that the learning health care system ethics framework we have proposed will be criticized as a premature and overly extensive reshaping of traditional research ethics and clinical ethics. Others may think we propose too little. We claim no more than a start on a subject that merits extensive investigation, and we welcome suggestions and commentary moving forward. The transformation to a learning health care system is still in its infancy. We are in the early days of a progressive realization of a lofty aspirational goal, but given the preventable harm, waste, and uncertainty about clinical effectiveness in health care, efforts to accelerate learning should be given high priority. Now is a good time to lay the ethical foundations of a learning health care system and to begin work on its specific moral commitments.

Acknowledgments

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References


2. Institute of Medicine, IOM Roundtable on Evidence-Based Medicine, The Learning Healthcare System, Olsen, Aisner, and McGinnis, eds., at 6, and see also 3.
3. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established in 1974 by the U.S. Congress and directed to “consider” the boundaries between research and accepted practice. The commission’s basic statement of the “boundaries problem” occurs in the first section of the Belmont Report, as cited below; for the history of the commission’s complex discussion of its congressional mandate, see T.L. Beauchamp and Y. Saghai, “The Foundations of the Distinction between Research and Practice,” *Theoretical Medicine and Bioethics* 33 (2012): 45-56.


7. Institute of Medicine, Committee on the Learning Health Care System in America, *Best Care at Lower Cost*, Smith et al., eds.


11. For example, *Best Care at Lower Cost* discusses the rising cost and complexity of health care in the United States and argues that the U.S. health care system must become a learning system because it has “prominent shortcomings and inefficiencies that contribute to a large reservoir of missed opportunities, waste, and harm” that threaten “the health and economic security of Americans”; Institute of Medicine, Committee on the Learning Health Care System in America, *Best Care at Lower Cost*, Smith et al., eds., pp. 1-2 to 1-3. Similarly, Lynn Etheredge discusses the need to generate information from routine clinical encounters to improve the quality and value of health care delivered to patients; Etheredge, “A Rapid-Learning Health System.”


28. Even those who do not support the social goal of just health care, as we have presented it, have reason to support the fifth obligation based on justice-related considerations having to do with the prevention of injustices in the conduct of research and clinical practice.


34. Walter Stewart, personal communication, November 5, 2012.


Governance that Accelerates Progress and Sustainability
Health care organizations face intensifying pressure to achieve the triple aims of better patient experience, better health, and affordability. Although all health systems grapple with these imperatives, the tripartite mission of research, education, and patient care presents particular challenges for academic health centers in responding to demands for high-value, patient-centered care and population health. In this Viewpoint, we propose that health reform offers an opportunity for academic health centers to create new synergies across mission areas to become exemplary learning health systems.

Tensions Between Mission Areas
Clinically oriented constituents at academic health centers are concerned that patient care is subservient to the other 2 mission areas, often sensing that clinical operations are valued less for their success in meeting patient needs than for providing teaching and research material and profit margins to subsidize the educational and scientific missions. Although the academic model has fueled tremendous accomplishments in highly specialized clinical services, few academic health centers consistently exemplify other attributes such as patient-centeredness, care integration, and efficiency.1,2 Esteem for faculty and departmental autonomy often impedes standardization of processes for everything from selection of orthopedic prostheses to agreement on recommended frequency for screening mammography. Faculty members and trainees who staff teaching practices frequently spend only 1 or 2 half days per week in ambulatory care, complicating timely patient access and continuity. Payers and patients have decreasing tolerance for excessive delays in ambulatory visits and hospital discharges and overzealous diagnostic testing as part of the routine at training- and research-intensive institutions.

A contrasting view is often expressed by academic health center research and education communities who voice concern that clinical operations already do not adequately accommodate the other academic missions. They are apprehensive that the clinical enterprise’s heightened attention to customer service, productivity, and affordability will imperil the educational and research missions. At the same time, many members of these constituencies acknowledge that academic health centers cannot truly teach high-quality medicine without consistently practicing great medicine, or excel in scientific discovery without discovering how to make their patient care services reliably excellent.

The Learning Health System
Academic health centers should replace the concept of a tripartite mission with a commitment to a single mission: the improvement of health and health care through advancing, applying, and disseminating knowledge. The concept of a Learning Health System, developed by the Institute of Medicine (IOM), provides a framework for achieving the integration of patient care, education, and research to achieve this goal. The IOM defines a learning health system as “one in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care.”3 To succeed as learning health systems, a spirit of continuous learning and knowledge translation should infuse and inform patient care, creating synergies between clinical, research, and educational endeavors. Although the IOM has articulated core principles of a learning health system such as informatics, transparency, and teamwork, it has not specifically addressed the uniquely transformative potential of this approach for academic health centers.

Implications for Educators
Schools for health professions should teach all learners the science of health system improvement and engage them in authentic roles in care improvement appropriate to their developmental stage.4 The typical early preceptorship experience for medical students consists of shadowing an experienced clinician who provides instruction in physical examination and history taking. Although students at this developmental stage do not have the diagnostic and treatment skills to add value for the practice at the level of formal patient care, they can at
Opinion Viewpoint

this stage become competent in motivational interviewing and begin to understand population health management. Some schools are teaching these skills early in the curriculum and involving students on care teams as health coaches to assist patients with behavior change and self-management support and extend the population health orientation of a practice by reaching out to patients overdue for routine preventive and chronic care services. Learners with more clinical experience, such as residents and advance practice nursing students, often have keen insights into what is and is not working well in clinical processes and should be routinely embedded in quality improvement teams.

Implications for Researchers

Academic health centers must match their prowess in the science of discovery with an equally earnest effort in translational and implementation science focused on health system improvement. As Woolf5 has observed, “all breakthrough and no follow-through” too often characterizes the academic research enterprise. Even when home to faculty members who are pioneers in developing and testing better methods of delivering care, academic health centers often do poorly in scaling up successful homegrown innovations within their own health system. Many factors impede this translation: segregation of research and health delivery on the organizational chart, an academic biomedical and research funding emphasis that rewards discovery more than application, and failure to invest resources and organizational wherewithal in the local translational process. Some academic health centers are developing a more integrated research and development enterprise that makes their own health delivery organization a laboratory for testing and systematically scaling up innovations to enhance health care value. Examples of successful translation to scale at academic health centers include virtual electronic specialty consultations, novel care coordination approaches for patients with complex needs, and expanded roles for medical assistants in primary care to proactively implement standing orders and scribe during visits.6,7

Implications for Health System Leaders

Integrating mission areas will require more than the clinical enterprise simply generating profits that subsidize education and research. It will require a strategic alignment whereby leaders assess and strengthen those educational and research assets of the organization that can enhance health system responsiveness to health care imperatives. The key to the learning health system approach is the recognition that achieving the goal of exemplary patient care and population health requires building and reinforcing a continuous, iterative, and synergistic cycle of discovery, education, and care delivery in which the effect of each component is enriched by its association with and learning from the other components. Such systems harness the energies and talents of learners to measure, study, and enhance health care performance. Researchers engage with clinicians, learners, and health system and population health leaders to ensure that knowledge translation is applied to continuous performance improvement. Insights from these experiences may then be incorporated into reformed health professions and research training curricula in a continuous feedback cycle. Magill and Baxley8 refer to this process as a “virtuous cycle,” wherein “robust scholarship is not only integral to our daily work of patient care and teaching, but each of these reinforces the others.”

Society needs academic health centers to train the next generation of health professionals and advance scientific knowledge and its application to improve health. Academic health centers must become more attentive to patient-centeredness, population health, and health care value.1 As centers of learning, academic health centers should accept the challenge to become exemplars of learning health systems and transform practices at their own institutions under a unified mission to improve health and health care through advancing, applying, and disseminating knowledge.

REFERENCES

Fostering the Well-Prepared Stakeholder Culture
Partnering with Patients to Drive Shared Decisions, Better Value, and Care Improvement

In February 2013, the Institute of Medicine’s Roundtable on Value & Science-Driven Health Care convened a workshop, gathering patients and experts in areas such as decision science, evidence generation, communication strategies, and health economics to consider the central roles for patients in bringing about progress in all aspects of the U.S. health care system. This Meeting Summary is being released in conjunction with a complete transcript of the event, the Workshop Proceedings. Over the course of 2 days, 31 speakers commented on the importance of patient and caregiver engagement in achieving the best care at lower cost.

The discussions highlighted the critical role and capacity for patients and families to be leaders in informed care decisions, knowledge generation, and value improvement.

Individual workshop participants identified a few overarching themes and messages.

**Overarching themes and messages:**

- **Culture dominates.** “Culture eats strategy for lunch every time,” as mom-turned-advocate Cristin Lind noted. Thus, improving the quality of the care experience and using limited resources wisely will require significant culture shifts.

- **“Listen first, listen fully.”** That's what Ekene Obi-Okoye, a premedical intern at the University of California, San Francisco, learned as she supported patients with breast cancer. By listening first and listening fully, patient and caregiver voices are integrated fully into every possible level of decision making—care, system design, and policy making—and the quality of care improves.

- **Patient engagement is a skill, not a trait.** Being an engaged patient and actively engaging patients are not intuitive skills. Patients and clinicians learn these skills over time and through partnership with a supportive care team.

- **Trust matters.** Effectively delivering cost and quality information requires trusted translators who convey information in ways that are easy to understand.

- **Prepared, engaged patients are a fundamental precursor to high-quality care, lower costs, and better health.** Achieving and exceeding these three basic aims of health and health care policy calls for partnering with patients as leaders and drivers of care improvement.

**INFORMED, SHARED CARE DECISIONS**

A meaningful care experience is when the patient is fully informed and the provider has elicited the patient’s preferences and goals.

Evidence strongly indicates that when patients are fully informed and engaged in making decisions about their care, patient satisfaction goes up, results improve, and health care costs go down, stated Gary Langer of Langer Research Associates and a number of other workshop participants. In pursuit of more and higher-quality shared decision making, the first workshop session explored how to increase demand for shared decisions, as well as the changes in infrastructure, culture, and training that would be necessary.
• **Patients want to be partners in their health.** When patients receive clear information about their choices, most want to be an equal decision maker when choosing their care plan, Langer observed in his presentation.

• **Strong and visionary leadership promotes culture change.** The leaders of health care organizations can ensure that shared decision making is part of routine practice by setting the standards, pointed out Grace Lin of the University of California, San Francisco.

• **Training can help patients and clinicians engage in shared decisions.** Informed conversations are facilitated by patients who learn to ask questions and clinicians who learn to listen fully, noted Sherrie H. Kaplan of the University of California, Irvine.

According to many workshop participants, improvements in reliable capture of data from the care experience will make knowledge generation more timely and clinically useful. But clinical data use requires individual patients not only to make informed choices about privacy and security, but also to be informed stakeholders in the knowledge generation process, remarked Susan Brown Trinidad of the University of Washington.

**Building trust and understanding is the foundational element in using health data for evidence development,** added Nancy E. Kass of Johns Hopkins Bloomberg School of Public Health. Clinicians frequently are asked to serve as trusted translators when it comes to discussing privacy, security concerns, and the potential benefits and harms of data sharing, a number of speakers pointed out. When patients and clinicians partner to make data more readily available, this enhances the real-time learning potential and leads to better care.

• **Various incentives promote data sharing.** Evette Ludman of the Group Health Research Institute explained that patients are motivated to share their data by altruism, trust, and clear explanations of impact, risks, and benefits.

• **Effective clinician communication strategies can help.** By facilitating conversations about new evidence development, clinicians can enable patients to advocate for using their health data for care improvement, observed patient advocate Mark Gorman.

• **Patients want to be asked about using their data.** Applying practical and trusted approaches to privacy and consent can address the imperative to draw, in a seamless fashion, on clinical data for scientific advances, Group Health’s Ludman continued.

• **Information feedback loops capture and apply lessons learned from the patient experience.** Kenneth D. Mandl, of Children’s Hospital Boston, Harvard Medical School, and Harvard-MIT Health Sciences and Technology, noted that bidirectional communication on patient-reported outcomes ensures that data are being used efficiently and effectively.

• **Distributed leadership fosters patient engagement.** When patients are partners in their health and owners of their data, health care quality improves, Genomera Genetic Alliance’s Greg Biggers remarked, echoing other speakers.
In an efficient health care system, care choices are democratized and based on the best evidence, J. Michael McGinnis of the Institute of Medicine summarized. Though the infrastructure and cultural changes necessary to transform the patient role are significant, empowering patients to become partners in—the health care system is a critical step on the road to achieving the best care at lower cost, McGinnis continued.

• **Patients look for choices they can understand easily and immediately.** Cost and quality information is more useful to patients when it is readily available, transparent, and presented in a meaningful way, stated John Santa of Consumer Reports Health Ratings Center.

• **Incentive feedback loops are a dynamic part of the care process.** Multiple panel members expressed support for making quality information transparent in order for the system to learn and improve.

• **Patients choose care tailored to their individual preferences.** Patients primarily care about choosing the care that is right for them given their individual circumstances, although concern about out-of-pocket costs is also increasing, Tresa Undem of Perry Undem observed.

• **Paying for health care is a social decision.** Although many health care choices are made individually, we pay for them communally, explained Marge Ginsburg of the Center for Healthcare Decisions. Given this, patients increasingly want to weigh in on the incentive structures and trade-offs that affect them, she continued.

In an efficient health care system, care choices are democratized and based on the best evidence, J. Michael McGinnis of the Institute of Medicine summarized. Though the infrastructure and cultural changes necessary to transform the patient role are significant, empowering patients to become partners in—the health care system is a critical step on the road to achieving the best care at lower cost, McGinnis continued.

**FIGURES: Patients want shared decision making.** with up to 81% saying they want an equal say in their care decisions (left). Although some patients were less willing to participate in shared decision making, the gap between patients of varying educational levels and language abilities largely disappeared when they were provided clear and understandable information (right).

Reprinted Courtesy of Blue Shield of California Foundation.
PLANNING COMMITTEE ON PARTNERING WITH PATIENTS TO DRIVE SHARED DECISIONS, BETTER VALUE, AND CARE IMPROVEMENT**

Christine Bechtel (Chair), Advisor and Former Vice President, National Partnership for Women & Families; Terry Adirim, Director, Office of Special Health Affairs, Health Resources and Services Administration; Leah Binder, Chief Executive Officer, The Leapfrog Group; Veronica Goff, Vice President, Institute on Health Care Costs and Solutions, National Business Group on Health (formerly); Mark Gorman, Patient Advocate, Former Director of Survivorship Policy, National Coalition for Cancer Survivorship; Paul Grundy, Global Director of Healthcare Transformation, IBM; Art Levin, Director, Center for Medical Consumers; Jim Mangia, President and Chief Executive Officer, St. John’s Well Child & Family Center; Lyn Paget, Managing Partner, Health Policy Partners; Eric Racine, Vice President, Advocacy, Sanofi U.S.; Susan C. Reinhard, Director, Public Policy Institute, AARP; Craig Robbins, Medical Director, Clinical Guidelines (KP Colorado), Kaiser Permanente; John Santa, Director, Consumer Reports Health Ratings Center, Consumers Union; Susan Sheridan, Deputy Director, Patient Engagement, Patient-Centered Outcomes Research Institute; and Susan Brown Trinidad, Research Scientist, University of Washington.

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

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The summary was reviewed by Christine Bechtel, National Partnership for Women & Families, and David Arterburn, Group Health Research Institute, to ensure that it meets institutional standards for quality and objectivity.

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Organizational Background
The Roundtable

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

What are the Roundtable’s vision and goals?

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

- Promote collective action and progress so that “By the year 2020, ninety percent of clinical decision will . . . reflect the best available evidence.” (Roundtable Charter, 2006)

How does the Roundtable work?

- Through stakeholder workshops and meetings: to accelerate understanding and progress toward the vision of a continuously improving and learning health system.

- Through joint projects through the work of six affinity group Innovation Collaboratives focused on:
  - Best clinical practices (health professional societies and organizations)
  - Clinical effectiveness research (innovative research scientists and institutions)
  - Communication of medical evidence (marketing experts and decision scientists)
  - Digital technology for health (health IT and care delivery experts)
  - Incentives for value in health care (health care purchasers and payers)
  - Systems engineering for health improvement (medical, engineering, and IT leaders)

How is the Roundtable making a difference?

- Describing the possible through the 13 publications in the Learning Health System series providing the foundation for the landmark IOM report Best Care at Lower Cost.

- Stewarding action projects of the Roundtable's Innovation Collaborative stakeholders, working cooperatively to advance science and value in health and health care. Examples include:

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<thead>
<tr>
<th>Value &amp; performance transformation</th>
<th>Public &amp; patient involvement</th>
<th>Science &amp; evidence improvement</th>
</tr>
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<tr>
<td>Documentation of cost and waste</td>
<td>Core metrics for better health at lower cost</td>
<td>Making the case for outcomes research</td>
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<tr>
<td>Improving the science of transparency</td>
<td>Cost and evidence as patient priorities</td>
<td>Patient role in knowledge generation</td>
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<td>Essential principles of team-based care</td>
<td>Essential principles for evidence communication</td>
<td>Cooperative clinical research (PedsNet)</td>
</tr>
<tr>
<td>CEO checklist for high-value care</td>
<td>Building patient and family leadership for system improvement</td>
<td>Common Rule update</td>
</tr>
<tr>
<td>Point-of-care evidence access</td>
<td></td>
<td>Digital infrastructure for a learning system</td>
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<td>Systems engineering for high-value care</td>
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<td>Strengthening the science of data-driven medicine</td>
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The Institute of Medicine’s Roundtable on Value & Science-Driven Health Care has been convened to help transform the way evidence on clinical effectiveness is generated and used to improve health and health care. Participants have set a goal that, by the year 2020, ninety percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence. Roundtable members will work with their colleagues to identify the issues not being adequately addressed, the nature of the barriers and possible solutions, and the priorities for action, and will marshal the resources of the sectors represented on the Roundtable to work for sustained public-private cooperation for change.

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

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

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

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

Activities include collaborative exploration of new and expedited approaches to assessing the effectiveness of diagnostic and treatment interventions, better use of the patient care experience to generate evidence on effectiveness and efficiency of care, identification of assessment priorities, and communication strategies to enhance provider and patient understanding and support for interventions proven to work best and deliver value in health care.
Core concepts and principles: For the purpose of the Roundtable activities, we define science-driven health care broadly to mean that, to the greatest extent possible, the decisions that shape the health and health care of Americans—by patients, providers, payers and policymakers alike—will be grounded on a reliable evidence base, will account appropriately for individual variation in patient needs, and will support the generation of new insights on clinical effectiveness. Evidence is generally considered to be information from clinical experience that has met some established test of validity, and the appropriate standard is determined according to the requirements of the intervention and clinical circumstance. Processes that involve the development and use of evidence should be accessible and transparent to all stakeholders.

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

Mark McClellan, MD, PhD (Chair)
Brookings Institution

Raymond J. Baxter, PhD
Kaiser Permanente

Paul Bleicher, MD, PhD
Optum Labs

David Blumenthal, MD, MPP
The Commonwealth Fund

Bruce G. Bodaken, MPhil
Blue Shield of California

Paul Chew, MD
Sanofi US

Helen Darling, MA
Nat Business Group on Health

Susan D. DeVore
Premier, Inc.

Judith Faulkner, MS
Epic Systems

Joseph J. Fifer, FHFMA
Healthcare Financial Mngmt Assn

Patricia A. Gabow, MD
Denver Health

Atul Gawande, MD, MPH
Brigham & Women’s Hospital

Gary L. Gottlieb, MD, MBA
Partners HealthCare System

James A. Guest, JD
Consumers Union

James Heywood
PatientsLikeMe

Ralph I. Horwitz, MD
GlaxoSmithKline

Paul Hudson
AstraZeneca

Brent C. James, MD, MStat
Intermountain Healthcare

Craig A. Jones, MD
VT Blueprint for Health

Gary Kaplan, MD
Virginia Mason Health System

Darrell G. Kirch
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Richard C. Larson
Mass Institute for Technology

Peter Long, PhD
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William D. Novelli, MA
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Sam Nussbaum, MD
WellPoint, Inc.

Jonathan B. Perlin, MD, PhD
HCA, Inc.

Richard Platt, MD, MS
Harvard

Michael Rosenblatt, MD
Merck & Company, Inc.

John W. Rowe, MD
Columbia University

Leonard D. Schaeffer
USC Price

Joe Selby, MD, MPH
Executive Director, PCORI

Mark D. Smith, MD, MBA
CA HealthCare Foundation

Glenn D. Steele, MD, PhD
Geisinger Health System

Jennifer Taubert, MBA
Johnson & Johnson

Reed V. Tuckson, MD
Connections, LLC

Debra Whitman, PhD, MA
AARP

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American Hospital Association

Ex Officio

Francis Collins, MD, PhD
National Institutes of Health
(Kathy Hudson, PhD, MS)

Karen B. DeSalvo, MD, MPH, MSc
Office of the Nat Coordinator for HIT

Thomas Frieden, MD, MPH
Centers for Disease Control & Prevention
(Chesley Richards, MD, MPH)

Margaret A. Hamburg, MD
Food and Drug Administration
(Peter Lurie MD, MPH)

Richard Kronick, PhD
Agency for HC Research & Quality

Robert A. Petzel, MD
Department of Veterans Affairs

Marilyn Tavenner, MHA, RN
Centers for Medicare & Medicaid Services
(Patrick Conway, MD, MS)

Mary Wakefield, PhD, RN
Health Resources & Services Admin

Jonathan Woodson, MD
Department of Defense

Members as of Apr 2014
Clinical Effectiveness Research Innovation Collaborative

Methods innovation and practice-based approaches

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

**Collaborative.** An *ad hoc* convening activity under the auspices of the IOM Roundtable, the Clinical Effectiveness Research Innovation Collaborative (CERIC) provides a venue for information exchange and knowledge sharing among researchers working to develop and apply innovative approaches to evidence generation for healthcare decisions. Work focuses on identifying key barriers to and opportunities for advancing the pace and progress of CER.
Participants. Individual researchers with research innovation interests, capacity, and activities from public and private organizations, leading academic research institutions, insurers, health product manufacturing companies, and product assessment companies. The aim is for an inclusive Collaborative—without walls—and participation in individual projects is structured according to interest, need, and practicality.

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

• *Field advancement mapping.* Cooperative development of a White Paper exploring the major institutional, organizational, and regulatory challenges and opportunities for expediting clinical effectiveness research.

• *Engaging health system leadership in CER.* A program of work that begins by engaging health system leadership on issues and opportunities to transform how evidence is generated and used to improve health and the value of delivered care as a fundamental part of their institutional processes, and provides a neutral forum to discuss and share insights from ongoing evidence application and development efforts.

• *Eliminating disparities.* An exploration of how features of a continuously learning health system can best address and close the gaps for our most salient health and health care disparities, with particular focus on opportunities from innovation in clinical effectiveness research.
Digital Learning Collaborative
Advancing the digital infrastructure for the learning health system

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

Collaborative. Formerly the Electronic Health Records Innovation Collaborative (EHRIC), the Digital Learning Collaborative (DLC) is an ad hoc convening activity under the auspices of the IOM Roundtable on Value & Science-Driven Health Care. It was created to provide a venue for joint activities that can accelerate progress towards the digital infrastructure necessary for continuous improvement and innovation in health and health care. This includes fostering a new culture of collaborative action among participants in the learning process—e.g. patients, clinicians, researchers, and product developers.
Participants. Participants include experts from public and private organizations with prominent activities and leadership responsibilities related to development and application of digital technology important to continuous improvement in health and health care. The aim is for an inclusive Collaborative—without walls—and participation in individual projects is structured according to interest, need, and practicality.

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

- Workshop series and report on the Digital Infrastructure for the Learning Health System. Cooperative work involving DLC participants with the Office of the National Coordinator and related government agencies to explore strategic considerations in accelerating learning from healthcare delivery.

- PEDSNet. A consortium of 15 leading pediatric care institutions, working together to create an organization providing networked clinical data from electronic health records for use in accelerating clinical research in pediatrics.

- Aligning health reform data needs and priorities. Engaging leaders from key federal health reform initiatives on strategies and opportunities to leverage health IT for program and monitoring alignment, across initiatives and in the support of population health.

- Data quality and learning from the digital health utility. Workshop to explore the data quality issues and strategies central to the increasing capture and use of digital clinical and patient-reported data for knowledge development.

REPRESENTATIVE PARTICIPANTS

ORGANIZATIONS
American Board of Pediatrics
Children's Hospital Boston
Children's Hospital of Philadelphia
Children's Hospital of Wisconsin
Cincinnati Children's Hospital Medical Center
Cleveland Clinic
Duke University Health System
Geisinger Health System
Google, Inc.
Harvard Medical School
Harvard Pilgrim Health Care
Hospital Corporation of America, Inc.
IBM Research
Intermountain Healthcare
Johns Hopkins Children's Center
Kaiser Permanente
Mayo Clinic
Microsoft, Inc.
Nationwide Children's Hospital
Nemours Children's Healthcare System
New York Presbyterian/Columbia
NorthShore University Health System
Partners HealthCare System
Primary Children's Medical Center
Radiological Society of North America
Seattle Children's Hospital
Stanford University
Texas Children's Hospital
The Children's Hospital-Denver
UC Davis Health System
UCLA School of Medicine
University of Alabama
University of Chicago
University of Michigan Medical School
University of Vermont
Vanderbilt University Medical Center

FEDERAL AGENCIES
U.S. Department of Health & Human Services
- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Food and Drug Administration
- Health Resources and Services Administration
- National Institutes of Health
- National Library of Medicine
- Office of the National Coordinator for HIT
U.S. Department of Defense (Health Affairs)
U.S. Department of Veterans Affairs
PCORnet: The National Patient-Centered Clinical Research Network

The Vision

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

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

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

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

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

A Network to Promote Research Done Differently and More Efficiently

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

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

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

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

Phase I: Building PCORnet

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

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

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

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

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

PCORnet represents a unique opportunity to make a real difference in the lives of patients and their families. Until now, we have been unable to answer many of the most important questions affecting health and healthcare. But by combining the knowledge and insights of patients, caregivers, and researchers in a revolutionary network with carefully controlled access to rich sources of health data, we will be able to respond to patient’s priorities and speed the creation of new knowledge to guide treatment on a national scale.
Biographies and Meeting Logistics
HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH

Planning Committee Biographies

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

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

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

**Meighan Girgus, MBA,** currently serves as the American Heart Association’s Chief Mission Officer. In this role, she oversees all of the organizations efforts in consumer health, communications, science operations, communications, advocacy and field health strategies. Prior to this appointment, Meighan served for seven years as the AHA’s Executive Vice President of Healthcare. Meighan has spent much of her career dedicated to helping change the care delivery system and has been integrally involved in multiple national panels and writing groups dedicated to fighting cardiovascular disease. Examples of these panels and papers include the groundbreaking “Recommendations for the Establishment of Primary Stroke Centers,” published in JAMA, which was the precedent for a radical shift in stroke care in the United States and the premise for The Joint Commission's primary stroke center certification program. She was a co-author of the “Recommendations for improving the quality of care through stroke centers and systems: an examination of stroke center identification options” which was published in Stroke and has been instrumental in redefining the type of care that is provided to stroke patients. She was a writing group member for the CDC’s “A Public Health Action Plan to Prevent Heart Disease,” and an expert panel member for its workgroup which published “Establishment of Data Elements for the Paul Coverdell National Acute Stroke Registry” in Stroke. Meighan participated in the NHLBI Workgroup on Peripheral Artery Disease: Developing a Public Awareness Campaign and on the National Institute of Neurological Diseases and Stroke, Stroke Progress Review Group. Most recently, she is a co-author of “Translating Research into Practice for Healthcare Providers: The American Heart Association’s Strategy for Building Healthier Lives Free of Cardiovascular Disease and Stroke,” and “Partnering to Reduce Risks and Improve Cardiovascular Outcomes - American Heart Association Initiatives in Action for Consumers and Patients,” both published in the journal Circulation. Additionally, she serves on the Board of Trustees for the Certification Commission for Healthcare Information Technology under the direction of Dr. Mark Leavitt. Meighan received her undergraduate degree from the University of Texas at Austin, her Masters in Business Administration from Southern California University and completed her Graduate Marketing Certification at Southern Methodist University.

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

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

Uma R. Kotagal, MBBS, MSc, is senior vice president for quality, safety and transformation and executive director of the James M. Anderson Center for Health Systems Excellence at Cincinnati Children’s Hospital Medical Center. As director of the Anderson Center, Dr. Kotagal oversees the development of disease management teams and development and institution of evidence-based clinical practice guidelines. Dr. Kotagal was director of the neonatal intensive care units at the University Hospital and at Cincinnati Children’s. She received her Master of Science in Clinical Epidemiology and Clinical Effectiveness from the Harvard School of Public Health, and refocused her clinical efforts on quality transformation at a systems level. She served as a visiting scholar at the Center for Risk Analysis at the Harvard School of Public Health and a visiting professor at the Tufts New England Medical Center, in the Division of Clinical Decision Making, completing further training in the field of decision and cost effectiveness analyses. Dr. Kotagal was born in Bombay, India, where she received her undergraduate and her MBBS from the University of Bombay. She completed rotating internships at the University of Bombay and at Detroit General Hospital. At Children's Hospital of Michigan, Dr. Kotagal completed her pediatric residency and went on to do a fellowship in neonatology. She completed a
fellowship in neonatal physiology at the University of Cincinnati. Dr. Kotagal is President of the Academy of Healthcare Improvement and a faculty member of the Institute for Healthcare Improvement. She also serves on the Board of Directors and as chair of the quality steering team of the Ohio Children’s Hospital Association, as a member of the advisory committee of the Toronto Patient Safety Center, as an associate editor of BMJ Quality and Safety and as a member of the Institute of Medicine.

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

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

Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI, is President, Clinical Services and Chief Medical Officer of Nashville, Tennessee-based HCA (Hospital Corporation of America). He provides leadership for clinical services and improving performance at HCA's 166 hospitals and more than 800 outpatient centers and physician practices. Current activities include implementing electronic health records throughout HCA, improving clinical “core measures” to benchmark levels, and leading patient safety programs to eliminate preventable complications and healthcare-associated infections. Before joining HCA in 2006, “the Honorable Jonathan B. Perlin” was Under Secretary for Health in the U.S. Department of Veterans Affairs. Nominated by the President and confirmed by the Senate, as the senior-most physician in the Federal Government and Chief Executive Officer of the Veterans Health Administration (VHA), Dr. Perlin led the nation’s largest integrated health system. At VHA, Dr. Perlin directed care to over 5.4 million patients annually by more than 200,000 healthcare professionals at 1,400 sites, including hospitals, clinics, nursing homes, counseling centers and other facilities, with an operating and capital budget of over $34 billion. A champion for implementation of electronic health records, Dr. Perlin led VHA quality performance to international recognition as reported in academic literature and lay press and as evaluated by RAND, Institute of Medicine, and others. Dr. Perlin has served previously on numerous Boards and Commissions including the National Quality Forum and the Joint Commission, and currently serves on the Boards of the National Patient Safety Foundation and Meharry Medical College. He chairs the U.S. Department of Health and Human Services Health IT Standards Committee and has been elected chair of the American Hospital Association for 2015. Recognized perennially as one of the most influential physician executives in the United States by Modern Healthcare, Dr. Perlin has received numerous awards including Distinguished Alumnus in Medicine and Health Administration from his alma mater, Chairman’s Medal from the National Patient Safety Foundation, the Founders
Medal from the Association of Military Surgeons of the United States, and is one of a dozen honorary members of the Special Forces Association and Green Berets. Broadly published in healthcare quality and transformation, Dr. Perlin is a Fellow of the American College of Physicians and the American College of Medical Informatics. He has a Master’s of Science in Health Administration and received his Ph.D. in pharmacology (molecular neurobiology) with his M.D. as part of the Physician Scientist Training Program at the Medical College of Virginia of Virginia Commonwealth University (VCU). Dr. Perlin has faculty appointments at Vanderbilt University as Adjunct Professor of Medicine and Biomedical Informatics and at VCU as Adjunct Professor of Health Administration.

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

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

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

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

Speaker Biographies

Karen DeSalvo, MD, MPH, MSc, is a physician who has focused her 20-year career toward improving access to affordable, high quality care for all people with a focus on vulnerable populations and to improving overall health. She has done this through direct patient care, medical education, 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 the U.S. Department of Health and Human Services, 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 in to 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 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 for low-income, uninsured and other vulnerable individuals that boosts a sophisticated health IT infrastructure. Dr. DeSalvo served as president of the Louisiana Health Care Quality Forum, the state’s lead for the health information exchange, and 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 in Public Health from Tulane University, and Master’s in Clinical Epidemiology from Harvard School of Public Health. She has an honorary doctorate from her alma mater, Suffolk University.

Christopher B. Forrest, MD, PhD, is faculty at the Children’s Hospital of Philadelphia, University of Pennsylvania School of Medicine. He holds an adjunct appointment in the Bloomberg School of Public Health. Dr. Forrest received his BA and MD degrees at Boston University as part of a dual-degree program, trained in pediatrics at the Children’s Hospital of Philadelphia, and completed a PhD in Health Services Research at Johns Hopkins University. He has authored numerous scientific manuscripts and reviews, and his research is supported by a broad mix of public, foundation, and private funders. Forrest is a general pediatrician with methodological expertise in health services and outcomes research and evaluation, health status assessment of children and adolescents, and primary care research. He is a recipient of the Nemours Award in Child Health Services Research. In his work on understanding how health evolves over the life course, Chris is leading a large, multi-site effort to elucidate the longitudinal relationships between health and school performance during the transition from middle childhood into adolescence.

Thomas L. Garthwaite, MD, 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; Director and Chief Medical Officer of the Los Angeles County
Department of Health Services; and Under Secretary for Health at the Veterans Health Administration in Washington, D.C. At the 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, MD,** is the CMO 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 ACO 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, MPH,** 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. Sarah’s research has included patient-centered communication, health literacy, quality of cancer care, improving the human subjects research process, and optimization of multi-site 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 healthcare 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 MPH, with an emphasis in epidemiology, and a BA in Psychology and Italian from Indiana University.

**David Grossman, MD, MPH,** 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 over 120 publications encompassing many aspects of injury control, Native American health, health services research and evidenced-based medicine and has been recognized by the Centers for Disease Control and Prevention 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 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); US Preventive Services Task Force (2008-2013); Board of Scientific Counselors, Centers for Disease Control and Prevention (2004-2013).
Ed Havranek, MD, directs the Center for Health Systems Research at Denver’s safety net healthcare system, Denver Health (DH). The Center is engaged in a broad range of activities, including leading DH’s engagement in the High Value Health Collaborative and developing patient-centered outcomes research infrastructure at DH under a grant from AHRQ. 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 1999-2005 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 the Centers for Medicare & Medicaid Services (CMS). His personal research interests are currently focused on the effects of racial and ethnic bias on healthcare.

Trent Haywood, MD, JD, 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 over 100 million people, 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, Center for Clinical Practices and the Center for Clinical Value. Dr. Haywood leads the National Council of Physician Executives (NCPE), which consists of chief medical officers and chief pharmacy executives that 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.

Susan Huang, MD, MPH, is an Associate Professor in the Division of Infectious Diseases and Health Policy Research Institute at the University of California Irvine School of Medicine, and the Medical Director of Epidemiology and Infection Prevention at UC Irvine Health. She received her MD degree from Johns Hopkins University School of Medicine and her MPH degree from the Harvard School of Public Health in Quantitative Methods. Her clinical epidemiologic research has focused on healthcare-associated infections - identifying the population burden, risk factors for acquisition and disease sequelae, and preventative strategies for containment. Dr. Huang is currently the lead investigator of three randomized clinical trials on preventing MRSA disease and other healthcare-associated infections. She serves as a member of the Healthcare Infection Control Practices Advisory Committee (HICPAC), a 14-member federal advisory committee that develops guidelines on infection control and prevention in healthcare settings. She is also a member of the Board of Scientific Counselors for the Antibiotic Resistance Working Group for the CDC, the Antibiotic Resistance Committee for the Infectious Diseases Society of America, and the IOM Clinical Effectiveness Research Innovation Collaborative.

Nancy Kass, ScD, is the Phoebe R. Berman Professor of Bioethics and Public Health, in the Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health and 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 (WHO) Ethics Review Committee Secretariat. Dr. Kass received her BA 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, 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 National Cancer Institute Committee to develop Recommendations for Informed Consent Documents for Cancer Clinical Trials, and served on the NCI’s central IRB. She has served as consultant
to the President's Advisory Committee on Human Radiation Experiments, to the National Bioethics Advisory Commission, and to the National Academy of Sciences. Current research projects examine ethics for a learning healthcare 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 PhD 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 Institute of Medicine and a Fellow of the Hastings Center.

Pete Knox, MS, 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. Bellin has been on the leading edge of quality for many years and is recognized nationally for superior results. Currently Pete is Executive Vice President, Chief Learning and Innovation Officer. In this 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 non-health care organizations and is a Senior Fellow at the Institute for Healthcare Improvement (IHI). His book titled “The Business of Healthcare” 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.”

Harold S. Luft, PhD, is Director of the Palo Alto Medical Foundation Research Institute and Professor Emeritus in the Philip R. Lee Institute for Health Policy Studies at UCSF 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 Institute of Medicine. He served six years on the IOM Council, chaired the National Advisory Council of AHRQ's predecessor, 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, including HMOs, 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 over 200 articles in scientific journals and five books, including Total Cure: The Antidote to the Health Care Crisis, Harvard University Press.

Peter Margolis, MD, PhD, is Professor of Pediatrics and 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 NIH Roadmap transformative research grant on redesigning systems for chronic illness care and several AHRQ and PCORI grants aimed at developing learning health systems.

Janice Nevin, MD, MPH, 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 in 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 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 the faculty member and the residency program director in the Department of Family and Community Medicine, 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 two-year faculty-development fellowship in family medicine at St. Margaret Hospital in Pittsburgh.

Sally Okun, RN, MMHS, is the Vice President for Advocacy, Policy and Patient Safety at PatientsLikeMe in Cambridge, MA. 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 reporting obligations of industry partners while collaborating in a social media environment. Okun participates on numerous collaboratives of the Institute of Medicine’s (IOM) Roundtable on Value and Science Driven Healthcare and the Committee on Core Metrics for Better Health at Lower Cost. Ms. Okun serves on the Advisory Panel on Patient Engagement for the Patient Centered Outcomes Research Institute’s (PCORI); the National Quality Forum’s Person-centered Care and Outcomes Committee and the Scientific Advisory Committee for the Reagan-Udall Foundation’s Innovation in Medical Evidence Development and Surveillance (IMEDS) Program and the Program Advisory Board of the Schwartz Center for Compassionate Health Care. Sally is a frequent speaker at clinical, advocacy and policy events and in April 2013 was the first nurse invited to give a TEDMED talk at Kennedy Center. Prior to joining PatientsLikeMe Sally, 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, MA Department of Mental Health, Hospice Education Network, and the Robert Wood Johnson Foundation. Okun received her Master’s degree from The Heller School for Social Policy & 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, MFS, Director of Stakeholder Engagement of the Clinical Trials Transformation Initiative, 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, Ms. Patrick-Lake founded the PFO Research Foundation in response to the lack of definitive scientific information regarding the condition of patent foramen ovale (PFO) after being a patient in an aborted clinical trial. Ms. Patrick-Lake has served as a patient representative at the FDA on a variety of advisory committees and panels, in workgroups for EMA and NIH/NINDS, as a guest lecturer and an external reviewer for 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, ACC Foundation's Patient-centered Care (PC3) Shared Decision Making Workgroup, DIA's Patient Fellowship Selection Committee, TVT Registry Stakeholder Advisory Committee, and is a board member for the Alliance for Headache Disorders Advocacy. She holds a BS (zoology) from University of Georgia and a Master of Forensic Sciences degree from National University in La Jolla, CA.

Rita F. Redberg, MD, MSc, has been a cardiologist and Professor of Medicine and Director of Women's Cardiovascular Services at the University of California, San Francisco since 1990. Dr. Redberg is currently the Chief Editor of JAMA Internal Medicine (formerly Archives of JAMA) 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 2003-2006 and was reappointed in 2012 as Chairwoman of MEDCAC. Dr Redberg is a member of the California Technology Assessment Forum, the Medical Policy Technology and Advisory Committee, and the Food and Drug Administration Cardiovascular Devices Expert Panel, and 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 Robert Wood Johnson Health Policy Fellow, 2003-2006. Dr. Redberg was a member of the Institute of Medicine’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 and is a member of the American College of Cardiology’s (ACC) 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, 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 of Science in Health Policy and Administration from the London School of Economics.

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

Patricia Smith is President and Chief Executive Officer of the Alliance of Community Health Plans (ACHP), a national leadership organization in Washington, D.C. 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 the Centers for Medicare and Medicaid Services (CMS). During her 2 years at CMS, she played a lead role in implementing the health plan changes and Medicare Part D drug benefit in the Medicare Advantage program. Ms. Smith was previously vice president at America’s Health Insurance Plans (AHIP) and senior vice president for policy at ACHP from 2001 to 2004. For 15 years, she led federal health care lobbying efforts for the American Association of Retired Persons (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 (CAPP). She is a graduate of the College of William & Mary in Williamsburg, Virginia.

John Steiner, MD, MPH, 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 BA degree from Yale University, his MD from the University of Pennsylvania School of Medicine, his internal medicine training at the University of Colorado, and his MPH degree from the University of Washington, where he was a Robert Wood Johnson 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 2007-11 he was the chair of the Health Systems Research scientific review group for the Agency for Healthcare Research and Quality. Dr. Steiner is the author or co-author of over 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, MD, is 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 2011-13 he was a Senior Vice President and Director of the Center for Comparative Effectiveness Research at the Washington DC based Lewin Group, and was formerly 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 – 2005 and led and contributed to several KP national initiatives in evidence based medicine, population health and use of Health IT. Dr. Wallace is currently Chair of the board of directors for AcademyHealth and a Board member of the eHealth Initiative, and 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 completed further training in Internal Medicine and Hematology at Strong Memorial Hospital and the University of Rochester.

James N. Weinstein, DO, MS, is Chief Executive Officer 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, serving a patient population of 1.5 million. Under his leadership, Dartmouth-Hitchcock is working to create a “sustainable health system” for patients, providers, payors, and communities. He is a Member of the Institute of Medicine (IOM) of the National Academy of Sciences. 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 with Mayo Clinic, Intermountain Health, TDI, and Denver Health, of the national High Value Healthcare Collaborative, a partnership of 19 health systems across the country, who have taken on the challenge of improving the quality of care while lowering costs. More than 70,000 physicians, treating 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 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 electronic health records 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 #1s in its field by SCI. Dr. Weinstein holds the Peggy Y. Thomson Chair in the
Evaluative Clinical Sciences at Dartmouth. He has been named one 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 has appeared before several panels and Committees considering these issues.
HEALTH SYSTEM LEADERS WORKING TOWARDS HIGH VALUE CARE THROUGH INTEGRATION OF CARE AND RESEARCH

Workshop Logistics

The Keck Center of the National Academies
500 5th Street NW | Washington, DC
April 23 and 24, 2014 | Keck 100

The Roundtable on Value & Science-Driven Health Care is looking forward to your participation on April 23 and 24. If you have any questions regarding workshop logistics, please contact Liz Johnston at ejohnston@nas.edu or 202-334-2265.

LOCATION:
The workshop will begin at 8:30am on April 23 and will end at 1:00pm on April 24. Breakfast will be served on site beginning at 8:00am on April 23, with the agenda commencing at 8:30am. While the agenda for this meeting has not been finalized, these times provide an accurate estimation for travel planning purposes.

LODGING
Suggested nearby hotels include:
The Hotel Monaco / 700 F St NW / 202-628-7177
Courtyard Washington Convention Center / 900 F St NW / 202-638-4600
Embassy Suites Convention Center / 900 10th Street NW / 202-739-2001
Henley Park Hotel / 926 Massachusetts Avenue NW / 202-638-5200
Fairfield Inn & Suites / 500 H Street NW / 202-289-5959

DIRECTIONS AND GROUND TRANSPORTATION
Airports: The meeting site is approximately 5 miles from Washington National Airport and approximately 30 miles from Dulles International Airport. Taxis are most easily hailed from F or E Streets, NW.
Parking: Free visitor parking is available in the Keck Facility garage, accessed via 6th Street, on the P1 level.

Walking directions from Metro to Keck:
1. The Gallery Place/Chinatown Metro station (YELLOW and GREEN lines) is two blocks away, and only a 15-minute ride from Reagan National Airport.
   - Exit the station by following signs to Seventh and F Streets/Arena.
   - Turn LEFT and walk EAST on F Street NW, two blocks past the Verizon Center.
   - Turn RIGHT on to Fifth Street NW.
   - Walk past the fire station parking lot. The next building on your right will be 500 Fifth St. NW.
2. The Judiciary Square Metro station (RED line) is located a block away
   - Exit the station by following signs to the Building Museum (F Street) exit, between Fourth and Fifth Streets NW.
   - Turn LEFT and walk WEST on F Street NW
   - Cross Fifth Street NW and turn LEFT.
   - Walk past the fire station parking lot. The next building on your right will be 500 Fifth St. NW.